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Message From Donna E. Shalala

Secretary of Health and Human Services

This nation is faced with many challenges in its efforts to improve the health status of all people living in the United States. One of the biggest challenges is to remedy the fact that approximately one-fourth of our adults continue to smoke and that tobacco use rates among our youth have increased since the early 1990s. Tobacco use, particularly cigarette smoking, remains the leading cause of preventable illness and death in this country. Our overall success in improving the health status of the U.S. population thus depends greatly on achieving dramatic reductions in the rate of tobacco use among both adults and young people.

Reducing tobacco use is a key component of *Healthy People 2010*, the national action plan for improving the health of all Americans for the first decade of the 21st century. No fewer than 21 specific national health objectives related to tobacco are listed, including a goal to more than halve the current rates of tobacco use among young people and adults. Attaining all of the *Healthy People 2010* tobacco use objectives will require significant commitment and progress in numerous areas.

This Surgeon General's report provides a major resource in our national efforts to achieve the *Healthy People 2010* tobacco use objectives. The research findings reviewed indicate that many strategies and approaches have been shown to be effective in preventing tobacco use among young people and in helping tobacco users end their addiction. The challenge to public health professionals, health care systems, and other partners in our national prevention effort is to implement these proven approaches.

The Secretary's Initiative to Prevent Tobacco Use Among Teens and Preteens coordinates federal and nonfederal efforts to reduce young people's demand for tobacco products. This Surgeon General's report highlights additional strategies and approaches that this initiative can expand upon. Only by a coordinated national effort will the tobacco use rates among our young people be reduced. Each day that we delay in developing a comprehensive national response to this problem, 3,000 additional teens and preteens become regular smokers. That statistic poses an urgent public health challenge and—given that we have at hand numerous strategies proven to be effective—a moral imperative.

Foreword

For more than three decades, the Surgeon General of the U.S. Public Health Service has released reports focused on tobacco use and the health of the American people. The tone and content of these reports have changed over the years. Early on, there was a need for critical review of the epidemiologic and biologic aspects of tobacco use. Today, the deleterious effects are well documented, and the reports have begun to investigate the social, economic, and cultural consequences of these effects and what can be done to address them. The present report—the 25th in the series—assesses past and current efforts to reduce the use of tobacco in this country and thereby ameliorate its disastrous health effects.

Tobacco use is an extraordinary phenomenon. Although substantial progress has been made since the initial report of the Surgeon General's Ad Hoc Committee in 1964, approximately a quarter of the U.S. adult population smokes, and the percentage of high school youth who smoke has steadily increased throughout the 1990s.

Results from community-based interventions and statewide programs show that a comprehensive approach to tobacco control is needed to curtail the epidemic. This report summarizes several effective approaches to reducing tobacco use and presents the considerable evidence—as well as the attendant controversies—supporting their application. Multifaceted school-based education programs that are performed in conjunction with community-based campaigns have met with substantial success. The management of nicotine addiction in persons who already smoke has the benefit of clinical tools, that is, systems for weaning persons from nicotine, the efficacy of which is clearly demonstrated. Product regulation, enforcement of clean indoor air standards, and protecting young people from the supposed attractiveness of cigarettes all promise substantial impact. By analyzing the economics of tobacco and by examining models that assess the effect of economic policies, we find that various approaches can mitigate the adverse outcomes associated with tobacco use—and can do so without the dire economic consequences claimed by those who profit from tobacco use.

But if the evidence is clear that tobacco use is harmful and if the tools are available to reduce its use, why has the reduction in prevalence been less than would be expected? The answer is very complex. As described in Chapter 1 of this report, numerous forces influence a person's decision to smoke, or if that person is a smoker, the forces that drive continued use. The most important force for smoking is the totality of industry activity, including advertising, promotion, organizational activity, support for ancillary issues, and political action, which maintains marketability and profitability of the product. Efforts to reduce tobacco use face a more than \$5 billion annual budget that the tobacco industry dedicates

to advertising and promotion aimed at sustaining or increasing tobacco use. Nonetheless, there is cause for optimism based on considerable public support for efforts to prevent children from becoming addicted to tobacco. If the recent pattern of increases in youth tobacco use can be reversed, we can make progress toward tobacco-free generations in the future.

> Jeffrey P. Koplan, M.D., M.P.H. Director Centers for Disease Control and Prevention and Administrator Agency for Toxic Substances and Disease Registry

Preface

from the Surgeon General, U.S. Department of Health and Human Services

Almost 50 years ago, evidence began to accumulate that cigarette smoking poses an enormous threat to human health. More than 30 years ago, an initial report from the Surgeon General's office made an unqualified announcement of tobacco's harm. Beginning in 1969, the series of Surgeon General's reports began meticulous documentation of the biologic, epidemiologic, behavioral, pharmacologic, and cultural aspects of tobacco use. The present report, an examination of the methods and tools available to reduce tobacco use, is being issued at a time of considerable foment. The past several years have witnessed major initiatives in the legislative, regulatory, and legal arenas, with a complex set of results still not entirely resolved.

This report shows that a variety of efforts aimed at reducing tobacco use, particularly by children, would have a heightened impact in the absence of countervailing pressures to smoke. Besides providing extensive background and detail on historical, social, economic, clinical, educational, and regulatory efforts to reduce tobacco use, the report indicates some clear avenues for future research and implementation. It is of special concern to derive a greater understanding of cultural differences in response to tobacco control measures. Since racial and ethnic groups are differentially affected by tobacco, elimination of disparities among these groups is a major priority.

Perhaps the most pressing need for future research is to evaluate multifocal, multichannel programs that bring a variety of modalities together. For example, as Chapter 3 demonstrates, school-based education programs are more effective when coupled with community-based initiatives that involve mass media and other techniques. As pointed out in Chapter 4, a combination of behavioral and pharmacologic methods improves the success rate when managing nicotine addiction. Synergy among economic, regulatory, and social approaches has not been fully explored, but may offer some of the most fruitful efforts for the future. Chapter 7 provides the preliminary data on new statewide, comprehensive tobacco control programs, which offer great promise as new models for tobacco control and combine multiple intervention modalities. Although all aspects—social, economic, educational, and regulatory—have not been combined into a fully comprehensive effort, it is exciting to contemplate the potential impact of such an undertaking to eventually ensure that children are protected from the social and cultural influences that lead to tobacco addiction, that all smokers are encouraged to quit as soon as possible, and that nonsmokers are protected from environmental tobacco smoke.

> David Satcher, M.D., Ph.D. Surgeon General and Assistant Secretary for Health

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Introduction

What works?

It would be a boon if the answer were as easy to state as the question. Programs to reduce the use of tobacco have a long history in the United States and in other countries, and the accumulated experience has provided considerable empirical understanding of the prospects and pitfalls of such efforts. Rigorous answers to formal evaluation questions are difficult to obtain, however, in part because of the wide variety of influences that are brought to bear on the use of tobacco. Researchers have little control over many of these influences and are only beginning to learn how to measure some of them.

Nonetheless, a substantial body of literature exists on attempts to reduce the use of tobacco. This report provides an overview of the major modalities that have been studied and used intensively, and it attempts, where possible, to differentiate their techniques and outcomes. The report also attempts a more difficult task: to provide some qualitative observations about how these efforts interact. The report is thus a prologue to the development of a coherent, long-term policy that would permit these modalities to be used as effectively as possible.

Development of the Report

This report of the Surgeon General was prepared by the Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, to report current information on the health effects of cigarette smoking and smokeless tobacco use. Previous reports have dealt with some of the issues included in this report, but a composite assessment of efforts to reduce tobacco use is a new topic for this series. However, the current report must acknowledge the considerable contributions of three prior monographs: Growing Up Tobacco Free, a report of the Institute of Medicine (Lynch and Bonnie 1994), Healthy People 2000: National Health Promotion and Disease Prevention Objectives, and Healthy People 2010, an ongoing work of the Office of Health Promotion and Disease Prevention (U.S. Department of Health and Human Services [USDHHS] 1991, 2000).

The current report is the result of the work of 16 experts in the field of reducing tobacco use who contributed initial drafts in major chapter areas. The chapters were reviewed separately by some 60 researchers and public health workers whose expertise was specific to particular subject areas. After revision, a preliminary draft volume was reviewed by an additional 40 experts, including representatives of the institutes and agencies within the Department of Health and Human Services that have special interests in reducing tobacco use.

Several concerns guided preparation of the report. First, it was clear that the primary countervailing influence against reducing tobacco use is the effort of the tobacco industry to promote the use of tobacco products. Although this report was not conceived as a documentation of such industry efforts, repeated reference to them is necessary to underscore the difficulties both in achieving desired outcomes and in evaluating the effectiveness of efforts to reduce the use of the industry's products. Second, the report has attempted to present the wide variety of techniques and methods used for tobacco control, but the disparate methods make comparisons difficult. The result is more a menu than a cookbook—a set of activities, as outlined in Chapter 7, whose combination depends on specific circumstances and the context in which they are undertaken. Third, a result of this methodological diversity is that rigorous evaluation of the ways in which tobacco reduction efforts interact remains part of the unfinished research agenda. Although interaction of interventive efforts is noted several places in the report (see, for example, the discussion of the interaction of school education with community-based programs in Chapter 3), such demonstration of synergy has been elusive.

Finally, during the report's preparation, a cascade of legal and legislative events substantially changed the landscape where the diverse efforts to reduce to-bacco use take place. Several legal rulings, still under adjudication, and the Master Settlement Agreement between states and the tobacco industry to recover costs of government programs have altered prospects for reducing tobacco use through large-scale social maneuvers. Many of these issues are still unresolved, and they are likely to influence activities in the coming years.

Major Conclusions

- Efforts to prevent the onset or continuance of tobacco use face the pervasive, countervailing influence of tobacco promotion by the tobacco industry, a promotion that takes place despite overwhelming evidence of adverse health effects from tobacco use.
- 2. The available approaches to reducing tobacco use—educational, clinical, regulatory, economic, and social—differ substantially in their techniques and in the metric by which success can be measured. A hierarchy of effectiveness is difficult to construct.
- 3. Approaches with the largest span of impact (economic, regulatory, and social) are likely to have the greatest long-term, population impact. Those with a smaller span of impact (educational and clinical) are of greater importance in helping individuals resist or abandon the use of tobacco.
- 4. Each of the modalities reviewed provides evidence of effectiveness:
 - Educational strategies, conducted in conjunction with community- and media-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents.
 - Pharmacologic treatment of nicotine addiction, combined with behavioral support, will enable 20 to 25 percent of users to remain abstinent at one year posttreatment. Even less intense measures, such as physicians advising their patients to quit smoking, can produce cessation proportions of 5 to 10 percent.
 - Regulation of advertising and promotion, particularly that directed at young people, is very likely to reduce both prevalence and uptake of smoking.
 - Clean air regulations and restriction of minors' access to tobacco products contribute to a changing social norm with regard to smoking and may influence prevalence directly.
 - An optimal level of excise taxation on tobacco products will reduce the prevalence of smoking, the consumption of tobacco, and the longterm health consequences of tobacco use.

- 5. The impact of these various efforts, as measured with a variety of techniques, is likely to be underestimated because of the synergistic effect of these modalities. The potential for combined effects underscores the need for comprehensive approaches.
- 6. State tobacco control programs, funded by excise taxes on tobacco products and settlements with the tobacco industry, have produced early, encouraging evidence of the efficacy of the comprehensive approach to reducing tobacco use.

Issues in Reducing Tobacco Use

Two themes have permeated the history of tobacco use in the United States. First, and most obviously, tobacco is an extraordinary economic fuel, and its powerful economic impact comes into direct conflict with its vast social costs. Second, antitobacco activity has a continuous history characterized by waxing and waning and by a changing mix of motivations and strategies. These two themes are inextricably linked, and their interaction provides a backdrop for current efforts to reduce tobacco use.

Such efforts take place in a complicated context. Chronic diseases have largely replaced infectious processes as the leading causes of death during the 20th century (Rothenberg and Koplan 1990). But this replacement has occurred during a period of remarkable gains in life expectancy. Mortality is now less than half of what it was in 1900. The single most important risk associated with the leading chronic diseases is cigarette smoking; the evidence for that statement fills 25 volumes of Surgeon General's reports on smoking and health, and these volumes are merely summaries of a massive literature. Since the first of these reports in 1964, the prevalence of smoking has declined by nearly half, and it is clear that the declining use of tobacco has contributed to the observed decline in mortality. But paradoxically, as life expectancy increases, an increasing proportion of deaths are caused by the chronic diseases associated with smoking—primarily cancer, cardiovascular disease, and emphysema. This interplay raises key questions.

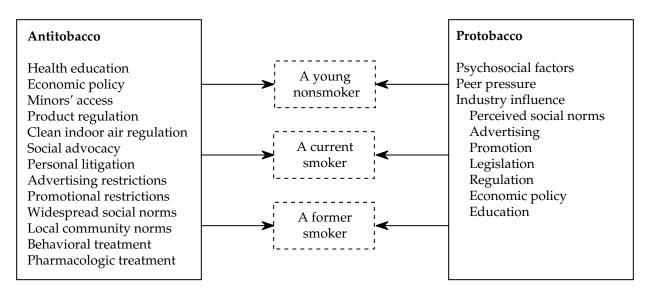
First, does the current smoking prevalence of about 25 percent represent a remarkable public health success, or is it evidence of continuing failure? The answer is yes to both questions. Health advocates can be both pleased with overall trends and loathe to declare success for a job unfinished, because goals and standards change with evolving efforts to reduce to-bacco use. If the worldwide public health response to

smallpox can be used as an analogy, the control program reached a point at which a single case was deemed unacceptable.

Second, why has the decline in smoking prevalence been slow? In the face of voluminous evidence about adverse health effects, prevalence has declined sluggishly (an average of about 0.5 percent per year since the mid-1960s). Currently, the decline exhibits epidemiologic signs of pausing in its downward trajectory, and it has even reversed in some population subgroups. There is no single, facile explanation for the persisting practice of tobacco use. If rationality were the only force at work, tobacco use would have been abandoned long ago. But as is shown in Figure 1.1, the forces that can be brought to bear on current or potential smokers are more complex and subtle than the mere awareness that smoking is harmful to one's health. A young person on the threshold of deciding to smoke may be subject to various influences, including the existence or nonexistence of targeted health education programs that discourage smoking, as well as of restrictions on access to cigarettes and a variety of regulations that determine the content and packaging of the product. Widespread and local norms, affecting this young person in the form of peer pressure, perceived smoking prevalence, and the commercial presentation of tobacco products, can affect the decision either way. The cost of cigarettes is likely to have significant influence on a young person, and other economic policies largely unseen by the potential smoker—can affect the outcome. Personal psychosocial factors undoubtedly play a role and are likely to interact with these other influences. Arrayed among and against such factors are the variety of conduits—also largely unseen by the current or potential smoker—through which the influences of the tobacco industry are manifested: use of advertising and promotion to alter perceived social norms, alteration or prevention of legislation that would inhibit smoking, legal mechanisms to influence regulation, political mechanisms to influence economic policy, and countereducation that can serve to encourage the uptake of smoking.

Whatever the precise interplay of these influences, the net result has been a slower decline than would be warranted by awareness of the well-publicized public health threat that smoking poses. The forces that have tried to accelerate the decline may be thought of collectively as "interventions," although the term, in a more narrow sense, is often reserved for circumscribed, planned, and measurable activities. Many of the maneuvers described in this report do not meet the narrower definition, but all share the common characteristic of being directed toward a reduction in tobacco use. With a broader definition in mind, Ramström (1995) has classified tobacco interventions by the point they affect on the spectrum of tobacco use. These classifications, depicted in Figure 1.2, are creating a nonsmoking norm, reducing stimuli to smoke, strengthening motivation to quit, and reducing impediments to quitting. Although the conceptualization is useful, a line could legitimately be drawn from each box to any other box in Figure 1.2, as these activities are all intimately tied to each other in both process and outcome. To borrow from the language

Figure 1.1. Influences on the decision to use tobacco



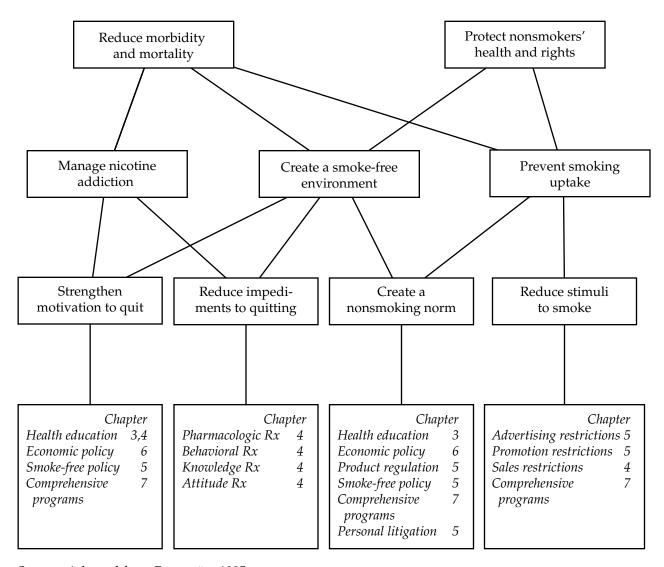
of statistics, the main effects of these efforts may be much less important than their interactions, both with each other and with the counterinfluences of the tobacco industry.

The result is a considerable challenge for evaluation. Suppose the young person in Figure 1.1 "decides" not to smoke, or the current smoker quits. Attribution of cause to this outcome in individual cases is highly unlikely. The totality of such decisions—which leads to a decline in prevalence—poses similar problems of attribution. Although the epidemiologic methods exist, data are rarely available to make attributive judgments. The challenge of evaluating these separate

efforts and strategies results from their disparate nature and the type of metric that may be appropriate to their evaluation (Table 1.1).

Management of nicotine addiction (Chapter 4), for example, is usually studied by using standard epidemiologic study design—often a prospective comparison of a study group and a control group—and the effect is measured by some form of the relative or attributable risk statistic. Educational strategies (Chapter 3), like other behavioral studies, may use similar statistics but usually invoke a different set of confounding factors to be considered; sorting out the relative influence of such factors often requires

Figure 1.2. Overview of relationships among interventions



Source: Adapted from Ramström 1995.

Table 1.1. Characteristics of interventions

Type of intervention	Targets	Tools	Study approaches	Outcome measurements
Educational	Children and adolescents, usually in school Administrative groups (e.g., members of health maintenance organizations) General population Health care providers Persons who smoke, usually in a health care setting General population of smokers in a commercial or quasicommercial setting	School curricula Interactive training Targeted services Mass media Pharmacologic methods Behavioral modification Reinforcing environment	Epidemiologic and behavioral: • Usually a comparison of "treatment" and "no treatment" groups • Control of confounding by behavioral and social variables Epidemiologic and behavioral: • Usually a comparison of "treatment" and "no treatment" groups • Control of confounding by behavioral and demographic variables	Relative risk Attributable risk Effect size (absolute or relative) Relative risk Attributable risk Effect size (absolute or relative)
Regulatory	Product manufacture Product sale Vendors and buyers Public venues Public transportation Worksites Health care sites	Local ordinance State regulation Federal regulation Federal law Nongovernment action (e.g., joint commission accreditation of hospital organization)	Observational Knowledge/attitude/ practice studies Surveillance Case study	Linear trend Cross-sectional comparison of proportions Case analysis results
Economic	Taxes Tariffs and trade Price supports	Local ordinance State regulation Federal regulation Federal law International agreements	Econometric analysis Trend analysis Multivariate models	Linear trend Parameter estimates (e.g., elasticities)
Social/Comprehensive	Legislators Media Communication networks Case-by-case strategy State/local programs	Media advocacy Direct advocacy Community interventions Countermarketing Regulation Policy formation	Observational Case study General epidemiologic methods Trend analysis Knowledge/attitude/practice studies	Linear trends Case study analysis Cross-sectional comparisons

complex multivariate procedures. Regulatory efforts (Chapter 5) are frequently evaluated after the effect (with a pre- and post-type of study design) or are evaluated according to ecological correlations with changes in epidemiologic trends. Economic measures (Chapter 6) depend for their evaluation on econometric information—that is, on administrative data sets and survey results that are subjected to correlation and trend analysis. Finally, comprehensive program strategies are often evaluated using surveillance data systems, trend analyses, and case studies.

In each instance, some form of evaluation is possible, but the ability to connect the intervention to the outcome differs greatly among these efforts, as does the ability to estimate impact. Theoretically, it might be possible to associate each effort with some presumed number of persons who start smoking or some number who quit, but to do so would usually require numerous assertions and assumptions. For example, to estimate the number of persons who would benefit, through prevention or cessation of smoking, from an educational strategy, assumptions would be needed about its generalizability to the U.S. population, the variability of its impact, the use-effectiveness to which it is put, the proportion of the population reached, and the permanence of its effect. It is even more difficult to create a set of assumptions for the impact of a regulation that is promulgated in an environment of declining prevalence and whose existence may depend on the prior emergence of the very changes it wishes to create. For example, a ban on smoking during airline flights, a measure intended not only to protect nonsmokers from environmental tobacco smoke (ETS) but also to promote a norm of nonsmoking, was possible only in an era when the dangers of ETS were widely known and when the danger and discomfort experienced by nonsmokers had begun to outweigh the inconvenience, discomfort, and even social ostracism experienced by smokers being subjected to such restrictions. It is virtually impossible to link a social strategy to a direct effect on prevalence, however successful by other criteria. (Many would argue, quite justly, that the impact measure of reducing prevalence by reducing uptake and increasing cessation is not the only outcome of interest. Unfortunately, proximal process measures are even more variable among the different strategies, and the ultimate outcome measures morbidity and mortality—are too distal to easily consider.)

Without a common metric, the various types of efforts to reduce tobacco use are difficult to compare quantitatively, although several attempts have been made (USDHHS 1998a; U.S. Department of the Treasury,

Office of Economic Policy, unpublished report, 1998). Perhaps a more qualitative approach could be used. One approach, illustrated in Table 1.2, would be to consider the potential span of impact (the proportion of the population, or population sectors) that the particular effort can exercise in the context of a qualitative estimate of its potential impact. Several examples of each type of effort are presented, and a qualitative assessment is made based on the data provided in the report. The assessments in Table 1.2 are by no means meant to be definitive but are meant to provide a framework for approaching the difficult issue of relative effectiveness. Although some observers would urge a more quantitative approach (e.g., using only randomized controlled trials as a measure of effectiveness), a number of effective modalities would likely be falsely discredited. For example, advocacy activity played a critical role in the formulation of the Food and Drug Administration's (FDA's) policy regarding regulation of tobacco products (see "Product Regulation" in Chapter 5), yet linking that policy, or antecedent advocacy work, directly to changing prevalence would be difficult.

In a qualitative assessment of relative impact, the examples provide a basis for a hierarchy of activities, but that hierarchy requires still another framework: consideration of the entity conducting the activity (individual, nongovernment citizens group, nongovernment agency, or government agency) and the organizational level at which the activity is conducted (local, state, national, or international). Thus, no single set of rules is available for invoking these efforts to reduce tobacco use, and relative efficacy depends on the context in which an effort takes place. For example, local efforts to reduce tobacco use might include regulatory ordinances (with potentially large impact on many people), education programs in schools (smaller impact on fewer people), and promotion of treatment for nicotine addiction (targeting a still smaller group). Specific local circumstances would dictate the specific activities. The federal government would more likely act to put in place economic measures and a variety of regulatory efforts (both types of interventions having very large span and size of impact), depending on the specific political context.

In summary, then, these efforts to reduce tobacco use line up side by side and not in relative order. Their use is predicated on the particular context in which they are to operate. Because they all face the same counterinfluence of the industry's tobacco promotion (the right-hand side of Figure 1.1), a reasonable case can be made that the large-scale strategies (economic and regulatory) have the greatest direct impact on that

Table 1.2. Examples of a qualitative assessment of intervention impact

Type of intervention	Specific modality	Span of impact	Size of impact
Educational	School curriculum	Large	Moderate
	Mass media	Large	Small
Clinical	Pharmacologic	Small	Moderate
	Behavioral (alone)	Small	Very small
Regulatory	Product manufacture	Very large	Very large
	Product sale	Large	Large
	Public venues	Large	Moderate
	Worksites	Large	Small
Economic	Taxation	Very large	Very large
	Tariffs and trade	Very large	Very large
Comprehensive programs	Statewide programs	Large	Large
	Case-by-case strategy	Unpredictable	Unpredictable

Note: Examples use a five-point ordinal scale (very small, small, moderate, large, very large), with the additional use of "unpredictable." (See text for the context for such assessment.)

barrier. But the context necessary for those large-scale efforts to work depends on public attitudes and social norms that must be influenced by other means.

In the 1990s, it became increasingly apparent that a public health success in reducing tobacco use requires activity on all fronts. A comprehensive approach—one that optimizes synergy from a mix of strategies—has emerged as the guiding principle for future efforts to reduce tobacco use. Such an approach makes moot the issue of a hierarchy of interventions, since a comprehensive approach presupposes an interdependence of the available strategies. A coordinated, cohesive infrastructure makes intuitive sense, since it permits a modular approach to the interventions themselves, but has been challenged on analytic grounds. In such a framework, attribution of success to particular program elements is difficult, and there is no experimental evidence (nor is there likely to be) that an approach that is comprehensive is superior to one that is not. Nonetheless, the 20th century's difficult experience with tobacco control (as described in Chapter 2) and the previous decade's success in changing social norms and generating assets (as discussed in Chapter 7) lend empirical credibility to the comprehensive approach.

Eliminating Disparities Related to Tobacco Use and Its Effects

The elimination of health disparities related to tobacco use poses a great challenge to this nation. This was not a main focus of the current report, because two other recent, important publications have emphasized the issue. The 1998 Surgeon General's report Tobacco Use Among U.S. Racial/Ethnic Minority Groups (USDHHS 1998b) was the first to address the diverse tobacco control needs of the four major U.S. racial/ethnic minority groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics. Healthy People 2010 (USDHHS 2000) presents two overarching goals: increase quality and years of healthy life and eliminate health disparities among different segments of the U.S. population. Evidence reviewed in these two publications highlights the significant disparities that exist in the United States. These publications also discuss the critical need for a greater focus on this issue, both in research and in public health action.

Summary and Implications

In fact, each of the approaches described in this report shows evidence of effectiveness. In some instances, the synergism that might be expected through interaction among these various efforts has been documented. The remainder of this chapter describes the major findings and implications for each type of activity and presents the conclusions of the other chapters.

Historical Review (Chapter 2)

The forces that have shaped the movement to reduce tobacco use over the past 100 years are complex and intertwined. In the early years (1880–1920), antitobacco activity—some of it quite successful—was motivated by moral and hygienic principles. After important medical and epidemiologic observations of the midcentury linked smoking to lung cancer and other diseases, and after the subsequent appearance of the 1964 report of the advisory committee to the Surgeon General on smoking and health (USDHEW 1964), the movement to reduce tobacco use was fueled by knowledge of the health risks that tobacco use poses and by reaction against the continued promotion of tobacco in the face of such known risks. Despite overwhelming evidence of adverse health consequences of smoking, the stubborn norm of smoking in the United States has receded slowly, in part because of such continued promotion that works synergistically with tobacco addiction. Although strategies have varied, health advocates have focused in recent years on the prevention of harm to nonsmokers and on the concept of smoking as a pediatric disease, with the consequent need for protecting young persons from forces influencing them to smoke.

Educational Strategies (Chapter 3)

The design of educational programs for tobacco use prevention and the methods used to evaluate them have become increasingly refined over the past two decades. Early studies tended to be confined to the school context, to have short duration, and to be of low intensity. Studies tended to focus on a single modality and to ignore the larger context in which prevention takes place. The reported size, scope, and duration of program effects have become larger in recent reports. In particular, several large programs have attempted a multifaceted approach that incorporates

other than school-based modalities. Improvements in evaluation designs have increased confidence in the validity of these reports. The pattern of consistency across this group of large studies also provides assurance that these effects can be achieved in a variety of circumstances when programs include the critical multiple elements that have been defined by this research literature.

To summarize the major findings, school-based social influences programs have significant and substantial short-term impacts on smoking behavior. Those programs with more frequent educational contacts during the critical years for smoking adoption are more likely to be effective, as are programs that address a broad range of educational needs. These effects have been demonstrated in a range of implementation models and student populations. The smoking prevention effects of strong school programs can be extended through the end of high school or longer when combined with relatively intensive efforts directed through other powerful channels, such as strategies that vigorously engage the influences of parents, the mass media, and other community resources. These conclusions have been codified in national guidelines for school programs to prevent tobacco use.

Thus, an extensive body of research findings document the most effective educational programs for preventing tobacco use. This research has produced a wide array of curricula, protocols, and recommendations that have been codified into national guidelines for schools. Implementing guidelines could postpone or prevent smoking onset in 20 to 40 percent of U.S. adolescents. Unfortunately, existing data suggest that evidence-based curricula and national guidelines have not been widely adopted. By one set of criteria, less than 5 percent of schools nationwide are implementing the major components of CDC's Guidelines for School Health Programs to Prevent Tobacco Use and Addiction (CDC 1994). Almost two-thirds of schools (62.8 percent) had smoke-free building policies in 1994, but significantly fewer (36.5 percent) reported such policies that included the entire school environment.

Schools, however, should not bear the sole responsibility for implementing educational strategies to prevent tobacco use. Research findings, as noted, indicate that school-based programs are more effective when combined with mass media programs and with community-based efforts involving parents and other community resources. In addition, CDC's school health

guidelines and numerous *Healthy People 2010* objectives recognize the critical role of implementing tobacco-free policies involving faculty, staff, and students and relating to all school facilities, property, vehicles, and events. Although significant progress is still required, the current evaluation base provides clear direction for the amalgamation of school-based programs with other modalities for reducing tobacco use.

Management of Nicotine Addiction (Chapter 4)

The management of nicotine addiction is a complex field that continues to broaden its understanding of the determinants of smoking cessation. Current literature suggests that several modalities are effective in helping smokers quit. Although the overall effect of such intervention is modest if measured by each attempt to quit, the process of overcoming addiction is a cyclic one, and many who wish to quit are eventually able to do so. The available approaches to management of addiction differ in their results.

Self-help manuals and minimal clinical interventions. Although self-help manuals have had only modest and inconsistent success at helping smokers quit, manuals can be easily distributed to the vast population of smokers who try to quit on their own each year. Adjuvant behavioral interventions, particularly proactive telephone counseling, may significantly increase the effect of self-help materials. Process measures are not routinely incorporated into self-help investigations, but the available process data suggest that persons who not only have a self-help manual but also perform the exercises recommended in the manual are more likely to quit smoking than are persons who try to quit smoking without them.

Substantial evidence suggests that minimal clinical interventions (e.g., a health care provider's repeated advice to quit) foster smoking cessation and that the more multifactorial or intensive interventions produce the best outcomes. These findings highlight the importance of cessation assistance from clinicians, who have access to more than 70 percent of smokers each year. Moreover, minimal clinical interventions have been found to be effective in increasing smokers' motivation to quit and are cost-effective (see "Cost-Effectiveness" in Chapter 4). However, research has not fully clarified the specific elements of minimal interventions that are most important to clinical success nor the specific changes they produce in smokers that lead to abstinence.

Intensive clinical interventions. Intensive programs—more formally systematic services to help people quit smoking—serve an important function in

the nation's efforts to reduce smoking, despite the resources the programs demand and the relatively small population of smokers who use them. Such programs may be particularly useful in treating those smokers who find it most difficult to quit. Because intensive smoking cessation programs differ in structure and content, evaluation is often hampered by variation in methodology and by a lack of research addressing specific treatment techniques. Because few studies have chosen to isolate single treatments, assessment of the effectiveness of specific approaches is difficult. Nonetheless, skills training, rapid smoking, and both intratreatment and extra-treatment social support have all been associated with successful smoking cessation. When such treatments are shown to be effective, they are usually part of a multifactorial intervention. Little clear evidence has implicated particular psychological, behavioral, or cognitive mechanisms as the agents of change. The specific impact of intensive interventions may be masked by the efficacy of several multicomponent programs, some of which have achieved cessation proportions of 30 to 50 percent. Thus, in their positive effect on smoking cessation and long-term abstinence rates, intensive interventions seem little different from other forms of counseling or psychotherapy. With intensive interventions, as with counseling, it is difficult to attribute the efficacy to specific characteristics of the interventions or to specific change mechanisms.

Pharmacologic interventions. Abundant evidence confirms that nicotine gum and the nicotine patch are effective aids to smoking cessation. The efficacy of nicotine gum may depend on the amount of behavioral counseling with which it is paired. The 4-mg dose (rather than the 2-mg dose) may be the better pharmacologic treatment for heavy smokers or for those highly dependent on nicotine. The nicotine patch appears to exert an effect independent of behavioral support, but absolute abstinence rates increase as more counseling is added to patch therapy. Nicotine inhalers and nicotine nasal spray are effective aids for smoking cessation, although their mechanisms of action are not entirely clear. All nicotine replacement therapies produce side effects, but these are rarely so severe that patients must discontinue use. Nicotine nasal spray appears to have greater potential for inappropriate use than other nicotine replacement therapies. Nicotine replacement therapies, especially the gum and the patch, have been shown to delay but not prevent weight gain following smoking cessation. All nicotine replacement therapies are thought to work in part by reducing withdrawal severity. The available evidence suggests that they do ameliorate some elements

of withdrawal, but the relationship between withdrawal suppression and clinical outcome is inconsistent.

Bupropion is the first nonnicotine pharmacotherapy for smoking cessation to be studied in large-scale clinical trials. Results suggest that it is an effective aid to smoking cessation. In addition, bupropion has been demonstrated to be safe when used in conjunction with nicotine replacement therapy. In the only direct comparison with a nicotine replacement product, bupropion achieved quit rates about double those achieved with the nicotine patch. Bupropion appears to delay but not prevent postcessation weight gain, and available literature contains inconsistent evidence about bupropion-mediated withdrawal relief. Bupropion does not appear to work by reducing postcessation symptoms of depression, but its mechanism of action in smoking cessation remains unknown.

Evidence suggests that clonidine is also capable of improving smoking cessation rates. Clonidine is hypothesized to work by alleviating withdrawal symptoms. Although clonidine may reduce the craving for cigarettes after cessation, it does not consistently ameliorate other withdrawal symptoms, and its effect on weight gain is unknown. Unpleasant side effects are common with clonidine use.

Antidepressants and anxiolytics are potentially useful agents for smoking cessation. At present, only nortriptylene appears to have consistent empirical evidence of smoking cessation efficacy. However, tricyclic antidepressants produce a number of side effects, including sedation and various anticholinergic effects, such as dry mouth.

In summary, research on methods to treat nicotine addiction has documented the efficacy of a wide array of strategies. The broad implementation of these effective treatment methods could produce a more rapid and probably larger short-term impact on tobacco-related health statistics than any other component of a comprehensive tobacco control effort. It has been estimated that smoking cessation is more cost-effective than other commonly provided clinical preventive services, including Pap tests, mammography, colon cancer screening, treatment of mild to moderate hypertension, and treatment of high levels of serum cholesterol.

Contemporaneously with the appearance of this report, research advances in managing nicotine addiction have been summarized in evidence-based clinical practice guidelines by the Agency for Healthcare Research and Quality (AHRQ). That document confirms that less intensive interventions, such as brief physician advice to quit smoking, could produce cessation rates of 5 to 10 percent per year. More intensive

interventions, combining behavioral counseling and pharmacologic treatment of nicotine addiction, can produce 20 to 25 percent quit rates at one year. Thus, the universal provision of even less intensive interventions to smokers at all clinical encounters could each year help millions of U.S. smokers quit (Fiore et al. 2000).

Progress has been made in recent years in disseminating clinical practice guidelines on smoking cessation. *Healthy People 2010* Objective 27-8 calls for universal insurance coverage of evidence-based treatment for nicotine dependency by both public and private payers. Similarly, CDC's *Best Practices for Comprehensive Tobacco Control Programs* advises states that tobaccouse treatment initiatives should include

- Establishing population-based counseling and treatment programs, such as cessation help lines.
- Making the system changes recommended by the AHRQ-sponsored cessation guidelines.
- Covering treatment for tobacco use under both public and private insurance.
- Eliminating cost barriers to treatment for underserved populations, particularly the uninsured (CDC 1999, p. 24).

Regulatory Efforts (Chapter 5)

Advertising and Promotion

Attempts to regulate advertising and promotion of tobacco products were initiated in the United States almost immediately after the appearance of the 1964 report to the Surgeon General on the health consequences of smoking. Underlying these attempts is the hypothesis that advertising and promotion recruit new smokers and retain current ones, thereby perpetuating a great risk to public health. The tobacco industry asserts that the purpose of marketing is to maintain brand loyalty. Considerable evidence has accumulated showing that advertising and promotion are perhaps the main motivators for adopting and maintaining tobacco use. Attempts to regulate tobacco marketing continue to take place in a markedly adversarial and litigious atmosphere.

The initial regulatory action, promulgated in 1965, provided for a general health warning on cigarette packages but effectively preempted any further federal, state, or local requirements for health messages. In 1969, a successful court action invoked the Fairness Doctrine

(not previously applied to advertising) to require broadcast media to air antitobacco advertising to counter the paid tobacco advertising then running on television and radio. Indirect evidence suggests that such counteradvertising had considerable impact on the public's perception of smoking. Not surprisingly, the tobacco industry supported new legislation (adopted in 1971) prohibiting the advertising of tobacco products on broadcast media, because such legislation also removed the no-cost broadcasting of antitobacco advertising. A decade later, a Federal Trade Commission (FTC) staff report asserted that the dominant themes of remaining (nonbroadcast) cigarette advertising associated smoking with "youthful vigor, good health, good looks and personal, social and professional acceptance and success" (Myers et al. 1981, p. 2-13). A nonpublic version of the report detailed some of the alleged marketing strategy employed by the industry; the industry denied the allegation that the source material for the report represented industry policy. Nonetheless, some of these concerns led to the enactment of the Comprehensive Smoking Education Act of 1984 (Public Law 98-474), which required a set of four rotating warnings on cigarette packages. The law did not, however, adopt other FTC recommendations that product packages should bear information about associated risks of addiction and miscarriage, as well as information on toxic components of cigarettes. In fact, many FTC-recommended requirements for packaging information that have been enacted in other industrialized nations have not been enacted in the United States.

The role of advertising is perhaps best epitomized by R.J. Reynolds Tobacco Company's Camel brand campaign (initiated in 1988) using the cartoon character "Joe Camel." Considerable research has demonstrated the appeal of this character to young people and the influence that the advertising campaign has had on minors' understanding of tobacco use and on their decision to smoke. In 1997, the FTC brought a complaint asserting that by inducing minors to smoke, R.J. Reynolds' advertising practices violated the Federal Trade Commission Act (Public Law 96-252). The tobacco company subsequently agreed to cease using the Joe Camel campaign. Although the FTC's act grants no private right of enforcement, a private lawsuit in California resulted in a settlement whereby the tobacco company agreed to cease its Joe Camel campaign; notably, the Supreme Court of California rejected R.J. Reynolds' argument that the Comprehensive Smoking Education Act of 1984 preempted the suit's attempt to further regulate tobacco advertising.

Product Regulation

Current tobacco product regulation requires that cigarette advertising disclose levels of "tar" (an allpurpose term for particulate-phase constituents of tobacco smoke, many of which are carcinogenic or otherwise toxic) and nicotine (the psychoactive drug in tobacco products that causes addiction) in the smoke of manufactured cigarettes and that warning labels appear on packages and on some (but not all) advertising for manufactured cigarettes and smokeless tobacco. The current federal laws preempt, in part, states and localities from imposing other labeling regulations on cigarettes and smokeless tobacco. Federal law (the Comprehensive Smokeless Tobacco Health Education Act of 1986 and the Comprehensive Smoking Education Act of 1984) requires cigarette and smokeless tobacco product manufacturers to submit a list of additives to the Secretary of Health and Human Services; attorneys for the manufacturers released such lists in 1994 to the general public. Smokeless tobacco manufacturers are required to report the total nicotine content of their products, but these data may not be released to the public. Tobacco products are explicitly protected from regulation in various federal consumer safety laws. No federal public health laws or regulations apply to cigars, pipe tobaccos, or fine-cut cigarette tobaccos (for "roll-your-own" cigarettes).

Although much effort has been devoted to considering the need for regulating nicotine delivery, tar content, and the use of additives, until recently no regulation had directly broached the issue of whether tobacco should be subject to federal regulation as an addictive product. Responding in part to several petitions filed by the Coalition on Smoking OR Health in 1988 and 1992, the FDA began serious consideration of the need for product regulation. Motivated by the notion that the cigarette is a nicotine delivery system, by allegations of product manipulation of nicotine levels, and by the concept that smoking is a pediatric disease and that young people are especially susceptible to cigarette advertising and promotion, in August 1995 the FDA issued in the Federal Register (1) a proposed rule of regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents and (2) an analysis of the FDA's jurisdiction over cigarettes and smokeless tobacco. The final regulations published by the FDA on August 28, 1996, differed only slightly from the proposed regulation. The announcement prompted immediate legal action on the part of the tobacco industry, advertising interests, and the convenience store industry, which challenged the FDA's jurisdiction over

tobacco products. In April 1997, a federal district court upheld the FDA's jurisdiction over tobacco products, but held that it lacked authority under the statutory provision relied on to regulate tobacco product advertising.

Although many of the FDA's regulations on tobacco sales and distribution were incorporated, to some extent, in the June 20, 1997, proposed settlement of lawsuits between 41 state attorneys general and the tobacco industry, the settlement presupposed congressional legislation that would uphold the FDA's asserted jurisdiction. After considerable congressional negotiation, no such legislation emerged. In August 1998, a three-judge panel of the United States Court of Appeals for the Fourth Circuit held that the FDA lacked jurisdiction to regulate tobacco products. In November 1998, the full Court of Appeals rejected the government's request for rehearing by the entire court. On March 21, 2000, in a 5 to 4 decision, the United States Supreme Court affirmed the decision of the United States Court of Appeals for the Fourth Circuit and held that the FDA lacks jurisdiction under the Federal Food, Drug, and Cosmetic Act to regulate tobacco products as customarily marketed. As a result of this decision, the FDA's August 1996 assertion of jurisdiction over cigarettes and smokeless tobacco and regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents (principally codified at 21 Code of Federal Regulations Part 897) are invalid.

Clean Indoor Air Regulation

Unlike the regulation of tobacco products per se and of their advertising and promotion, regulation of exposure to ETS has encountered less resistance. This course is probably the result of (1) long-standing grassroots efforts to diminish exposure to ambient tobacco smoke and (2) consistent epidemiologic evidence of adverse health effects of ETS. Since 1971, a series of rules, regulations, and laws have created smoke-free environments in an increasing number of settings: government offices, public places, eating establishments, worksites, military establishments, and domestic airline flights. As of December 31, 1999, smoking was restricted in public places in 45 states and the District of Columbia. Currently, some 820 local ordinances, encompassing a variety of enforcement mechanisms, are in place.

The effectiveness of clean indoor air restrictions is under intensive study. Most studies have concluded that even among smokers, support for smoking restrictions and smoke-free environments is high. Research

has also verified that the institution of smoke-free workplaces effectively reduces nonsmokers' exposure to ETS. Although most studies indicate that smoke-free environments have not reduced smoking prevalence, such environments have been shown to decrease daily tobacco consumption and to increase smoking cessation among smokers.

Minors' Access to Tobacco

There is widespread approval for restricting the access of minors to tobacco products. Recent research, however, has demonstrated that a substantial proportion of teenagers who smoke purchase their own tobacco, and the proportion varies with age, social class, amount smoked, and factors related to local availability. In addition, research has shown that most minors can easily purchase tobacco from a variety of retail outlets. It has been suggested that a reduction in commercial availability may result in a reduced prevalence of tobacco use among minors.

Several approaches have been taken to limiting minors' access to tobacco. All states prohibit sale or distribution of tobacco to minors. More than two-thirds of states regulate the means of sale through restrictions on minors' use of vending machines, but many of these restrictions are weak, and only two states have total bans on vending machines. Restrictions on vending machines are a subclass of the larger category of regulation of self-service cigarette sales; in general, such regulation requires that cigarettes be obtained from a salesperson and not be directly accessible to customers. Such policies can reduce shoplifting as well, an important source of cigarettes for some minors.

Regulations directed at the seller include the specification of a minimum age for sale (18, in all but two states and Puerto Rico), a minimum age for the seller, and the prominent in-store announcement of such policy. Providing merchant education and training is an important component of comprehensive minors' access programs. Penalties for sales to minors vary considerably; in general, civil penalties have been found to be more effective than criminal ones. Requiring licensure of tobacco retailers has been found to provide a funding source for compliance checks and to serve as an incentive to obey the law when revocation of the license is a provision of the law. Applying penalties to business owners, instead of to clerks only, is considered essential to preventing sales to minors. Tobacco retail outlets and the tobacco industry have vigorously opposed this policy. An increasing number of states and local jurisdictions are imposing sanctions against minors who purchase, possess, or use tobacco products. Sanctions against both buyers and sellers are enforced by a variety of agencies and mechanisms. Because regulations in general may be more effective if generated and enforced at the local level, considerable energy is devoted to the issue of opposing or repealing preemption of local authority by states. Public health analyses have resulted in strong recommendations that state laws not preempt local action to curb minors' access to tobacco.

Litigation Approaches

Private litigation shifts enforcement of public health remedies from the enterprise or the government to the private individual—typically, victims or their surrogates. In the tort system, the coalescence of instances in which injurers are forced to compensate the injured can create a force that generates preventive effects. Although relatively inefficient as a system for compensating specific classes of injuries, the tort system is justified by its generation of preventive actions and by its flexibility. Tobacco represents an atypical pattern of litigation and product modification, because private law remedies have not yet succeeded in institutionalizing recovery for tobacco injuries or have not yet generated significant preventive effects. In the case of tobacco, regulation has been the predominant control, and such regulation has been distinctive in relying primarily on notification requirements rather than safety requirements.

Private litigation against tobacco has occurred in several distinct waves. The first wave was launched in 1954 and typically used one or both of two legal theories: negligence and implied warranty. Courts proved unreceptive to both these arguments, and this approach had receded by the mid-1970s. In many of these and subsequent cases, legal devices and exhaustion of plaintiff resources figured prominently in the defendants' strategy. A second wave began in 1983 and ended in 1992. In these cases, the legal theory shifted from warranty to strict liability. The tobacco industry based its defense on smokers' awareness of risks and so-called freedom of choice. For example, plaintiffs argued that the addictive nature of nicotine limited free choice; defense counsel rebutted by pointing to the large number of former smokers who successfully quit. Taking freedom-of-choice defense even further, counsel argued that the claimant's lifestyle was overly risky by choice or was in some way immoral. The case that symbolized the second-wave litigation was that filed by Rose Cipollone, a dying smoker, in 1983. The Supreme Court accepted the tobacco industry's defense that federal law requiring warning labels on product packages had preempted claims under state law that imposed liability for failure to warn. The Supreme Court left open several other approaches, but the likelihood of recovery seemed small, and counsel for the Cipollone estate withdrew.

In the third wave, begun soon after the Cipollone decision and still ongoing, diverse legal arguments have been invoked. This third wave of litigation differs from its predecessors by enlarging the field of plaintiffs, focusing on a range of legal issues, using the class action device, and making greater attempts to use private law for public policy purposes. These new claims have been based on theories of intentional misrepresentation, concealment, and failure to disclose, and such arguments have been joined to a new emphasis on addiction. For example, in one case that ended as a mistrial, plaintiffs were barred from presenting evidence that the tobacco companies may have manipulated nicotine levels. The class action device has figured prominently in these new cases, which have included claims of smokers as well as claims of those who asserted that they have been injured by ETS. Arguably the most notable series of third-wave claims brought against tobacco companies is the proposed 1997 settlement of suits brought by 41 state attorneys general attempting to recover the states' Medicaid expenditures for treating tobacco-related illnesses. In the absence of congressional legislation needed to give that settlement the force of law, four states made independent settlements with the tobacco industry. Notably, each state obtained a concession guaranteeing that it would benefit from any more favorable agreement that another state might later obtain from the tobacco industry. Subsequently, a multistate Master Settlement Agreement was negotiated in November 1998 covering the remaining 46 states, the District of Columbia, and five commonwealths and territories. Another notable recent development is the filing of large claims by other third-party payers, such as large health care plans.

Perhaps in partial response, the level of litigation initiated by the tobacco industry itself has increased in recent years and has included a number of well-publicized cases, including a threatened suit against the media to prevent airing of a program that accused a tobacco company of manipulating nicotine levels. The company was successful in making the network withdraw the program, even though similar information was later made public in other contexts. Although the industry continues aggressive legal pursuit of its interests on a number of fronts, litigation against the industry has had undoubted impact on

tobacco regulation and is likely to continue to play a key role in efforts to reduce tobacco use.

Overview and Implications

Tobacco products are far less regulated in the United States than they are in many other developed countries. This level of regulation applies to the manufactured tobacco product; to the advertising, promotion, and sales of these products; and to the protection of nonsmokers from the involuntary exposure to ETS from the use of these products. As with all other consumer products, adult users of tobacco should be fully informed of the products' ingredients and additives and of any known toxicity when used as intended. Additionally, as with other consumer products, the manufactured tobacco product should be no more harmful than necessary given available technology. The sale, distribution, and promotion of tobacco products need to be sufficiently regulated to protect underage youth from influences to take up smoking. Finally, involuntary exposure to ETS remains a common public health hazard that is entirely preventable by appropriate regulatory policies.

Such are the basic, reasonable regulatory issues related to tobacco products. Yet these issues remain unresolved as the new millennium begins. When consumers purchase a tobacco product, they receive little information regarding the ingredients, additives, or chemical composition in the product. Although public knowledge about the potential toxicity of most of these constituents is negligible, findings in this report conclude that the warning labels on cigarette packages in this country are weaker and less conspicuous than in other countries. Further, the popularity of "low tar and nicotine" brands of cigarettes has shown that consumers may be misled by another, carefully crafted kind of information—that is, by the implied promise of reduced toxicity underlying the marketing of these products.

Current regulation of the advertising and promotion of tobacco products in this country is considerably less restrictive than in several other countries, notably Canada and New Zealand. The review of current case law in this report supports the contention that greater restrictions of tobacco product advertising and promotion could be legally justified. In fact, the report concludes that regulation of the sale and promotion of tobacco products is needed to protect young people from smoking initiation.

ETS contains more than 4,000 chemicals; of these, at least 43 are known carcinogens (Environmental Protection Agency 1992). Exposure to ETS has serious health effects (USDHHS 2000b). Despite this

documented risk, research has demonstrated that more than 88 percent of nonsmokers in this country aged 4 years and older had detectable levels of serum cotinine, a marker for exposure to ETS (Pirkle et al. 1996). The research reviewed in this report indicates that smoking bans are the most effective method for reducing ETS exposure. Four *Healthy People 2010* objectives address this issue and seek optimal protection of nonsmokers through policies, regulations, and laws requiring smoke-free environments in all schools, worksites, and public places.

Despite the widespread support among the general public, policymakers, and the tobacco industry for restricting the access of minors to tobacco products, a high proportion of underage youth smokers across this country continue to be able to purchase their own tobacco. National efforts by the Substance Abuse and Mental Health Services Administration to increase the enforcement of state laws to comply with the Synar Amendment and by the FDA to implement the access restrictions defined in their 1996 rule have reduced the percentage of retailers in many states who sell to minors. Unfortunately, nine states failed to attain their Synar Amendment targets in 1999. Additionally, the March 2000 Supreme Court ruling that the FDA lacks jurisdiction to regulate tobacco products has suspended all enforcement of the agency's 1996 regulations. Although several states have increased emphasis on this issue as part of their state-funded program efforts, the loss of the FDA's program removes a major infrastructure in support of these state efforts. The current regulatory environment poses considerable challenges for the interweaving of regulation into a comprehensive, multicomponent approach to tobacco use control and prevention.

Economic Approaches (Chapter 6)

The argument for using economic policy for reducing tobacco use requires considerable technical and analytic understanding of economic theory and data. Because experiments and controlled trials—in the usual sense—are not available to the economist, judgment and forecasting depend on the results of complex analysis of administrative and survey data. Such analyses have led to a number of conclusions regarding the importance of the tobacco industry in the U.S. economy and regarding the role of policies that might affect the supply of tobacco, affect the demand for tobacco, and use different forms of taxation as a possible mechanism for reducing tobacco use.

Supply. The tobacco support program has successfully limited the supply of tobacco and raised the price of tobacco and tobacco products. However, the principal beneficiaries of this program are not only the farmers whose income is supported but also the owners of the tobacco allotments. If policies were initiated to ameliorate some short-run effects, the tobacco support program could be removed without imposing substantial losses for many tobacco farmers. Eliminating the tobacco support program would lead to a small reduction in the prices of cigarettes and other tobacco products, which would lead to slight increases in the use of these products. However, because the support program has created a strong political constituency that has successfully impeded stronger legislation to reduce tobacco use, removing the support program could make it easier to enact stronger policies that would more than offset the impact that the resulting small reductions in price would have on demand.

Throughout the 1980s and 1990s, competition within the tobacco industry appeared to have decreased as a result of the favorable deregulatory business climate and an apparent increase in collusive behavior. This reduction in competition, coupled with the addictive nature of cigarette smoking, has magnified the impact that higher cigarette taxes and stronger smoking reduction policies would have on demand.

The recent expansion of U.S. trade in tobacco and tobacco products through multinational agreements, together with the U.S. threat of retaliatory trade sanctions were other countries to impede this expansion, is nearly certain to have increased the use of tobacco products worldwide. Such an increase would result in a consequent global rise in morbidity and mortality related to cigarette smoking and other tobacco use. These international trade policy efforts conflict with current domestic policies (and the support of comparable international efforts) that aim to reduce the use of tobacco products because of their harmful effects on health.

Industry importance. Although employment in the tobacco industry is substantial, the industry greatly overstates the importance of tobacco to the U.S. economy. Indeed, most regions would likely benefit—for example, through redistribution of spending and changes in types of job—from the elimination of revenues derived from tobacco products. Moreover, as the economies of tobacco-growing regions have become more diversified, the economic importance of tobacco in these areas has fallen. Higher tobacco taxes and stronger prevention policies could be joined to other efforts to further ease the transition from tobacco in major tobacco-producing regions. Finally, trading

lives for jobs is an ill-considered strategy, particularly with the availability of stronger policies for reducing tobacco use.

Demand. Increases in the price of cigarettes will lead to reductions in both smoking prevalence and cigarette consumption among smokers; relatively large reductions are likely to occur among adolescents and young adults. Limited research indicates that increases in smokeless tobacco prices will similarly reduce the use of these products. More research is needed to clarify the impact of cigarette and other tobacco prices on the use of these products in specific sociodemographic groups, particularly adolescents and young adults. Additional research also is needed to address the potential substitution among cigarettes and other tobacco products as their relative prices change.

Taxation. After the effects of inflation are accounted for, federal and average state excise taxes on cigarettes are well below their past levels. Similarly, average cigarette excise taxes in the United States are well below those imposed in most other industrialized countries. Moreover, U.S. taxes on smokeless tobacco products are well below cigarette taxes. Studies of the economic costs of smoking report a wide range of estimates for the optimal tax on cigarettes. However, when recent estimates of the costs of ETS (including the long-term costs of fetal and perinatal exposure to ETS) are considered, and when the premature death of smokers is not considered an economic benefit, a tax that would generate sufficient revenues to cover the external costs of smoking is almost certainly well above current cigarette taxes. The health benefits of higher cigarette taxes are substantial. By reducing smoking, particularly among youth and young adults, past tax increases have significantly reduced smokingrelated morbidity and mortality. Further increases in taxes, indexed to account for the effects of inflation, would lead to substantial long-run improvements in health.

The revenue potential of higher cigarette and other tobacco taxes—obviously not in itself a goal—is considerable; significant increases in these taxes would lead to sizable increases in revenues for many years. However, because of the greater price responsiveness of adolescents and young adults and the addictive nature of tobacco use, the long-run increase in revenues is likely to be less than the short-run gain. Nevertheless, current federal and most state tobacco taxes are well below their long-run revenue-maximizing levels.

In short, the research reviewed in this report supports the position that raising tobacco prices is good public health policy. Further, raising tobacco excise taxes is widely regarded as one of the most effective tobacco prevention and control strategies. Research indicates that increasing the price of tobacco products would decrease the prevalence of tobacco use, particularly among minors and young adults. As noted, however, this report finds that both the average price of cigarettes and the average cigarette excise tax in this country are well below those in most other industrialized countries and that the taxes on smokeless tobacco products are well below those on cigarettes. Making optimal use of economic strategies in a comprehensive program poses special problems because of the complexity of government and private controls over tobacco economics and the need for a concerted, multilevel, political approach.

Comprehensive Programs (Chapter 7)

Community-based interventions were originally developed as research projects that tested the efficacy of a communitywide approach to risk reduction. A number of national and international efforts to control cardiovascular disease (in the United States, notably the Minnesota, Stanford, and Pawtucket studies) used controlled designs. The results from these and other studies were largely disappointing, particularly regarding prevention and control of tobacco use. Other large-scale research efforts, such as the Community Intervention Trial (COMMIT) for Smoking Cessation, also failed to meet their primary goals for smoking reduction and cessation. Similarly, the results to date from numerous worksite-based cessation projects suggest either no impact or a small net effect (summarized in Chapter 4).

As these studies were under way in the 1970s and 1980s, health promotion—an organized approach to changing social, economic, and regulatory environments-emerged as a more effective mechanism for population behavior change than traditional health education. Although the aforementioned communitybased research projects used a health promotion perspective, they lacked the reach and penetration required for effective social change. In any event, the results made clear the distinction between a specific program (even one using multiple modalities) and a comprehensive multimessage, multichannel approach that used some or all of the modalities described in Chapters 3 through 6. The legal and economic events of the 1990s most notably large excise tax increases and the settlements with the tobacco industry for reimbursement of Medicaid costs incurred by caring for smokers—have provided those states with the resources necessary to mount such a comprehensive approach. The early results are encouraging, as exemplified by results from California, Massachusetts, Oregon, and Florida. The well-funded, coherent, and organized approach to tobacco prevention and control provides a credible counterweight to the advertising and promotional efforts of the tobacco industry and fosters a powerful nonsmoking norm.

On a broader scale, other social initiatives can also serve some of these same purposes through means that are not directly related to changing population behavior. For example, direct advocacy—the presentation of information to decision makers to encourage their support for nonsmoking policies—has been pursued vigorously by health advocates since the organization of grassroots movements for nonsmokers' rights in the early 1970s. Much of the clean air legislation now in place may be attributed in part to such direct advocacy. An interesting observation that supports the logic behind comprehensive programs is that initial shortcomings in direct advocacy activity may have been related to a failure of coordination among grassroots groups and professional organizations. In recent years, in part as the result of electronic networking and mediating by the Advocacy Institute, a more unified approach to reducing tobacco use has been achieved among the participating organizations.

Media advocacy—the use of mass media to advance public policy initiatives—has also been effective in placing smoking issues in the public eye and maintaining a continued impetus for reducing tobacco use. Case analysis of several instances of such activity—advocacy opposing the promotion of the "X" cigarette, the marketing of "Dakota" cigarettes, the Philip Morris-sponsored Bill of Rights tour, and the attempted marketing of "Uptown" cigarettes—highlights several successes but also indicates that such activities do not always achieve their immediate aims. Nonetheless, considerable experience has been gained in seizing such opportunities.

Countermarketing activities can promote smoking cessation and decrease the likelihood of initiation. Countermarketing campaigns also can have a powerful influence on public support for tobacco control activities and provide an educational climate that can enhance the efficacy of school- and community-based efforts. For youth, the CDC has estimated that the average 14-year-old has been exposed to more than \$20 billion in imagery advertising and promotions since age 6, creating a "friendly familiarity" for tobacco products. The recent increase in movie depictions of tobacco use further enhances the image of tobacco use as glamorous, socially acceptable, and normal. In light

of the ubiquitous and sustained protobacco messages, countermarketing campaigns need to be of comparable intensity and duration to alter the general social and environmental atmosphere supporting tobacco use.

In sum, the comprehensive approach that has been developed within the statewide tobacco control programs has produced results that led the Institute of Medicine (2000) to conclude that "multifaceted state tobacco control programs are effective in reducing tobacco use" (p. 4). Although these initial results are encouraging, they need to be considered from the perspective of the less favorable results from the community trials. Nevertheless, although our knowledge about the mechanisms by which these new comprehensive tobacco control efforts function is imperfect, the results are sufficiently favorable to support the continued application of this model. But, accountability and program evaluation must be emphasized in these new statewide tobacco control programs to improve our understanding of how the various components of the comprehensive programs work.

Perhaps the most important aspect of comprehensive programs has been the emergence of statewide to-bacco control efforts as a laboratory for their development and evaluation. The number of states with such programs grew slowly in the early and mid-1990s, but in recent years there has been a surge in funding for such efforts fueled by the state settlements with the tobacco industry. Although the data on the impact of these programs on per capita consumption, adult prevalence, and youth prevalence are generally favorable, the uniform data systems needed to conduct more controlled evaluations of these efforts are still emerging. The challenge for the new millennium will be to ensure that these ever increasing comprehensive statewide tobacco control programs are as efficient and effective as possible.

The review of statewide tobacco control programs indicates that reducing the broad cultural acceptability of tobacco use necessitates changing many facets of the social environment. In addition, this report stresses—as does the *Best Practices* (CDC 1999) document—that these individual components must work together to produce the synergistic effects of a comprehensive

program. However, both of these findings highlight the complexity involved in evaluating these types of programs.

Within the current statewide tobacco control programs, each of these various modalities discussed in this report is represented with varying degrees of intensity. As noted above, some of the recommendations for actions within these modalities could most effectively be done at the national rather than the state level. Thus, the overall efficacy of these emerging statewide programs will depend in some ways on public health advances at the national level. Again, this synergy between the statewide and national efforts adds greater complexity to the evaluation issue.

Finally, this report concludes that the span of impact of these educational, clinical, regulatory, economic, and social approaches indicates the importance of their sustained and long-term implementation. Program evaluation and research efforts are needed to improve our understanding of how these various elements work. Although knowledge about the efficacy of comprehensive programs is imperfect, evidence points to early optimism for their continuance. With the expansion of tobacco control surveillance and evaluation systems and increases in the number and diversity of statewide tobacco control programs, critical questions can be answered about how to make these efforts more efficient and effective.

A Vision for the Future—Reducing Tobacco Use in the New Millennium (Chapter 8)

Chapter 8 outlines broad strategies and courses of action for tobacco control in the future. Six future challenges are outlined: continuing to build the scientific base, responding to the changing tobacco industry, using a comprehensive approach in reducing tobacco use, eliminating health disparities, improving dissemination of state-of-the-art interventions, and influencing tobacco use in developing nations.

Chapter Conclusions

Following are the specific conclusions for each chapter of the report. Note that Chapters 1 and 8 have no conclusions.

Chapter 2. Historical Review

- In the years preceding the development of the modern cigarette, and for some time thereafter, antismoking activity was largely motivated by moralistic and hygienic concerns. Health concerns played a lesser role.
- 2. In contrast, in the second half of the 20th century, the impetus for reducing tobacco use was largely medical and social. The resulting platform has been a more secure one for efforts to reduce smoking.
- 3. Despite the growing scientific evidence for adverse health effects, smoking norms and habits have yielded slowly and incompletely. The reasons are complex but attributable in part to the industry's continuing stimulus to consumption.

Chapter 3. Educational Strategies

- Educational strategies, conducted in conjunction with community- and media-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents.
- Although most U.S. schools have tobacco use prevention policies and programs in place, current practice is not optimal.
- 3. More consistent implementation of effective educational strategies to prevent tobacco use will require continuing efforts to build strong, multiyear prevention units into school health education curricula and expanded efforts to make use of the influence of parents, the mass media, and other community resources.

Chapter 4. Management of Nicotine Addiction

- 1. Tobacco dependence is best viewed as a chronic disease with remission and relapse. Even though both minimal and intensive interventions increase smoking cessation, most people who quit smoking with the aid of such interventions will eventually relapse and may require repeated attempts before achieving long-term abstinence. Moreover, there is little understanding of how such treatments produce their therapeutic effects.
- 2. There is mixed evidence that self-help manuals are an efficacious aid to smoking cessation. Because these materials can be widely distributed, such strategies may have a significant public health impact and warrant further investigation.
- Programs using advice and counseling—whether minimal or more intensive—have helped a substantial proportion of people quit smoking.
- 4. The success of counseling and advice increases with the intensity of the program and may be improved by increasing the frequency and duration of contact.
- 5. The evidence is strong and consistent that pharmacologic treatments for smoking cessation (nicotine replacement therapies and bupropion, in particular) can help people quit smoking. Clonidine and nortriptylene may have some utility as second-line treatments for smoking cessation, although they have not been approved by the FDA for this indication.

Chapter 5. Regulatory Efforts

Advertising and Promotion

 Since 1964, numerous attempts to regulate advertising and promotion of tobacco products have had only modest success in restricting such activity.

- 2. Current regulation in the United States is considerably less restrictive than that in several other countries, notably Canada and New Zealand.
- Current case law supports the contention that advertising does not receive the protections of free speech under the First Amendment to the Constitution that noncommercial speech does.

Product Regulation

- 1. Warning labels on cigarette packages in the United States are weaker and less conspicuous than those of other countries.
- Smokers receive very little information regarding chemical constituents when they purchase a tobacco product. Without information about toxic constituents in tobacco smoke, the use of terms such as "light" and "ultra light" on packaging and in advertising may be misleading to smokers.
- Because cigarettes with low tar and nicotine contents are not substantially less hazardous than higher-yield brands, consumers may be misled by the implied promise of reduced toxicity underlying the marketing of such brands.
- 4. Additives to tobacco products are of uncertain safety when used in tobacco. Knowledge about the impact of additives is negligible and will remain so as long as brand-specific information on the identity and quantity of additives is unavailable.
- Regulation of tobacco product sale and promotion is required to protect young people from influences to take up smoking.

Clean Indoor Air Regulation

- Although population-based data show declining ETS exposure in the workplace over time, ETS exposure remains a common public health hazard that is entirely preventable.
- Most state and local laws for clean indoor air reduce but do not eliminate nonsmokers' exposure to ETS; smoking bans are the most effective method for reducing ETS exposure.

 Beyond eliminating ETS exposure among nonsmokers, smoking bans have additional benefits, including reduced smoking intensity and potential cost savings to employers. Optimal protection of nonsmokers and smokers requires a smoke-free environment.

Minors' Access to Tobacco

- 1. Measures that have had some success in reducing minors' access include restricting distribution, regulating the mechanisms of sale, enforcing minimum age laws, having civil rather than criminal penalties, and providing merchant education and training. Requiring licensure of tobacco retailers provides both a funding source for enforcement and an incentive to obey the law when revocation of the license is a provision of the law.
- 2. The effect of reducing minors' access to tobacco products on smoking prevalence requires further evaluation.

Litigation Approaches

- 1. Two historic waves of tobacco litigation were initiated by private citizens, were based largely on theories of negligence and implied warranty, and were unsuccessful.
- A third wave has brought in new types of claimants, making statutory as well as common-law claims and using more efficient judicial procedures. Although several cases have been settled for substantial money and have yielded public health provisions, many other cases remain unresolved.
- 3. Private law initiative is a diffuse, uncentralized activity, and the sum of such efforts is unlikely to produce optimal results for a larger policy to reduce tobacco use. On the other hand, the litigation actions of individuals are likely to be a valuable component in some larger context of strategies to make tobacco use less prevalent.

Chapter 6. Economic Approaches

- The price of tobacco has an important influence on the demand for tobacco products, particularly among young people.
- Substantial increases in the excise taxes on cigarettes would have considerable impact on the prevalence of smoking and, in the long term, reduce the adverse health effects caused by tobacco.
- 3. Policies that influence the supply of tobacco, particularly those that regulate international commerce, can have important effects on tobacco use.
- 4. Although employment in the tobacco sector is substantial, the importance of tobacco to the U.S. economy has been overstated. Judicious policies can be joined to higher tobacco taxes and stronger prevention policies to ease economic diversification in tobacco-producing areas.

Chapter 7. Comprehensive Programs

- The large-scale interventions conducted in community trials have not demonstrated a conclusive impact on preventing and reducing tobaccouse.
- 2. Statewide programs have emerged as the new laboratory for developing and evaluating comprehensive plans to reduce tobacco use.
- Initial results from the statewide tobacco control programs are favorable, especially regarding declines in per capita consumption of tobacco products.
- 4. Results of statewide tobacco control programs suggest that youth behaviors regarding tobacco use are more difficult to change than adult ones, but initial results of these programs are generally favorable.

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Introduction

Like many other social phenomena, the use of tobacco has created a tapestry of themes, motivations, and social forces, woven together with a complexity that has begun to capture the interest of social historians (Brandt 1990; Burnham 1993; Klein 1993; Tate 1999). Tobacco has economic, social, and political reverberations and is intimately tied to collective images and attitudes. Nonetheless, some simplification is possible: the history of tobacco use can be thought of as the conflict between tobacco as an agent of economic gain and tobacco as an agent of human harm. An exhaustive history would not be content with such a simple contrast, but it serves the purpose of this chapter. The chief barrier to reducing tobacco use—the path of most resistance—is a powerful industry whose efforts to promote tobacco have continued to shape public opinion and social norms. Against this background, the chapter considers the underlying forces that have motivated the movement to reduce smoking. Many recent events that are of critical historical importance for nonsmoking are considered in other segments of the report (e.g., social advocacy actions [Chapter 7]; taxation-based initiatives in states [Chapter 7]; Food and Drug Administration regulations regarding minors as the target of tobacco advertising [Chapter 5]; and proposed national legislation, settlement and attempted settlement of various lawsuits against the tobacco companies, and criminal proceedings against tobacco companies [Chapter 5]). As noted in Chapter 1, some of the most dynamic changes in the history of smoking control efforts are currently taking place, and we are not sufficiently distanced from these events to evaluate them fully. This chapter will consider, rather, the changing thematic content—religious, hygienic, medical, and social—of the movement to reduce smoking that has presaged the current events.

Early Events

In North America, the history of tobacco use precedes written records. After American Indians introduced tobacco to the European colonists, tobacco was transported from the colonies to Europe, where it quickly became a widely used consumer item. Just as quickly, however, the use of tobacco became controversial. Critics of the day attacked tobacco use as morally irresponsible, extravagant, and a habit of people of base condition (Best 1979). In England, King James I published an antitobacco tract in 1604 that, among other things, offered an early critique of secondhand smoke: the royal author expressed his concerns that a husband who smoked might "reduce thereby his delicate, wholesome, and cleane complexioned wife to that extremitie, that either shee must also corrupt her sweete breath therewith, or else resolve to live in a perpetuall stinking torment" (quoted in Apperson 1916, p. 206). In many countries of northern Europe, tobacco use was criminalized (Best 1979). Part of the objection in England and elsewhere was that trading gold to Spain for tobacco—the best tobacco

came from Spain's colonies—was dangerous to the state economy. But with the English colonization of Virginia and the growing need in England, and elsewhere in Europe, for more state revenue, governments turned their policies around, despite continued moral objections to tobacco use. King James I himself set aside his previous objections and sought ways for the crown to profit from the tobacco trade (Morgan 1975; Best 1979).

Of all the novel consumer goods the New World made available to the Old World, "tobacco enjoyed the most rapid diffusion" (Shammas 1990, p. 80) among people of different income levels, who bought it on a fairly regular basis. Closer to the source, mass consumption was even more pronounced: in the American colonies during the 18th century, yearly consumption averaged between 2 and 5 pounds per capita (Shammas 1990). When used medicinally, tobacco was favorably regarded; but in its widespread use for pleasure, "it was considered harmful and faintly immoral" (Morgan 1975, p. 91; see also Stewart 1967).

Although that reputation for immorality never entirely vanished, by 1776, tobacco was not only a valued consumer good but also the economic foundation of the colonies' independence movement. "King Tobacco Diplomacy" was a central element in gaining French support for the struggling colonies; tobacco,

one historian reports, "helped to buy American independence" (Morgan 1975, p. 6). Thomas Jefferson thought well enough of tobacco to propose that its leaves be carved into the pillars in one of the Capitol rotundas in Washington (U.S. House of Representatives 1969).

The Rise of the Cigarette

Before the 20th century, tobacco was used predominantly for chewing, pipe smoking, inhaling (as snuff), and cigar smoking. The cigarette was an innovation that appeared sometime early in the 19th century. The term "cigarette" first made its appearance in English in the 1840s (Apperson 1916). For reasons including cost and ease of use (discussed later in this chapter), the product quickly caught on among tobacco users. In the United States, cigarette smoking increased enough during the Civil War for cigarettes to become subject to federal tax in 1864 (Tennant 1950). But it was not until its manufacture was mechanized that the cigarette became a major tobacco product.

James Albert Bonsack patented a cigarette rolling machine in 1881 that, by the late 1880s, produced cigarettes at 40 times the rate of a skilled hand worker (Tennant 1950; Chandler 1977). The mechanization of cigarette manufacture, like that of a number of other products in the late 19th century (such as prepared cereals, photographic film, matches, flour, and canned food products such as soup), precipitated a marketing revolution. Industries that developed "continuous process" production (Chandler 1977, p. 249) could increase unit production without increasing production costs—the main production problem of the day. The cigarette industry, like these others, could now produce almost unlimited quantities of product at minimal cost per additional unit. When James Buchanan Duke installed two Bonsack machines in 1884 and arranged the next year an advantageous leasing arrangement with Bonsack, his cigarette output soared. Within a decade, his unit cost of producing cigarettes dropped to one-sixth of what it had been (Chandler 1977). In 1890, following a series of price wars made feasible by these cost savings, Duke merged with several competitors to form The American Tobacco Company. With the production problem solved and competition reduced, the focus of business thinking shifted to marketing. At a time when national advertising of many products was in its infancy, The American Tobacco Company was innovative and expansive in its promotional efforts (U.S. Department of Health and Human Services [USDHHS] 1994).

Popularity and Protest

The growing popularity of cigarette smoking coincided with the years of populist health reform in the 19th century. Antitobaccoism was a standard feature of various writings on personal health, which held that any "stimulant" was unhealthy (Nissenbaum 1980). Some of these health beliefs were tied to a religious orientation. Ellen Gould Harmon White, the prophetess who founded the Seventh-day Adventists, spoke out strongly against tobacco. In 1848, her first vision concerning healthful living taught her the religious duty of abstaining from tobacco, tea, and coffee. She attacked these products for the money squandered on them and for their dangers to health. White may have picked up these views from Captain Joseph Bates, a Millerite (follower of William Miller, whose millenarian group believed that the Second Coming of Christ would occur in 1843). Not until 1855, however, did tobacco abstention become a larger theme among the Adventists. In that year, the group's Review and Herald printed two lead articles attacking "the filthy, health-destroying, God-dishonoring practice of using tobacco" (quoted in Numbers 1976, p. 40).

This protest was an integral part of the complex antitobacco crusading at the time. In addition to the religious motif, there was the considerable influence of the hygiene movement, which branded "tobaccoism" a disease, tobacco a poison (Burnham 1989, p. 6), and dubbed cigarettes "coffin nails" (Tate 1999, p. 24).

Spearheaded by the American Anti-Tobacco Society, which was founded in 1849, antitobacco critics found tobacco a cause of ailments ranging from insanity to cancer. During this time, cigarettes were often considered narcotics because they seemed to have addicting qualities (Tate 1999). This litany of physiological ills ascribed to tobacco use did not prove to have the social power of the announcement, a century later, that numerous medical studies had found a direct link between smoking and specific diseases that, as was understood only in that later century, often took decades to manifest themselves. Between 1857 and 1872, George Trask published the *Anti-Tobacco Journal* in Fitchburg, Massachusetts, attacking the filth (especially of chewing tobacco), the dangers to health, and the costliness of tobacco (Tennant 1971). Early 19th century popular health movements tended to ally themselves with "nature" and "natural" remedies in opposition to professional medicine; by the late 19th century, health movements were more likely to take medical professionals as their spokesmen (Burnham 1987).

One such professional was Dr. John Harvey Kellogg, Seventh-day Adventist and director of the famous Adventist-founded Battle Creek (Michigan) Sanitarium, whose main concern was improving diet. Kellogg argued that tobacco was a principal cause of heart disease and other illnesses and that it adversely affected both judgment and morals (Schwarz 1970). Along with Ellen Gould Harmon White and her husband, a Millerite preacher, Kellogg organized the American Health and Temperance Association in 1878, which opposed the use of alcohol, tea, coffee, and tobacco. Later, Kellogg served as president of the Michigan Anti-Cigarette Society and, after World War I, as a member of the Committee of Fifty to Study the Tobacco Problem.

Other organizational efforts directed specifically at cigarettes began in the last two decades of the 19th century. These efforts were generally directed at saving boys and young men from the dangers of cigarette smoking. In New York City, the president of the board of education, a smoker himself, set up the Consolidated Anti-Cigarette League and won the pledges of 25,000 schoolboys not to smoke until they turned 21 (Troyer and Markle 1983).

The first to call for cigarette prohibition was the National Woman's Christian Temperance Union (WCTU) (Tate 1999). Led by Frances Willard, a friend of Harvey Kellogg, who was further inspired by her brother's death from smoking-related illnesses, the WCTU as early as 1875 made plans to instruct members of its youth affiliate, the Juvenile Work, about the dangers of tobacco, as well as the hazards of alcohol.

In 1883, the WCTU established the Department for Overthrow of Tobacco Habit, which was renamed the Department of Narcotics in 1885 (Lander 1885; Tate 1999).

The campaign against tobacco became a permanent part of the WCTU. Reports from their annual meetings documented the accomplishments of state and local chapters in combating smoking. In 1884, the superintendent of the Department for Overthrow of Tobacco Habit acknowledged the difficulty of the task before her: "With a spittoon in the pulpit and the visible trail of the vice in countless churches, with its entrenchments bearing the seal of respectability, its fortifications so long impregnable will yield slowly and unwillingly to the mightiest opposing forces" (WCTU 1884, p. v). She noted that tobacco was a habit costing people "more than the support of all [their] ministers of the gospel" or than the price of educating their children; that it caused disease, "especially the loss of sight, paralysis, prostration, and scores of ailments hitherto credited to other sources"; and that it "lower[ed] the standard of morality" (WCTU 1884, p. v).

The WCTU was one group that pressed with some success for legislation to prohibit the sale of tobacco to minors. 1 By 1890, such laws had been passed in 23 states. Connecticut and New York enacted penalties for both the underaged smoker and the merchant who sold to the minor (WCTU 1890). In New York, the strengthened law arose out of WCTU lobbying. "We found so many evasions of the law as it stood," the WCTU reported at its annual meeting in 1890, "that we decided our only way to save the boys was to amend the law, so as to punish the boy who was found using tobacco in any public place, street or resort" (WCTU 1890, p. 185). The Department of Narcotics organized a letter-writing campaign that mobilized women, educators, and ministers (p. 185). By 1897, the Department of Narcotics report could proudly claim, "everything points to the death of the little coffin nail, if our women will only continue faithful" (WCTU 1897, p. 343).

¹The laws prohibiting sales to minors began in New Jersey and Washington as early as 1883, Nebraska in 1885, and Maryland in 1886. By 1940, all states except Texas had laws of this sort on the books (Gottsegen 1940). By 1964, Texas had joined the list, but Louisiana and Wisconsin had repealed their laws as unenforceable (USDHHS 1989). The legality of the laws was confirmed by the United States Supreme Court (*Austin v. Tennessee*, 179 U.S. 343, 21 S. Ct. 132 [1900]), and a Federal Court of Appeals ruled in 1937 to uphold the authority of local jurisdictions to ban vending machine sales of cigarettes in the effort to protect minors (USDHHS 1989).

Announcements of tobacco's death were premature, but cigarette sales declined in the last years of the 19th century. Most likely, the decline was precipitated by the "Plug War," in which The American Tobacco Company bought several plug tobacco producers and sharply cut prices, attracting cigarette users back to other tobacco products. Moreover, as the country came out of the depression of the 1890s, cigar smokers who had shifted to the cheaper cigarettes moved back to their preferred smoke (Sobel 1978). But the campaign against the cigarette certainly had a legislative impact. Cigarettes were prohibited for both adults and minors by law—if only temporarily—in North Dakota in 1895, Iowa in 1896, Tennessee in 1897, and Oklahoma in 1901. Eleven states had some general anticigarette legislation by 1901, and almost all state legislatures had considered curbs on cigarette sales (Outlook 1901).

In 1899, Lucy Page Gaston, a WCTU activist, set up the Chicago Anti-Cigarette League (changed to the National Anti-Cigarette League in 1901 and to the Anti-Cigarette League of America in 1911). The league focused on the dangers of cigarettes to boys. Gaston sponsored frequent rallies, at which a chorus of young nonsmoking men provided the music (Duis 1983; Tate 1999). One of the innovations of Gaston's crusade was the establishment of a smoking cessation clinic in Chicago (Troyer and Markle 1983). Gaston, whose long career against tobacco would culminate with her bid for the Republican presidential nomination in 1920 on an antitobacco platform (*New York Times* 1920), worked tirelessly lobbying for antitobacco legislation.

Such legislation continued to pass, particularly in midwestern and some western states—Indiana, Nebraska, and Wisconsin in 1905; Arkansas in 1907; and Kansas, Minnesota, South Dakota, and Washington in 1909. But evasion of the laws was apparently easy. Cigarette "makings" (e.g., cigarette papers and cigarette tobacco) were sold even if cigarettes were not, and some retailers sold matches for a higher-thanusual price and gave away cigarettes with them (Warfield 1930; Sobel 1978). Other retailers and smokers evaded the law through a product wrapped in a tobacco leaf rather than paper (*New York Times* 1905).

The WCTU was not alone in its efforts. Several businesses and prominent individuals were outspoken in the crusade against tobacco use, some going so far as to support Gaston's proposed (and defeated) 20th amendment to the Constitution that would have outlawed the manufacture and shipment of tobacco products (Junod 1997). Henry Ford attacked the habit of cigarette smoking and enlisted Thomas Edison to investigate its dangers (Brandt 1990). According to

Harper's Weekly (1910), many railroads and other firms would not hire smokers. Sears, Roebuck and Company and Montgomery Ward Holding Corporation refused to employ smokers (Porter 1947–48). The Non-Smokers' Protective League of America was established in 1911 with a distinguished board of directors, including Harvey W. Wiley, chief chemist of the U.S. Department of Agriculture and father of the (1906) Pure Food and Drug Act; James Roscoe Day, chancellor of Syracuse University; and David Starr Jordan, president of Stanford University (New York Times 1911). Dr. Charles G. Pease, a physician and dentist, was the leader of this group. "Almost single-handed," according to a New York Times report (1928, p. 7), Pease won a 1909 prohibition against smoking in the subways. In 1917, he opposed sending tobacco to American soldiers in Europe.

But the New York Times reported in 1928 that "little has been heard from Dr. Pease since" (p. 7). Indeed, the anticigarette movement by then was waning. Cigarette prohibition was repealed in Indiana in 1909; Washington in 1911; Minnesota in 1913; Oklahoma and Wisconsin in 1915; South Dakota in 1917; Nebraska in 1919; Arkansas, Idaho, Iowa, and Tennessee in 1921; Utah in 1923; North Dakota in 1925; and Kansas in 1927 (Gottsegen 1940). Legislatures in other states—including Lucy Page Gaston's home state of Illinois—considered but did not enact anticigarette bills (Duis 1983). Even the WCTU, at the time judged "the most powerful and the most formidable organization which is actively opposing the use of tobacco" (Brown 1920, p. 447), in 1919 voted against supporting tobacco prohibition. The organization pledged to keep to an educational rather than a legislative campaign (New York Times 1919).

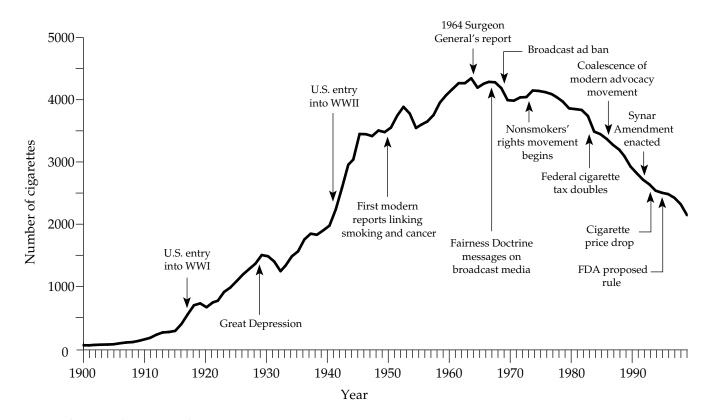
A major weapon against the tobacco prohibition movement was the American soldier. Cigarettes had been popular among the armed forces since the Civil War. By 1918, during World War I, cigarettes were part of the army's daily ration (Dillow 1981); soldiers used cigarettes for relief during the extremes of tedium and tension characteristic of the profession. General John Joseph Pershing himself is supposed to have said, "You ask me what we need to win this war. I answer tobacco, as much as bullets" (quoted in Sobel 1978, p. 84). "The soldiers, we are told, must have their tobacco," a newspaper editorialized in 1915: "The cigarette is the handiest form in which this can be sent" (Lynn [Mass.] Evening News 1915, p. 4). Even the Young Men's Christian Association altered its antitobacco stance and, along with the International Red Cross and other charitable and patriotic organizations, sent cigarettes off to the soldiers in the field (Schudson 1984). This outspoken, soldier-directed sentiment in favor of the cigarette was thus a large-scale factor in the reversal of anticigarette laws. A representative question that fueled the repeal effort in Kansas in 1927 was, "If cigaret[te]s were good enough for us while we were fighting in France, why aren't they good enough for us in our own homes?" (*Literary Digest* 1927, p. 12; see also Smith 1973).

Weakened but not vanquished by these legislative setbacks, the war on tobacco persevered. In 1921, the Loyal Temperance Legion reported holding anticigarette essay contests, distributing antitobacco blotters in schools, and stubbing out 125,000 cigars and cigarettes (WCTU 1921). The Department of Narcotics held up its own end; in 1929, for instance, it held poster contests, cooperated in antitobacco work with

other civic organizations, sponsored 214 debates on tobacco, and ran essay contests producing more than 50,000 essays against tobacco use (WCTU 1929). Religious denominations, including the Presbyterians, Methodists, and Baptists, also took a stand against tobacco (Troyer and Markle 1983). The antitobacco position was especially strong among the Mormons (Latter-day Saints). A motto of the Mormon youth organization in 1920, "We stand for the non-use and nonsale of tobacco" (quoted in Smith 1973, p. 360), seems to have presaged the current low prevalence of tobacco use in Utah.

Such dedicated opponents did not prevent the popularity of the cigarette—an inexpensive, easy-to-use form of tobacco product—from increasing in the 1920s (Figure 2.1; the demographic and epidemiologic

Figure 2.1. Adult per capita cigarette consumption and major smoking and health events, United States, 1900–1999



Note: The 1999 data are preliminary.

Sources: Adapted from Warner 1985; U.S. Department of Health and Human Services 1989; Creek et al. 1994;

U.S. Department of Agriculture 2000.

details of cigarette consumption have been documented in detail in prior reports [USDHHS 1989, 1994] and will not be repeated here). Men in substantial numbers either switched from other tobacco forms or took up smoking, and women in smaller but visible numbers began taking up tobacco use—in the form of cigarette smoking—for the first time, even as the frequently women-led antitobacco efforts continued. By the 1930s, cigarettes accounted for more than one-half of all tobacco consumption (Schudson 1984).

In response to these trends, the WCTU campaigned for strict enforcement of laws forbidding the sale of tobacco to minors, attacked advertising that claimed or suggested health benefits, and criticized smoking among women. In 1927, the Department of Narcotics reported that chapters across the country had sponsored thousands of antismoking events and strategies. For example, the Portland, Oregon, chapter successfully protested a leading department store's use of a female mannequin holding a cigarette. Members stubbed out 219,560 cigarettes and 39,713 cigars. The WCTU also lobbied for laws prohibiting smoking in places where food was displayed for sale and reported that 21 states had enacted such laws (Schudson 1993).

As the cigarette's popularity increased, so did concerns about its health consequences. Serious research of the day sought to link tobacco with a variety of conditions (Burnham 1989), but uncovered little new ground (Tate 1999), while sobering results were often lost amid a welter of overblown charges. For example, the common observation at the time that cigarette smokers seemed more dependent on their habits than other tobacco users, now explained by increased blood nicotine levels (Tate 1999), led one writer in 1912 to warn that users would naturally progress from tobacco to alcohol to morphine (Sinclair 1962). Similar unsubstantiated charges have often made better headlines than the results of serious scientific studies over the years. In 1930, one doctor claimed that 60 percent of all babies born to mothers who smoked died before reaching the age of two (Sinclair 1962). Smoking was said to depress intelligence and academic achievement (Troyer and Markle 1983). One historian writing in 1931 recalled a widely distributed antismoking poster that wordlessly voiced these concerns by showing a woman who had a cigarette in her mouth and was holding a baby; the poster bore "no words—the mere presentment, it was hoped, would have a deterrent effect" (Corti 1931, p. 266).

That image of mother and child projected an antismoking message that, typical of its time, contained both a moral and a medical objection to smoking. Historian Allan M. Brandt has observed that antitobacco crusaders early in the century "saw no tension in seeing the cigarette as ungodly and unhealthy; they equated moral dangers and health risks" (Brandt 1990, p. 159). A 1925 WCTU pamphlet held that because the brain's higher functions develop last, youthful smokers would have "impaired morals, weak will, lack of religious and spiritual development, and a shocking incapacity for unselfishness and consideration of the rights of others" (p. 9). One of the moral dangers that remained a theme in anticigarette propaganda was the danger smoking posed to thrift, as cigarettes were a needless expense, especially among the poor (Brown 1920).

Although anticigarette crusaders had medical objections to smoking, they did not have any medical consensus behind them. Medical opinion was generally noncommittal. Most physicians counseled that tobacco in moderation was not harmful (*Hygeia* 1928; Tobey 1930; Johnson 1932). Media reports even located medical research that suggested that smoking had health benefits. During World War I, army surgeons praised cigarettes for providing the wounded relaxation and relief from pain (*New York Times* 1918); a Paris physician claimed that tobacco use might prevent the development of microbial infections (*New York Times* 1923); and a famous mountain climber said that smoking helped breathing at high altitudes (*New York Times* 1922).

Without a strong medical component, the objection against tobacco use was scarcely distinguished from any number of other protest targets of the reform movement early in the century. Lacking as strong an opponent as, for example, the alcohol temperance movement, tobacco use continued unabated. In the instance of cigarettes, use proliferated.

The Attraction of Cigarettes

Throughout its boom period, from the 1920s until the mid-1960s, cigarette smoking was generally regarded as a consumer activity rather than as a medical problem. In its commercial essence, the cigarette is simply a "package," as a Philip Morris Companies Inc. memorandum has suggested, for a "product" (*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 [1992], cited in Lynch and Bonnie 1994, p. 60). In fact, the cigarette is by far the most commercially successful package for the product—tobacco, itself a delivery device for nicotine—yet devised. Such thinking fits well with the notion that consumption is an act of imagination—that is, that one buys not the product but rather the attributes for which the product is merely the vehicle (Fox and Lears 1983).

Each vehicle for nicotine delivery has different social propensities. The unique qualities of the cigarette as a tobacco form were critical in its role as the agent through which tobacco use was made both available and acceptable to all social classes. Put simply, cigarettes not only made tobacco cheaper (through automated production) but also easier to use. This utility stemmed from several distinctive features that separated cigarettes from other modes of tobacco use and fueled the spread of the smoking habit.

The first distinctive feature of the cigarette is its mildness. This attribute, along with its inexpensive unit cost, made the cigarette especially appealing to boys. Before the cigarette became popular, adolescent males were likely to first try smoking by using cigars, a practice that required a degree of skill to draw in but not inhale the strong smoke. The unpleasant side effects resulting from failing this tobacco rite of passage were largely avoided when new smokers tried cigarettes, which used a milder form of tobacco that was meant to be inhaled. Many of the legislative efforts during the 1890s and after were directed not at tobacco use generally but at cigarettes exclusively because they were so accessible to boys and young men and because they were inhaled (Outlook 1901). A 1907 Wisconsin court decision used this issue of adolescent accessibility to justify a regulatory distinction between cigarettes and other forms of tobacco. The cigarette, the decision stated, was able "... to remove the protection which nature placed in the way of acquiring habits of use of the more vigorous tobacco commonly used in cigars. Before the day of the cigarette, mastery of the tobacco habit was obstructed by agonies of nausea usually sufficient to postpone it to a period of at least reasonable maturity" (State v. Goodrich, 113 N.W. 388, p. 390 [Wis. 1907]).

Mildness was especially characteristic of cigarettes smoked after the 1870s, when cigarette tobacco was made milder by being flue-cured rather than firecured. Moreover, the stronger Turkish tobaccos that were popular in the early 20th century became unavailable with the interruption of trade during World War I; thus, blended American tobaccos came into wider use, making the cigarette an even milder product than before (Tennant 1950).

The inhalability of the milder tobaccos used in cigarettes is the source of a second important distinction between cigarettes and other forms of tobacco. Because the smoke of pipes, cigars, and dark tobacco is relatively alkaline, its nicotine dose is absorbed through the linings of the mouth and nose. Flue-cured "blond" or light-colored tobacco, from which American cigarettes are normally blended, produces slightly

acidic tobacco smoke; the nicotine dose thus must be inhaled to be absorbed. Drawn into the lungs through cigarette smoking, nicotine is absorbed into the systemic circulation more quickly than in other forms of smoking—hence the greater potential for nicotine addiction (Lynch and Bonnie 1994).

A third distinctive feature of the cigarette is its relative convenience and disposability. This mild and quickly consumed tobacco product seemed to contemporaries "peculiarly adaptable to the temperament of the American people in an age when things are done hurriedly and yet with greater efficiency than at any previous time" (Young 1916, p. 119). The *New York Times* editorialized in 1925 that the cigarette was "short, snappy, easily attempted, easily completed or just as easily discarded before completion—the cigarette is the symbol of a machine age in which the ultimate cogs and wheels and levers are human nerves" (*New York Times* 1925, p. 24). Facility of use was further augmented by the introduction of the safety match just before World War I (Burnham 1989).

In short, cigarettes had a "natural adaptability" to the rhythms of urban life (Tennant 1950, p. 142). Cigarettes fit more easily than other forms of tobacco into brief moments of relaxation, they were more readily used while working, and they were more easily managed without the use of one's hands. Cigarettes helped combat the tedium of industrial work. Particularly before workplace smoking restrictions were widespread, cigarettes could, in the words of one commentator, "not only help pace out a day—on the production line, in the typing pool, behind a lunch counter or waiting on a welfare line—but they could give you a steady flow of small rewards to keep on trucking" (Blair 1979, p. 33). Cigarettes organized and controlled the passage of time; a cigarette, writes Richard Klein, is "a clock" (Klein 1993, p. 24).

After World War I, cigarettes, which were less costly to use than cigars or pipe tobacco, became part of a more general "throwaway ethic" reflected in other consumer developments of the day (Busch 1983). The disposable razor blade came into widespread use during and after World War I (Schudson 1984); in 1927, U.S. wristwatch production surpassed pocket watch production, as the more conveniently consulted wristwatch had won favor among soldiers (Busch 1983).

Changing attitudes about hygiene also stimulated this predilection for convenience and disposability. Between 1909 and 1936, 45 states banned the common drinking cup used in public facilities such as railroads; the railroads became the first principal customers for the paper cup and paper cup dispensers (Busch 1983). Disposable sanitary napkins and

Kleenex tissues also became mass-market items for the first time in the 1920s (Busch 1983). From a strictly hygienic perspective, the cigarette appeared to give a cleaner smoke than the cigar. A Lucky Strike advertisement directly contrasted the neatness of cigarettes to the messiness of cigars, which require more oral manipulation: "Spit Is an Ugly Word, but It's Worse on the End of Your Cigar" (Tennant 1950, p. 286). This advertisement also played on an earlier scandal in which cigar makers were purported to have used spit to seal the cigar's leaf wrapper (John C. Burnham, telephone conversation with Richard B. Rothenberg, May 25, 1995). For a generation working in offices and riding to work in subways, streetcars, and automobiles, milder smoke was less irritating to others. Both the strong fumes of cigar and pipe smokers and the unsightly by-products of snuff and chewing tobacco users were generally more objectionable than the smoke and ashes of cigarette smokers. Historian Cassandra Tate has concluded that one of the lessons of the first antismoking campaign is that "any successful social reform movement carries within it the seeds of a backlash" while "incessant warnings can fade into the ozone of the commonplace" (Tate 1999, p. 155).

An important part of the cigarette's convenience was its readiness of use. Some smokers still rolled their own cigarettes in the 1920s and 1930s, but these consumers were a small segment of the market (Tennant 1950). By far, most smokers during these key decades of rising cigarette popularity used cigarettes prerolled by the manufacturer. (Cigars were also prerolled, but by hand rather than by machine, and thus at considerable expense to the buyer.) The cigarette's ready-made convenience was immediately apparent when compared with, for example, the care required to load a pipe so that it burned neither too quickly (thereby overheating the bowl) nor too slowly (thereby requiring frequent relighting). The cigarette was far more easily lit and drawn than other smoked tobacco products.

One final distinctive feature of the cigarette is its cultural connotation as a minor moral transgression. Smoking cigarettes is—and has always been—considered slightly illicit. A practice that "looked so strange, felt so pleasant, accomplished so little, and cost so much [although less than cigar or pipe smoking] could not be unopposed" (Tennant 1950, p. 115). The pleasure it offers is culturally mediated—that is, part of the pleasure of smoking is the guilt connected with it. None of the marketing efforts of the tobacco giants ever fully legitimized the image of smoking—and there is some suspicion that they never meant to (Burnham 1993). As one sympathetic cultural observer has put it, part of the seductive quality of the cigarette

is "beauty [that] has never been understood or represented as unequivocally positive; the smoking of cigarettes, from its inception in the nineteenth century, has always been associated with distaste, transgression, and death" (Klein 1993, p. xi). A modern parallel is the recent cachet of smoking as a sexual fetish, with images available on the Internet (Hwang 1996, p. 5). Culturally, in fact, interviews have shown that cigarettes became a generational marker for the transforming generation that had come of age during World War I, as well as for the reform-minded generation of the Vietnam War era (Tate 1999).

Women and Cigarettes

Several features of the cigarette helped make it a particularly suitable product for, and symbol of, the liberation of women, who came to smoking in growing numbers beginning in the 1920s. Just as the cigarette "fairly leaped" into its rightful position as "the smoke of manly men" with the aid of stories and pictures from the World War I front ([New York] Tobacco Leaf 1914, p. 6, quoted in Young 1916, p. 228), so for young women after the war smoking was "perhaps the one most potent symbol" of the new sense of freedom and equality (Fass 1977, p. 292). For the growing number of women who attended college in the 1920s, smoking was "a welcome form of notoriety" (p. 293). Objections to women's smoking betrayed a traditional double standard, for such opposition arose from the twin cultural perceptions that cigarettes were not moral and were not feminine. Smoking "implied a promiscuous equality between men and women and was an indication that women could enjoy the same vulgar habits and ultimately also the same vices as men" (p. 294). But while they were tokens of equality with men, cigarettes were also amorphic, making men appear more manly and women more womanly (Tate 1999).

Aware of (and perhaps sharing) these objections, cigarette manufacturers were initially cautious about targeting this potential new market. As late as 1924, the editor of a tobacco trade journal wrote that "all responsible tobacco opinion [found the idea of women smoking so] novel... that it would not be in good taste for tobacco men as parties in interest to stir a particle toward or against a condition with whose beginnings they had nothing to do and whose end, if any, no one can foresee" (Wessel 1924, p. 6). Even advertisements with women in mind did not dare picture them actually smoking.

This initial caution was dictated by canny attention to the political environment. Cigarette manufacturers feared a backlash in legislation or public opinion if they too aggressively sought female consumers (Tennant 1950). In light of anticigarette legislation arising during the 1920s, and particularly in light of the ongoing experiment in alcohol prohibition, this anxiety was reasonable.

The cigarette industry's caution was short-lived. As the 1920s advanced, appeals to women through tobacco marketing were increasingly direct. In 1926, the Chesterfield brand ran a then-controversial advertisement wherein a woman urged a male companion to "Blow Some My Way" (Ernster 1985, p. 336). In 1927, Lucky Strike advertisements showed a famous female opera star recommending Luckies as soothing to the throat and a famous actress assuring readers that Luckies did not irritate the throat (Schudson 1984). And in 1928, Luckies were advertised with the dietconscious slogan, "Reach for a Lucky Instead of a Sweet" (Ernster 1985, p. 336).

Winds of Change

The industry's direct appeal to the new market of female smokers likely reflected less boldness than it did a recognition of a prevailing wind of cultural change, of which the women's movement was only a single component. In the 1920s, on the heels of the 19th Amendment, women's growing assertion of their equality with men was part of a larger shift in American culture, the move to a more modern culture from the somewhat puritanical milieu that supported the populist reform movement. In the language of one observer, the change was from a culture of middle-class respectability to one of "lower-order parochialism" sponsored and encouraged by industries that catered to the minor vices (Burnham 1993, p. 16). The 1920s saw the triumph of "a new behavioral ethic" (Brandt 1990, p. 157), one of consumerism and self-indulgence rather than the self-denial that had been, for example, the traditional lot of women. Through the marketing of cigarettes, the tobacco companies strategically exploited this development among the less puritanical and self-recriminating members of both sexes.

Even at the time, opinion was divided on whether the massive marketing efforts of the cigarette giants motivated the change toward a society of smokers or only took advantage of a cultural and behavioral shift already under way. In 1940, by which time the cigarette had clearly triumphed over other forms of tobacco, one study of the tobacco industry concluded, "how much of increased cigarette consumption is due to advertising and how much to fashion is impossible to determine. The latter influence is still imponderable" (Gottsegen 1940, p. 204).

Fashion and advertising were not the only two factors. Three other matters were potentially important: (1) the physical product itself was not a constant, (2) the price was variable, and (3) society changed in ways that influenced consumption. For example, before the explosion of cigarette marketing in 1914 (Burnham 1989), men smoked more than women, the rich smoked more than the poor, and urban dwellers smoked more than rural inhabitants. (For a more comprehensive account of the demographic dynamics, see USDHHS 1989.) With growth in the movement for women's equality, a rising per capita income in real dollars, and the long-term trend toward urbanization, there would likely have been an increase in cigarette sales even if tobacco companies had not marketed the product aggressively.

Regardless of what directed the impetus, per capita consumption of all forms of tobacco was remarkably steady from 1913 to 1945 (Figure 2.1), rising when real income per capita rose, falling when real income fell (Tennant 1950). The spectacular growth in cigarette consumption reflected not only the introduction into the tobacco market of new consumer groups (such as women) but also, as was previously noted, a major shift among existing male smokers from other forms of tobacco use to the cigarette. Annual per capita consumption of tobacco hovered at 7 pounds from 1915 through the late 1930s, except for a transient decline in the early 1930s that was coincident with a drop in per capita income in the early years of the Great Depression (Tennant 1950). It is possible, however, that actual consumption of tobacco per unit of weight increased because of less work in both the manufacturing and the use of the increasingly popular cigarette. World War II, like World War I, served to increase and promote cigarette smoking, to which numerous war novels, movies, and other public images testify (Klein 1993). A 1943 treatise observed that the cigarette achieved a heroic standing from its association with soldiers during World War II (Gehman 1943). In short, between about 1920 and 1950, "cigarettes became an acceptable and noncontroversial part of U.S. life" (Troyer and Markle 1983, p. 124).

Medical Warnings

Medical opinion at first took little heed of the growing popularity of cigarettes. Physicians tended to take an ambivalent or qualified position on the cigarette phenomenon. For instance, although Dr. James J. Walsh wrote in 1937, "We physicians of the older generation who have seen the smoking of cigarettes grow from what seemed scarcely more than a toy into what is now one of the most significant of social institutions are under an obligation to the rising generation to warn them of the serious dangers associated with the abuse of cigarettes in our day" (Walsh 1937, p. 665), even Walsh admitted to smoking an occasional cigarette himself. He further attested that many doctors he knew smoked 20 or 30 cigarettes a day and yet were "as healthy as the proverbial trout" (p. 665). He held that "not the cigarette smoke so much as the excess of it" (p. 665) brought about serious conditions like Buerger's disease.

The Puritan temperament that had fueled anticigarette activity early in the century was on the defensive. Antipathy to Puritan moralism was strong enough to weaken faith in any research tainted by it. For example, Alton Ochsner's suggestions in the 1930s and 1940s of a connection between cigarette smoking and lung cancer were discounted by his colleagues because he was known to be "an anti-smoking enthusiast" (Burnham 1989, p. 18). During these crucial times when cigarette smoking became widespread, "physicians tended to absorb the common sense of the general population" (p. 11). By the 1930s, common sense, in some measure influenced by the advertising claims of the era, held that smoking in moderation was not a health hazard (Burnham 1993).

In 1938, Raymond Pearl published one of the first significant epidemiologic studies that indicated smoking to be "statistically associated with an impairment of life duration" (Pearl 1938, p. 217, quoted in Breslow 1982, p. 134; see also Brandt 1990). But only in the late 1940s and early 1950s did definitive evidence begin to accumulate from various sources and studies showing the association between cigarette smoking and overall mortality. First retrospective and then large-scale prospective studies confirmed that smoking was associated with higher death rates; excess mortality was especially pronounced for coronary artery disease and lung cancer.

In the late 1940s and early 1950s, research linked lung cancer to smoking. The initial report by Wynder

and Graham (1950) just preceded an article by Doll and Hill (1950). Subsequent articles by Doll and Hill (1952), Levin (1953), and others confirmed the association. Levin's contribution was of particular interest, because he derived the formula for attributable risk in a footnote to the article—an overt demonstration of the link between the smoking etiology and the emerging methodology of epidemiologic analysis.

Public Dissemination

The findings from these and other studies of the era were publicized in a 1952 Christian Herald article. In December 1952, that article was reprinted in the widely circulated magazine Reader's Digest as "Cancer by the Carton" (Norr 1952). Popular concerns aroused by this publicity apparently led to an almost immediate decline in cigarette consumption (Tennant 1971). The decline was temporary but severe enough to lead the tobacco companies to step up their market promotion of the relatively new filter-tip cigarette. Originally intended to attract new smokers by offering a milder smoking experience, the filtered cigarette assumed a marketing prominence that was seen as a tacit acknowledgment that there might be a health risk in smoking (Fortune 1953). Whether for smoking comfort or for supposed health advantage, the market share of filter brands increased from less than 1 percent in 1952 to 73 percent in 1968 (Tennant 1971).

The nonprofit consumer advocacy organization Consumers Union paid attention to smoking throughout the 1950s. Early mentions in the organization's monthly magazine Consumer Reports, like so much commentary elsewhere, warned only against excessive smoking. In 1953, Consumer Reports found the evidence connecting smoking to lung cancer "suggestive" and recommended that until further research results were available, "those who can" should reduce smoking to a "moderate" level, which was defined as not more than one pack a day (p. 74). In the same issue, however, the magazine reminded readers that smoking had health benefits; specifically, smoking reduced "the inner nervous tensions and strains resulting from man's exposure to the stresses and responsibilities imposed by society" (p. 74). Smoking, the magazine further observed, relieved such pressure in a way less harmful than alcohol or overeating (Consumer Reports 1953).

In 1954, medical advisers for Consumers Union spoke more strongly about the research link between smoking and lung cancer, but the organization remained vague in its advice to smokers (Consumer Reports 1954). In the absence of further scientific support, this tentativeness was not surprising. It was hard to imagine that a habit so widespread, so apparently normal, so integrated into American culture, and so ennobled by its wartime use could turn out to be fundamentally destructive. In 1954, the American Cancer Society's (ACS) Tobacco and Cancer Committee adopted a resolution recognizing an association between cigarette smoking and lung cancer (Breslow 1982), but the board of directors did not consider the possibility of a causal association. Efforts of the physician members of the board were blocked by lay members in meetings that were themselves "filled with smoke" (Breslow 1977, p. 849).

By 1958, Consumers Union agreed that the medical research provided nearly definitive evidence on the risk of lung cancer posed by smoking. The organization further argued that smokers should not try to allay their concerns by switching to filter cigarettes, as no evidence indicated that filters reduced the risk of cancer. Smokers were thus advised "to cut out or cut down" on cigarettes (*Consumer Reports* 1958, p. 636).

Toward a Medical Consensus

With growing sentiment, in and beyond the medical community, that there were serious risks to tobacco use, government agencies became more concerned about tobacco advertising that stated or implied health benefits to the cigarette. Several times during the 1950s, the Federal Trade Commission (FTC) issued orders against cigarette advertising that made health claims. Congress also took an interest in tobacco advertising; in 1957, Representative John A. Blatnik (D-MN) held hearings on deceptive filter-tip cigarette advertising (Neuberger 1963). The Surgeon General first brought the Public Health Service into the scene by establishing a scientific study group in 1956 to appraise the effects of smoking on health. The study group determined that there was a causal relationship between excessive smoking of cigarettes and lung cancer. Surgeon General Leroy E. Burney issued a statement in 1957 that "the weight of the evidence is increasingly pointing in one direction: that excessive smoking is one of the causative factors in lung cancer" (Burney 1958, p. 44). In an article he subsequently published in the Journal of the American Medical Association, Burney reiterated this view and went even further: "The weight of evidence at present implicates smoking as the principal etiological factor in the increased incidence of lung cancer" (Burney 1959, p. 1835).

Much of the medical profession, however, remained ambivalent on the issue. In an editorial several weeks after Burney's article, the journal itself argued against taking the Surgeon General too seriously: "Neither the proponents nor the opponents of the smoking theory [that cigarette smoking causes cancer] have sufficient evidence to warrant the assumption of an all-or-none authoritative position" (Talbott 1959, p. 2104).

In June 1961, the presidents of the ACS, the American Public Health Association, the American Heart Association (AHA), and the National Tuberculosis Association (later the American Lung Association [ALA]) urged President John F. Kennedy to establish a commission to study the health consequences of smoking (U.S. Department of Health, Education, and Welfare [USDHEW] 1964). Early in 1962, representatives of these organizations met with Surgeon General Luther L. Terry, who then proposed establishing an advisory committee to assess available knowledge and make recommendations concerning smoking and health. In April, Terry provided the Secretary of Health, Education, and Welfare a fuller proposal asking to reevaluate the Public Health Service's position on smoking. Among the factors prompting his call for action, Terry cited new studies on the adverse consequences of smoking, the 1962 Royal College of Physicians report (which had been summarized that year in Reader's Digest [Miller 1962]), and other evidence of a shift in medical opinion against smoking as well as similar views among the national voluntary organizations. Terry also pointed to efforts to reduce tobacco use in Britain, Denmark, and Italy; to Senator Maurine (Brown) Neuberger's (D-OR) proposal that Congress create a commission on smoking; and to a request from the FTC for guidance on the labeling and advertising of tobacco products.

In the summer, Terry announced the appointment of a committee to review all of the data on the medical effects of smoking. The committee was established after consultation with representatives of relevant government agencies, the voluntary health organizations, the American Medical Association (AMA), the American College of Chest Physicians, and the Tobacco Institute. Each organization was empowered to veto any names proposed for the committee; people who had taken public positions on the questions at issue were eliminated from consideration.

While the committee reviewed the data, actions were being urged or taken in response to the evidence that had emerged. Leroy Collins, former governor of Florida and president of the National Association of Broadcasters, urged broadcasters in 1962 to "make corrective moves" on their own to limit or regulate tobacco advertising to which children might be exposed. "We cannot ignore the mounting evidence that tobacco provides a serious hazard to health," he asserted (*New York Times* 1962, p. 71). Also in 1962—a busy year for efforts to reduce smoking—Air Force

Surgeon General Major General Oliver K. Niess ordered an end to the distribution of free cigarettes in Air Force hospitals and flight lunches (Neuberger 1963). Smoking education was a growing phenomenon in public schools, where materials were provided by the ACS and other voluntary organizations. Church groups (particularly the Seventh-day Adventists) and temperance organizations continued their campaign against smoking. And although the AMA remained silent on the issue, at least eight state medical societies had adopted resolutions on smoking and health.

Turning Point: The Surgeon General's Report

Social movements may be precipitated or strengthened by events that "dramatize a glaring contradiction between a highly resonant cultural value [such as health] and conventional social practices [such as smoking]" (McAdam 1994, p. 40). Rarely in social history, however, can a single such event be identified as a key source of social change. The publication of the 1964 Surgeon General's report on smoking and health might qualify as such a rarity. The Surgeon General's report consolidated and legitimized 15 years of growing evidence of the dangers of smoking to health (USDHEW 1964). Its publication "marked the beginning of a revolution in attitudes and behaviors relating to cigarettes" (Brandt 1990, p. 156). "Beginning" should be stressed, because abandonment of cigarettes was not precipitous. Smoking prevalence did begin a persistent but hardly precipitate decline in 1965 of 0.5 percent per year (USDHHS 1989). Cigarette sales kept increasing and would not peak until the late 1970s. Although per capita cigarette consumption reached its highest level in 1963, the year before the report's publication, it did not begin a steady year-to-year decline until 1973 (USDHHS 1994).

Thus, the Surgeon General's report was certainly a pivotal event, but it did not change smoking patterns overnight. Why this was so—why people did not, upon learning of the report's findings, immediately cease either beginning or continuing to smoke—is a complex phenomenon, even if one disregards the major role of nicotine addiction. On the one hand, a change in behavioral norms can be precipitated by a change in what people generally believe. On the other hand, people do not always act in their own

best interests, even in response to clearly stated facts (Schudson 1984; USDHHS 1989). The outcome in a conflict between cultural mores (in this instance, beliefs instilled through the social, behavioral, and physiological habit of smoking, reinforced by marketing) and scientific fact (as represented in the widely publicized findings of the Surgeon General's report) often depends on how the latter is diffused—that is, on whether new information can become so broadly and effectively transmitted and received that it becomes accepted knowledge that then supplants habit. As one sociologist has observed, "The diffusion of new knowledge is a major cause of collective searches for new norms in the modern world" (Davis 1975, p. 53).

A Stubborn Norm

In the case represented by the Surgeon General's report, the diffusion of new knowledge was impeded by the entrenched norm of smoking, a widespread practice fueled by the persistent and pervasive marketing of cigarettes (see "Advertising and Promotion" in Chapter 5). During the decade preceding the report, many social norms were established or strengthened through the dominant new mass medium, television. Whatever effect television advertising had on cigarette sales, the constant presence of cigarettes both in advertisements and in the real and imaginary lives of the medium's "stars" was a strong force in reinforcing smoking as a norm. Furthermore, TV-related marketing coincided with, and helped bring to the public's attention, the availability of the filtertipped cigarette-thereby not only reinforcing the smoking norm but also helping screen the imputed health hazards of smoking (USDHHS 1994).

The smoking norm could be found in the most unlikely settings and thus gave rise to considerable cognitive dissonance. The first significant government response to the report was the FTC's 1964 ruling that warning labels be required on cigarette packs and that tobacco advertising be strictly regulated (see "Attempts to Regulate Tobacco Advertising and Packaging" in Chapter 5). The resulting legislation that was passed, however (the Federal Cigarette Labeling and Advertising Act of 1965 [Public Law 89-92]), undermined much of the original proposal's strength by requiring a more weakly worded warning label than the FTC had proposed (USDHHS 1994). Furthermore, the act not only preempted the FTC's ruling but also prohibited the FTC or any other federal, state, or city authority from further restricting cigarette advertising until after the expiration of the law on June 30, 1969. In 1969, former Surgeon General Terry would refer to the 1965 act as a "hoax on the American people" (U.S. House of Representatives 1969, p. 267, citing Dr. Terry).

This dissonance between legislative intent and legislative action was detectable, in more than one sense, in the smoke-filled congressional hearings at the time. In 1967, for example, when Dr. Paul Kotin, director of the Division of Environmental Health Sciences, National Institutes of Health, came to testify about the health hazards of cigarette smoking, Senator Norris Cotton (R-NH) asked, "Is it going to prejudice anybody if I smoke my pipe?" Dr. Kotin replied, "I trust it won't prejudice anybody any more than my smoking my pipe will" (U.S. Senate 1968, p. 14). Dr. Kotin's smoking was a topic of conversation again in congressional hearings in 1969. Dr. Kotin along with Surgeon General William H. Stewart, Dr. Kenneth Milo Endicott (director of the National Cancer Institute), and Dr. Daniel Horn (director of the National Clearinghouse on Smoking and Health) came together to testify in favor of stronger health warnings on cigarette packages and legislation requiring similar warnings in all cigarette advertising. At one point, Representative Dan H. Kuykendall (R-TN) asked Surgeon General Stewart, "Isn't [Dr. Kotin] one of the most knowledgeable men in this field?" When the Surgeon General replied affirmatively, Kuykendall returned, "Why doesn't he quit smoking?" Kuykendall then directly asked Kotin whether he was sure that smoking a pipe did not cause lip cancer; Kotin responded, "A risk I am willing to take, sir" (U.S. House of Representatives 1969, p. 167). The next day, Representative Tim Lee Carter (R-KY) observed that, in fact, all four of the men in the delegation, including the Surgeon General, were smokers (U.S. House of Representatives 1969). Actions undermine words, and scenes such as these were symbolic of a strong wish not to believe in the health consequences of smoking. Given that the nation's chief health policymakers did not, or were not able to, apply to their own behaviors the very evidence they had gathered, the strength with which the smoking norm persisted among the general population is more easily comprehended.

Economic and Social Impedance

General economic conditions also supported the continuation of smoking. The 1960s and early 1970s was a time of general prosperity. Real cigarette prices rose in the 1960s but declined in the 1970s (USDHHS 1994). The affordability of cigarettes increased from 1965 to 1980 and served as an economic counterweight to the growing awareness of tobacco's ill effects (Lynch and Bonnie 1994) (see also "Effect of Price on Demand for Tobacco Products" and "Taxation of Tobacco Products" in Chapter 6).

Another compelling social condition may have further limited the initial impact of the Surgeon General's report. From the early 1960s to 1973, American military personnel were engaged in Vietnam. During this period, 8.7 million Americans served in the military, including 2.7 million in Vietnam (Moss 1990). Whether the Vietnam War encouraged smoking has not been a topic of speculation, probably because of that war's more publicized role in supposedly encouraging the use of marijuana and other drugs (Klein 1993). But the norm of smoking would only have been strengthened by the mobilization of a large military force bringing several million young men and women into a setting where smoking was traditionally held to offer relief from both stress and boredom, and where it was part of a lingering cultural image of the heroic soldier. Moreover, the prevalence of cigarette smoking was and has remained higher in the military than in the population at large (in 1992, 35 vs. 26 percent) (Lynch and Bonnie 1994).

Delayed Effects and Delayed Actions

A significant biologic explanation for the delayed effect of the 1964 report can be found in the delayed progression of smoking-related diseases, which generally take substantial time to fully manifest themselves in chronic illness and death. The cigarette's tremendous growth in popularity during the decades preceding the Surgeon General's report would thus

have only begun to show its vast health consequences. In 1965, an estimated 180,000 persons died from smoking-related diseases (USDHHS 1989); over the next two decades, that yearly estimate increased to 337,000, even though smoking prevalence had been steadily declining since the early 1970s (USDHHS 1989). First-time or long-time smokers in the mid-1960s to mid-1970s thus had far less opportunity than the next generation to personally witness the tragic but convincing demonstration of the health consequences of smoking. It might be hypothesized that this somber proof of the Surgeon General's report at last evoked a meaningful response among the surviving relatives and friends of the deceased.

From Disease Treatment to Risk Management

Another possible reason for the delayed response to the Surgeon General's report was its less-than-traditional medical perspective. The report's medical researchers were reporting not the kind of traditional clinical data that physicians were used to encountering in their literature but rather data from epidemiologic studies that indicated the risks of smoking. Eventually, such data would be persuasive enough to mark a perceptual shift to "a new kind of numeracy among medical researchers and clinicians alike" (Burnham 1989, p. 19). But in 1964, most physicians were not prepared to understand—much less be persuaded by—the epidemiologic data represented in the report, nor to incorporate a public health model into their medical practice.

Accordingly, the medical profession did not quickly jump on the smoking reduction bandwagon that began rolling with the Surgeon General's report. The American Medical Association Alliance House of Delegates, in fact, refused to endorse the report when it appeared in 1964 (Burnham 1989). Medical personnel increasingly warned people against smoking, but this precept did not carry over into practice. In 1964, smoking remained as acceptable in medical settings as it was elsewhere. Moreover, although 95 percent of physicians in that year saw smoking as hazardous, 25 percent continued to smoke (Burnham 1989); even by the mid-1970s, nearly one in five physicians was a smoker (Nelson et al. 1994). The AMA was criticized by other health organizations for not taking a more aggressive stance to reduce tobacco use. As late as 1982, for example, the association was faulted for helping prepare for Newsweek a 16-page "personal health care" supplement, in which the only advice provided on smoking was that a smoker should discuss the risks with a personal physician and should refrain from smoking in bed (Iglehart 1984). Soon thereafter, the AMA had become an active advocate (see "Toward a National Policy to Reduce Smoking," later in this chapter). By 1990–1991, only 3.3 percent of physicians smoked, although smoking rates among nurses were significantly higher (Nelson et al. 1994).

Some social critics of the time tacitly welcomed what they saw as a rare reluctance by the establishment to embrace a social movement. Sociologists and other outside observers of American medicine had noted a previous tendency of the establishment to "medicalize" social problems, such as tobacco use and alcohol abuse. From this perspective, medicine was viewed askance as an "institution of social control," as a "new repository of truth, the place where absolute and often final judgments are made by supposedly morally neutral and objective experts" (Zola 1972, p. 487). Implicit in this criticism was the fear that the medical establishment was using its considerable clout-its professional domination of the world of facts—to translate all social ills into clinical terms that could be treated in a clinical setting. One such critic, medical sociologist Eliot Freidson, wrote that the physician who calls alcoholism a disease "is as much a moral entrepreneur as a fundamentalist who claims it is a sin" (Freidson 1974, p. 253).

But the medical establishment's initial hesitancy to join the movement to reduce smoking likely had little to do with scruples about overstepping its purview. There is no dispute that cancer is a disease and little dispute that the medical profession is the expert social authority for defining and treating it. The "moral entrepreneurship" of the Surgeon General's 1964 report was not to declare cancer a medical problem but rather to declare smoking a health risk—hence the central position of epidemiologic data in the report.

Thus, while organized medicine followed slowly and sometimes reluctantly in the wake, and while social skeptics worried about the Orwellian implications, a battery of public health officials, politicians, and consumer advocates, armed with the findings of the Surgeon General's report, moved against the persisting social and medical problem of smoking. Ultimately, the broad cultural current that distrusted medical moral entrepreneurship embraced these efforts. The "demedicalizing" movement, which sought to make health care both a personal matter and a political matter rather than one wholly under the guardianship of physicians (Starr 1982), supported a practice of medicine that took a preventive stance instead of an exclusively therapeutic one. Preventive action—to prevent smoking, and

thereby to prevent unnecessary illness and death from smoking-related illnesses—was precisely the solution called for in the epidemiologically based recommendations of the 1964 Surgeon General's report.

The Diverse Momentum of the Movement to Reduce Smoking

Another reason for the languid pace of change in smoking prevalence after 1964 is that it took time to assemble an active dissemination and lobbying force around the Surgeon General's report. In the present period, so many different groups are active in antismoking activity, and so many different strategies are operating, that sorting them becomes difficult. Since 1964, the campaign to reduce smoking refers to "the entirety of changes in the social environment spawned by scientific and social interest in the hazards of smoking" (Warner 1989, p. 144); this movement covers not only specific activities but also "the changing social norms that have accompanied them" (p. 144). The span of activities involves persons, private organizations, and government agencies, all with different motivations: those ideologically committed to a movement to reduce smoking, those who operate profit-making businesses, those seeking public office, and those in public office who mandate laws and regulations. Important actors have included national health organizations, medical researchers, organized medicine, government regulatory agencies and health departments, school officials, voluntary organizations in health, lobbying groups for reducing smoking, private firms dealing with the health or insurance needs of employees, smoking cessation clinics, and individual medical practitioners.

The industry-funded Tobacco Institute began distributing smoking education materials in 1984 (USDHHS 1994), although with a different agenda. For example, the institute's "It's the Law" program purports to discourage minors from purchasing cigarettes (Tobacco Institute 1990), but the program focuses on the legal responsibilities of the purchaser rather than the vendor, characterizes smoking as an "adult behavior" (which may make it more attractive to adolescents), does not address the dangers of smoking, and, in one assessment, was ineffective in preventing illegal sales (DiFranza et al. 1996).

The work of the Tobacco Institute highlights what may be the foremost obstacle to changing the social norm of smoking: the multifaceted actions of the industry in preventing prevention. In an analysis of tobacco industry tactics, the Advocacy Institute (1995) has defined nine areas of activity: intimidation, alliances, front groups, campaign funding, lobbying, legislative action, buying expertise, philanthropy, and advertising and public relations (see the text box). In its discussion of well over 100 instances in these areas, documented largely from media reports, the Advocacy Institute does not accuse the tobacco industry of illegal activity but rather of a far-ranging and systematic effort to ensure the continued use of tobacco. Taken together, and backed by the enormous resources of the industry, these efforts have considerable impact in promoting tobacco use and retarding efforts to reduce or prevent it. Because of the considerable litigation now directed at the industry, however (see Chapter 5), the public is more aware of these efforts and may prove more resistant than previously to this powerful commercial subterfuge.

Support From Business

The supportive role of businesses in the movement to reduce smoking probably did not arise from a spontaneous realization that preventive measures could improve employee health. Already shouldering new costs from complying with health-related (but non-tobacco-related) new federal legislation, such as the Occupational Safety and Health Act of 1970 (Public Law 91-596) and the Toxic Substances Control Act (1976) (Public Law 94-469), many companies in the 1970s sought ways to control the rapidly rising costs of health care (Iglehart 1982). Supporting or enacting policies to curb a proven health risk (such as smoking) that had expensive consequences simply made good business sense.

A special case is insurance. Beginning with State Mutual Life Assurance Company of America in 1964, life insurance companies began offering discounted policies for nonsmokers (Cowell 1985). By 1987, approximately 80 percent of life insurance companies offered discounts to nonsmokers (Schauffler 1993).

Framework of Tobacco Industry Tactics

The Advocacy Institute has developed an overview of tobacco industry strategy, with extensive documentation taken from current media reporting. The documentation provides examples of each of the strategies listed below.

I. Intimidation

- A. Legal (harassing suits, subpoenas, injunctions, outspending plaintiffs)
- B. Economic (withdrawal of advertising, withdrawal of business operations)
- C. Political (retribution directed at elected and other officials)
- D. Personal (harassing researchers, advocates, and reporters)

II. Alliances

- A. Strong allies (subsidiaries, trade associations, advertising industry, tobacco farmers)
- B. Weak allies (labor unions, lawyers' associations, doctors' associations)

III. Front Groups

- A. Political groups (Michigan Citizens for Fair Taxes, Californians for Statewide Smoking Restrictions)
- B. Scientific groups (Council for Tobacco Research U.S.A. Inc., Healthy Buildings International)
- C. Smokers' rights groups (National Smokers Alliance)

IV. Campaign Funding

- A. Candidate funding
- B. Continued contributions after election
- C. Direct funding of interest groups and caucuses
- D. Political party funding
- E. Funding state ballot initiatives, or funding opposition to initiatives

V. Lobbying

- A. Support of lobbyists at state and national levels
- B. Seeking alliances with other lobbying groups on specific issues
- C. Gifts and contributions to specific causes
- D. Generating grassroots activity

Source: Advocacy Institute 1995

VI. Legislative Action

- A. Preemption
- B. Weakening or diluting legislation, or making it unenforceable
- C. Adding unrelated clauses to, or changing, the contents of legislative bills
- D. Shifting debate (stressing personal freedom rather than health; promoting smokers' rights)

VII. Buying Expertise

- A. Enlisting outside experts (economists, epidemiologists, medical researchers, statisticians, legal counsel)
- B. Creating the Council for Tobacco Research U.S.A. Inc.

VIII. Philanthropy

- A. Buying innocence by association (financial support to wide range of organizations)
- B. Funding (women's groups, racial and ethnic minority groups, homeless shelters, acquired immunodeficiency syndrome [AIDS] groups, arts groups, educational initiatives, community-based nonprofit organizations, sporting events)

IX. Advertising and Public Relations

- A. Issue framing (choice, civil rights, personal freedom)
- B. Advertising to promote corporate character
- C. Disinformation (health effects, economic importance of tobacco)

Health insurance rates, in contrast, have not typically distinguished between smokers and nonsmokers. Acceptable actuarial data on additional medical expenses incurred by smokers did not exist until the early 1980s; at present, discounts for nonsmokers or surcharges for smokers have not been widely adopted by health insurance companies (Schauffler 1993). Nonetheless, both the health insurance and the life insurance industries have become active in smoking-related public policy. In 1977, the trade associations of the two industries formed the Center for Corporate Public Involvement to take up public policy issues that affected them. By 1980, the organization was urging its members to adopt workplace nonsmoking policies, and by 1984, it had become an active lobbyist supporting legislation to reduce tobacco use (Schauffler 1993).

The Attack on Advertising

In the 1970s and 1980s, the movement to reduce smoking was in part the work of grassroots activity, in part the work of professional consumer advocates, and in part the work of the public health bureaucracy. In 1966, a complaint filed with the Federal Communications Commission (FCC) by John F. Banzhaf III called for the application of the Fairness Doctrine to mandate reply time to cigarette advertising on television and radio broadcasts (see also "Attempts to Regulate Tobacco Advertising and Packaging" in Chapter 5). The FCC agreed with Banzhaf's complaint and on June 2, 1967, ordered broadcasters to provide "significant" air time for antismoking messages. Banzhaf, anticipating and forestalling an almost certain appeal from the tobacco industry, appealed his own victory (Whiteside 1971). Under the guise of seeking equal rather than significant broadcast time, Banzhaf succeeded in having his original ruling upheld and in having its application specified: television and radio stations were required to run one counteradvertisement, free of charge, for every three cigarette commercials. This policy lasted until 1971, when a ban on cigarette broadcast advertising went into effect.

The campaign to ban or regulate cigarette advertising has been one of the most visible and emotionally compelling of all the subthemes in the campaign to reduce smoking. (Highlighted in this section, this theme is discussed in greater detail in "Attempts to Regulate Tobacco Advertising and Packaging" in Chapter 5.) All along, opponents have apparently "resented most of all the ubiquity and presumed power of cigarette advertising" (Patterson 1987, p. 224). These critics have argued that advertising is a powerful force blinding Americans to the health consequences of

smoking, but the tobacco industry has maintained a vigorous defense of its right to advertise (Patterson 1987).

In 1969, congressional hearings considered banning cigarette advertising on television and radio; strengthening health warnings on packages; extending the warnings to all cigarette advertising; and ending the preemptive ban on FTC, state, and local regulatory activity. This time, the tobacco industry did not benefit, as they had during hearings in previous years, from the hesitancy of those conducting the hearings. Since 1964, public concern about the health hazards of smoking had been growing, and although the tobacco industry had powerful supporters in the U.S. House of Representatives, in the Senate, Warren Grant Magnuson (D-WA) and Frank E. Moss (D-UT) were canny and committed antagonists. Recognizing it would have to make some concessions, the industry agreed to a television and radio advertising ban.

This concession may not have been unwilling. There is some indication that since the Fairness Doctrine was invoked in 1966, the resulting counteradvertisements were hurting cigarette sales more than the cigarette commercials were helping (Hamilton 1972). With the passage in 1969 of the Public Health Cigarette Smoking Act (Public Law 91-222), which contained the ban on cigarette advertising on television and radio, the counteradvertisements vanished. The tobacco industry shifted its advertising to print and, perhaps even more notable, shifted its marketing budget from advertising toward promotion. The latter move exposed vast audiences to cigarette brands through techniques such as sponsoring sports events and, later, merchandising brand-touting items such as T-shirts and caps. Nonetheless, the elimination of cigarette advertising from the nation's most powerful medium was at the very least a stunning symbolic defeat for the tobacco industry. At the same time, the presence of cigarettes was gradually fading in television programming; by 1982, fictional television characters smoked nine times fewer cigarettes than they had before 1964 (Signorielli 1993).

Toward a National Policy to Reduce Smoking

Victories through federal administrative agencies or through direct assault on Congress were rare. The first chairman of the new (1973) Consumer Product Safety Commission claimed authority to set standards for cigarettes or even to ban them, but Congress in 1976 passed legislation to deny the commission that

authority (Walsh and Gordon 1986). In 1972, the Civil Aeronautics Board required a nonsmoking section on commercial air flights, in part because of some voluntary action already taken; in 1983, responding to a Court of Appeals ruling that nonsmokers were inadequately protected, the board banned smoking altogether on flight segments up to two hours—but almost at once Congress passed legislation to reverse this move (Walsh and Gordon 1986).

In the executive branch, several voices spoke out against smoking. During his tenure as Surgeon General and thereafter, Dr. Jesse L. Steinfeld was an active participant in the national and international movement to reduce smoking (Steinfeld et al. 1976). Joseph A. Califano, President Jimmy Carter's Secretary of Health, Education, and Welfare, declared in 1978 that smoking was "Public Health Enemy Number One." When Califano was designated Secretary, he had no notion that reducing smoking should be a significant effort of the Secretary's department, but experts he

consulted invariably urged that his public health efforts include a major campaign on that topic (Califano 1981).

Over the years, the main voluntary organizations increased their aggressive posture against smoking. In 1982, the ACS, the ALA, and the AHA established the jointly sponsored Coalition on Smoking OR Health as a Washington-based lobbying organization. The coalition represented some 5 million volunteers across the country, at least some of whom were physicians and other civic leaders who could influence particular legislators (Pertschuk 1986). In 1985, the AMA called for a complete ban on tobacco advertising and promotion (Troyer 1989). Also that year, a rotating series of four more specific, more severe, and larger print warning labels replaced the traditional warning that "The Surgeon General has determined that cigarette smoking is dangerous to your health" (Waxman 1985; see "Attempts to Regulate Tobacco Advertising and Packaging" in Chapter 5 for discussion of this regulatory process).

From Antismoking to Nonsmokers' Rights

The rhetoric of the smoking controversy in the 1950s and 1960s focused on the scientific evidence linking smoking and disease. In the wake of the 1964 Surgeon General's report and subsequent research and reports, the battle over the credibility of the scientific evidence was essentially over. In what has been called "a remarkable demonstration of creative lobbying" (Jacobson et al. 1992, p. 39), the tobacco industry sought to shift the debate from the medical consequences of smoking to the legal implications of impeding the personal freedom of smokers to smoke and of tobacco companies to advertise their wares under the protection of the First Amendment. The tactic appeared to work. By the late 1970s, the effort to reduce smoking was foundering "on a traditional American libertarian ethic: 'It's my body and I'll do with it as I please'" (Brandt 1990, p. 167). Serious discussion on the ethics of legislation to reduce smoking emerged (Goodin 1989). To bring a public health perspective back into the center of the debate, a countershift to nonsmokers' rights seemed strategically sound (Jacobson et al. 1992). During the 1980s, this strategy acquired a conceptual foundation that was framed in a persuasive vocabulary when the

terms (and the concerns they aroused) "passive smoking," "ambient smoke," "secondhand smoke," and most commonly, "environmental tobacco smoke" (ETS) increasingly appeared in research reports and public debate.

Regulations, Legislation, and Lobbying for Nonsmokers

Evidence mounted in the 1970s and 1980s that smoking was not only an annoyance but also a health hazard to nonsmokers. The 1972 Surgeon General's report on smoking and health became the first of the series to include a review of the effects of ETS. A year earlier, Surgeon General Steinfeld had called for a national "Bill of Rights for the Non-Smoker." The call was answered when the National Interagency Council on Smoking and Health developed a Non-Smoker's Bill of Rights and promoted the nonsmokers' rights theme among its 34 member agencies (Schmidt 1975). At the same time, the first successful efforts were made to segregate smokers and nonsmokers in public places. In 1971, United Air Lines became the first

major carrier to institute separated "smoking" and "nonsmoking" sections on its airplanes.

Analogous to private citizens who were active in the antismoking movement early on, some private businesses took the initiative to introduce worksite regulations for reducing smoking. Typically, the private firms would begin with a mild antismoking policy that was made stricter over time. A life insurance company in Connecticut, for instance, in 1976 restricted smoking in parts of the employee cafeteria. In 1983, smoking was prohibited throughout the cafeteria and was also banned from all conference rooms. In 1986, all smoking at the workplace was prohibited except in designated restrooms and lounges. Moreover, the company instituted an educational campaign about smoking hazards and provided subsidies for employees who attended smoking cessation clinics (Petersen et al. 1988). Other firms have also turned to carrots as well as sticks, paying employees bonuses if they stop smoking for a given length of time (Fielding 1984).

States began advancing legislation against ETS in the early 1970s. In 1973, Arizona passed the first statewide ban on smoking in public places. This important step for nonsmokers' rights, which was initiated by a private citizen, Betty Carnes, was defeated in a vote in 1972 but passed on its second try and a year later was further strengthened (Schmidt 1975). Two years later, Minnesota passed the first statewide act to keep indoor air smoke free; the legislation required no-smoking areas in all buildings open to the public unless a posted sign explicitly permitted smoking. By 1975, legislation had passed in 10 states to regulate smoking in public places (Schmidt 1975); more than 30 states and hundreds of local jurisdictions had done so by 1985 (Koop 1985). By 1990, smoking was restricted to some extent in public places or worksites in 44 states, and hundreds of cities and towns had passed their own, often more rigorous ordinances (Rigotti and Pashos 1991). In cities with populations of 25,000 or more, local smoking restrictions reached more than two-thirds of citizens in various public and private settings, and one-half of these restrictions could be judged comprehensive.

The courts supported these public and private efforts to protect nonsmokers' rights. In 1976, a Superior Court of New Jersey ruled that an office worker with an allergy to tobacco smoke had the right to a smoke-free office. New Jersey was also the site of a comprehensive ruling in 1978 that restricted smoking in restaurants and other public places; this was the first such regulation to be enacted by administrative rule (through the State of New Jersey Department of Health) rather than by new legislation, though the rule

was never actually implemented (Regina Carlson, memorandum to John Slade, September 30, 1996).

At the federal level, government acted not only legislatively to regulate public behavior in the states but also administratively to regulate domains the government itself directly controlled. For instance, cigarettes were removed from military C rations and K rations in 1975, and smoking was restricted in all federal government buildings in 1979. Smoking was banned in the White House in 1993 (Stephanopoulos 1993).

Behind many of these reforms in industry and government were the unified efforts of private citizens. How these grassroot activists could band together to form powerful lobbying groups for nonsmokers' rights was shown in the transformation of a segment of the Group Against Smokers' Pollution (GASP), Inc., a national organization founded in 1971. In 1976, local California chapters of GASP banded together and tried but failed to effect statewide ordinances to protect nonsmokers. In 1981, the chapters became Californians for Nonsmokers' Rights and began focusing on local legislative activity. Five years later, the group became a national organization that took its successful locallevel approach to sites throughout the country. By 1986, more than 75 ordinances had been enacted in California alone; nationwide, more than 400 had been enacted by 1990 (Samuels and Glantz 1991). In 1985, Los Angeles banned smoking in most public places and in businesses employing four or more persons if nonsmokers requested it (Fritschler 1989). California has now banned smoking in practically all public places (Tobacco Education and Research Oversight Committee 1995).

By the 1980s, the movement to reduce smoking proceeded along many avenues and through a wide set of loosely coordinated organizations. This lack of systematic action has concerned activists in the movement, who bemoan duplication of effort, lack of communication, organizational rivalries, and the lack of a federal effort and policy. At the same time, the movement has clearly benefited from its multiple locations; the movement is represented by active legislative efforts in hundreds of small communities as well as by a strong presence in Washington, DC, and in state capitals (see also "Direct Advocacy" in Chapter 7 for a discussion of the influences of these advocacy activities).

ETS: From Annoyance to Carcinogen

The powerful call for nonsmokers' rights added considerable momentum to the campaign to reduce smoking. The Surgeon General's report in 1979

reviewed further research on ETS. Considerable public interest was aroused by a Japanese study, published early in 1981, that found a high incidence of lung cancer among nonsmoking women married to smoking men (Hirayama 1981; *Newsweek* 1981). While locallevel smoking restrictions began to gather force, often proving more comprehensive than statewide legislation, the evidence on passive smoking accumulated. On releasing his 1982 report on smoking and health, Surgeon General C. Everett Koop observed that ETS might be a serious public health problem (Troyer 1989); two years later, he spoke of solid evidence on this point (quoted in Molotsky 1984, p. 1).

The growing urgency of a public health focus on ETS set the stage for two authoritative messages that ETS posed a definite danger to all. In 1986, the National Research Council report Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects found that ETS exposure increased the risk for lung cancer by 30 percent in nonsmokers and had deleterious effects on the respiratory health of children (National Research Council 1986). The same year, the Surgeon General released The Health Consequences of Involuntary Smoking, which concluded that "involuntary smoking is a cause of disease, including lung cancer, in healthy nonsmokers" (USDHHS 1986, p. 13). That report also found that children of smoking parents have an increased incidence of respiratory infections and that separating smokers and nonsmokers

within the same air space "may reduce, but does not eliminate" exposure of nonsmokers to tobacco smoke (p. 13).

Critics charged that the evidence on passive smoking was weak, but the evidence and the authoritative conclusions of the Surgeon General and the National Academy of Sciences added support for stronger acts to limit or prohibit smoking indoors. In 1987, Congress banned smoking on domestic air trips shorter than two hours; in 1990, the ban was effectively extended to all domestic commercial air travel.

Two further developments raised public (and public policy) awareness of ETS to a level that positioned it in the front ranks of the campaign to reduce smoking. In 1991, the National Institute for Occupational Safety and Health, Centers for Disease Control, issued the report Environmental Tobacco Smoke in the Workplace, which concluded that ETS can cause lung cancer and other health problems (National Institute for Occupational Safety and Health 1991). More important, in December 1992, the Environmental Protection Agency (EPA) classified ETS as a "Class A" carcinogen, the most dangerous class of carcinogens. The agency's final report, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, concluded that ETS is a human lung carcinogen responsible for some 3,000 deaths annually from lung cancer among nonsmokers (EPA 1992).

The Impact of the Movement to Reduce Smoking

The campaign against tobacco promotion is, in a sense, a public health hybrid. It is in part a public health movement, like those oriented to ensure that food and drugs are pure and that water supplies and air quality are clean—movements that look to improve upon the collective provision of healthful environments. But because the campaign to reduce smoking necessarily seeks to alter personal behavior, it is perceived or cast by some as a moral reform movement. "We are in the midst of one of those periodic moments of repression," writes one observer, "when the culture, descended from Puritans, imposes its hysterical visions and enforces its guilty constraints on society, legislating moral judgments under the guise of public health, all the while enlarging the power of surveillance and

the reach of censorship to achieve a general restriction of freedom" (Klein 1993, p. 3). Such critics worry about possible erosions of civil liberties and express irritation with the puritanical cast of the movement to reduce smoking (Berger 1986; Hitchens 1994; Leonard 1994; Laqueur 1995). One recent historian refers to health reform movements of this and the past century as "hygienic ideologies," because the movements have sometimes reached levels of "devotion, asceticism, and zeal" that virtually mark them as "hygienic religion" (Whorton 1982, p. 4). In sum, the arguments have pitted this moralism against the freedom to choose (Sullum 1996). In doing so, issues of addiction and corporate responsibility are sidestepped (Hilts and Collins 1995).

It would be hard to deny that moral zealotry has entered into the contemporary movement to reduce smoking. But it would be equally hard to argue that zealotry is the dominant element in the movement. The contemporary campaign to reduce smoking, like some elements of the early 20th-century efforts, has been fueled by medical research and, more recently, by revelations about the additional but secret medical research carried on by tobacco companies themselves on nicotine and other addictive substances (Kluger 1996). But leadership has been both medical and nonmedical and has been oriented to conventional public policy mechanisms rather than to moral reformation. Where the broad contemporary health movement has "an ambivalent orientation toward science and technology" and "draws upon Americans' significant and growing distrust of physicians" (Goldstein 1992, pp. 30-1), the movement to reduce smoking firmly embraces establishment medical research. Its sometimes inventive and ingenious strategies notwithstanding, the movement has typically avoided ideological ends and has instead worked toward concrete, public policy objectives. In this respect, it is self-consciously political, adopting a style found now in many health movements (e.g., AIDS, breast cancer, and even advocates of specific health care reforms).

Whether or not the movement to reduce smoking has avoided the finger-pointing associated with many ideological movements is debatable. On the one hand, the movement has tended to demonize the tobacco companies rather than the smokers who use their products. This distinction may arise partly because, some cultural icons aside, smoking has rarely been perceived as a feature of personal behavior that is central to someone's identity. Placing the burden elsewhere than on the smoker has been amply reinforced by the research-steered perceptual transition of smoking as "habit" to smoking as "addiction." As codified by the 1988 Surgeon General's report (USDHHS 1988) and reiterated more recently (Lynch and Bonnie 1994), smoking is now medically viewed as nicotine addiction, and as the title for Chapter 4 states, smoking cessation is now the management of such addiction. This transition has had considerable impact on overall strategy for reducing smoking, especially in litigation approaches (see "Litigation Approaches" in Chapter 5).

On the other hand, as regulations against smoking become more widespread, the tendency to stigmatize smokers may increase (Troyer 1989). Moreover, some critics have complained of an ideology that smacks of political conservatism, in that the focus for the problem is turned away from the product source

(the manufacturer) and to the user-victim (the smoker); this blame-the-victim perspective also characterizes sociopolitical movements that divert public attention to personal behaviors and away from larger, corporate sources of environmental health risks, such as industrial pollution and workplace hazards (Crawford 1979).

In at least one sense—that of social values—efforts to reduce smoking have been moralistic. The contemporary reform movement can fairly be characterized as middle-class—that is, its values are those connected with traditional values such as deferred gratification, self-control, and personal responsibility (Goldstein 1992). Nonsmokers may feel morally superior to smokers, and former smokers may pride themselves on their personal accomplishment and self-denial. As one cultural observer has pointed out, former smokers especially may be "tediously zealous about the addiction they have left behind" (Styron 1987, p. 284).

The net result, whatever the role of moral issues, is the main emphasis the movement places on changing the social conditions that enable, and the cultural conditions that legitimatize or romanticize, smoking. In this sense, the movement to reduce smoking is an old-fashioned populist movement that seeks to defend the "public interest" against the moneyed corporations, the purveyors of death and disease. It is now less an "anti-smoking" political movement and more a campaign against tobacco promotion.

A reflection of this broadly populist attitude has been the movement's lack of any real links to partisan politics. Senators Wallace F. Bennett (R-UT) and Richard L. Neuberger (D-OR) were among the first to seek curbs on the tobacco industry (Fritschler 1989). In the early 1980s, Republican Senators Robert W. Packwood (R-OR) and Orrin G. Hatch (R-UT) introduced legislation to require more explicit warning labels on cigarette packages (Troyer 1989). House Democrats have been both key defenders and key critics of the tobacco industry. In the White House, Democratic President Lyndon B. Johnson remained silent on the preemptive Federal Cigarette Labeling and Advertising Act of 1965, but White House pressure helped support the Tobacco Institute's efforts to pass the bill (Pertschuk 1986); the President signed the act into law privately in his office, without guests or comment (Fritschler 1989). Similarly, Democratic President Jimmy Carter refused to take a position on tobacco (Fritschler 1989), but he regarded USDHEW Secretary Joseph Califano's crusade against tobacco as "an enormous political liability" (Califano 1985, p. 360). The absence of political affiliation for the antitobacco movement may be

altered, however, by recent changes in the party composition of elected officials from tobacco-producing states.

The efficacy of efforts to reduce smoking, independent of other social changes beginning early in the 20th century, is hard to determine. Students of 19th-century temperance, for example, have concluded that although the temperance efforts likely accelerated the antebellum decline in alcohol consumption, the decline may have been more deeply tied to independent changes in styles of liquor consumption (Aaron and Musto 1981). The antismoking movement of the early 20th century, despite temporary gains, had little long-term effect on stopping the rapid growth of smoking; though noteworthy, the emergence of antismoking legislation in some midwestern and western states was brief and showed little convincing evidence of enforcement.

But neither the temperance movement of the 19th century nor the antismoking movement early in the 20th century commanded the significant allies and the range of weapons of the contemporary effort to reduce smoking. The critical factor has been definitive medical research linking smoking to cancer, heart disease, chronic obstructive pulmonary disease, and adverse outcomes of pregnancy (USDHHS 1989). Beginning in 1964, the imprimatur of the Surgeon General of the United States provided a symbolic centerpiece that has given inestimable momentum to the campaign. The all-but-unanimous and compelling character of the epidemiologic research in that first report and its successors is the chief factor that leads to the conclusion, "As a target of opportunity for public health action, smoking stands alone" (Walsh and Gordon 1986, p. 127).

Measuring the overall impact of the rich and multifaceted effort to reduce smoking is difficult, in part because current prevalence should not be judged against an arbitrary historical benchmark (for instance, against prevalence at the time of the 1964 Surgeon General's report) but against an estimate of what prevalence would have been in the absence of such efforts. The events of the past decades that coincided with these efforts are clear: cigarette consumption rose steadily from the 1930s until 1963, fluctuated, then fell from 1973 to the present. But such broad-brush observations provide little insight into cause and effect, especially given the multiplier effect of certain social actions, the differential changes in demographic and social subgroups, and the influence of forces extraneous to smoking (Warner 1989).

It is problematic, for example, to try to assess the relative impact of, on the one hand, government educational actions and government regulatory actions and, on the other hand, changing social norms—two factors that are clearly interrelated. The impact of government curbs on smoking in public places (see "Clean Indoor Air Regulation" in Chapter 5) may actually be bound up with "voluntary adjustments to new information" (Zimring 1993, p. 97). Similarly, doubts have been raised as to the influence of curbs on tobacco advertising (Schudson 1993; see "Advertising and Promotion" in Chapter 5), because such restrictions have occurred in conjunction with a growing stigmatization of smoking. Once nonsmoking is established as a norm, the minority status of smokers makes them "more vulnerable to negative social evaluations. . . . As smokers, the group most interested in defending the moral position of the cigarette smoker, become both less numerous and less influential, smoking behavior and the people who engage in it become more vulnerable to social reinterpretation" (Zimring 1993, p. 106). Such a reinforcing chain of events may permit curbs on advertising, rather than the reverse.

It is equally difficult to gauge or predict the influence of government restrictions. On the one hand, a regulation may be an educative force—for example, by reminding people to take their Surgeon General seriously. In some instances (such as indoor prohibitions and access restrictions), government actions interpose a physical barrier. On the other hand, legal or otherwise formal barriers could have an unintended effect on individual predisposition, as the abiding aura of antisocial behavior can be at least as great a stimulus for some as it is a deterrent for others. Finally, the psychological and social pathways by which economic actions of government affect smoking are complex.

Sorting through this complexity is critical to understanding appropriate policy and action for reducing smoking. The ensuing chapters assess the available evidence to judge the efficacy of educational efforts (Chapter 3), the management of nicotine addiction (Chapter 4), regulatory efforts (Chapter 5), economic approaches (Chapter 6), and comprehensive programs (Chapter 7). This brief history of the antismoking movement provides a backdrop to such assessment and may furnish some perspective on future directions.

Conclusions

- 1. In the years preceding the development of the modern cigarette, and for some time thereafter, antismoking activity was largely motivated by moralistic and hygienic concerns. Health concerns played a lesser role.
- In contrast, in the second half of the 20th century, the impetus for reducing tobacco use was largely medical and social. The resulting platform has been a more secure one for efforts to reduce smoking.
- 3. Despite the growing scientific evidence for adverse health effects, smoking norms and habits have yielded slowly and incompletely. The reasons are complex but attributable in part to the industry's continuing stimulus to consumption.

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Introduction

Trends in Tobacco Use Among Young People

Smoking prevalence among youth underwent a sustained and substantial decline for about a decade from the mid-1970s to the mid-1980s. The Monitoring the Future study, funded by the National Institute on Drug Abuse, has assessed the substance use behaviors of large representative samples of high school seniors annually since 1975 (Giovino et al. 1994; Johnston et al. 1994). The data from this multiyear study have shown that daily cigarette smoking reached a peak of about 29 percent among high school seniors in 1977. Daily smoking then declined steadily until 1986, falling below 19 percent, but has shown little change since. Detailed analyses of trends in smoking by adolescents in 1974– 1991, based on Monitoring the Future data and two other national health behavior survey series, also have shown consistent evidence that smoking prevalence among adolescents has generally been stable since about 1985 (Nelson et al. 1995). In 1997, daily cigarette smoking in the month before the survey was reported by 24.6 percent of high school seniors, the highest level since 1979, when 25.4 percent reported daily smoking. Longterm trends show that daily smoking among seniors was at a 25-year high of 28.8 percent in 1976 and 1977, declined to 21.3 percent in 1980, varied in the range of 18–21 percent from 1980 to 1991, and decreased to 17.2 percent in 1992. After that, seniors' daily cigarette use increased steadily to reach 24.6 percent in 1997, then decreased to 22.4 percent in 1998 and remained statistically unchanged at 23.1 percent in 1999 (Johnston et al. 1999). A recent report with more current prevalence estimates and trend data from 1991 through 1997 shows that current cigarette use increased overall and for white, black (the racial/ethnic terms "black" and "African American" are both used in this report, according to the usage in the study cited), and Hispanic high school students (Centers for Disease Control and Prevention [CDC] 1998). Even so, the prevalence of smoking among African American high school seniors was lower than that for Asian Americans/Pacific Islanders and for American Indians/Alaska Natives (US Department of Health and Human Services [USDHHS] 1998).

Although the decade-long decline in smoking prevalence among young people stalled in the mid-1980s, it has persisted among all major adult population groups in the United States (Giovino et al. 1994).

Changes in prevalence among young people thus do not seem to be closely linked to changes among adults (Reid et al. 1992) and may be more heavily influenced by other social forces. Downward trends in smoking by adults may, for instance, be partly the result of the continued accumulation of scientific knowledge about the long-term health consequences of smoking and of secondary exposure to cigarette smoke (USDHHS 1989; Environmental Protection Agency 1992). That no such downward trend was observed among most groups of adolescents in the past decade may reflect other factors: prices of tobacco products decreased (see Chapter 6); during the 1980s, public education efforts to prevent tobacco use among young people diminished; and youth-oriented marketing by cigarette manufacturers intensified (Nelson et al. 1995). Moreover, because of the highly addictive nature of cigarette smoking, the recent increases in prevalence of smoking among young people could carry over into their adulthood and eventually arrest or reverse the long-term declines that have persisted for decades (CDC 1994a; Giovino et al. 1994).

In a similar vein, a major portion of tobacco consumption at the beginning of the 20th century was in the form of spitting tobacco. The emergence of machine-made cigarettes as the dominant form of tobacco use in the 1930s (see Chapter 2) was accompanied by a 38.4-percent decline in total smokeless tobacco production from 150.2 million to 92.5 million pounds between 1944 and 1968.

In the early 1970s, however, the market for smokeless tobacco reemerged. Between 1970 and 1981, the production of fine-cut tobacco, used in the manufacture of moist snuff, increased threefold from 4.8 million to 15.2 million pounds (USDHHS 1986). Sales of moist snuff have increased every year since the Federal Trade Commission (FTC) began monitoring it, from 36.1 million pounds in 1986 to 55.3 million pounds in 1997 (FTC 1999). Loose leaf chewing tobacco has seen a slight decline in sales over this period, from 65.7 million pounds in 1986 to 51.8 million pounds in 1997.

The growth in the sales of moist snuff has been attributed to a smokeless tobacco advertising and marketing campaign that encourages young non-users to experiment with low nicotine starter products with the intent of graduating new users to higher nicotine brands as dependence progresses (Connolly 1995).

The basis and success of this "graduation" strategy is supported by laboratory and epidemiologic data as well as tobacco industry documents. Smokeless tobacco manufacturers appear to be able to manipulate the nicotine-dosing characteristics of their products and have developed moist snuff products with a wide range of bioavailable nicotine (Henningfield et al. 1995; Djordjevic et al. 1995; Food and Drug Administration 1996; Tomar and Henningfield 1997). A national longitudinal study found that young males were twice as likely to switch from a brand with low or medium nicotine delivery to a high nicotine delivery product than to switch in the opposite direction (Tomar et al. 1995). Advertising and promotional expenditures have increased for nearly every year between 1986 and 1997, from \$76.7 million to \$150.4 million (FTC 1999). In 1997, \$103.6 million was spent for advertising and promotion of moist snuff.

Smokeless tobacco use is primarily a male behavior. Use of snuff and chewing tobacco by young males increased sharply through the 1970s and early 1980s. Data from the National Health Interview Survey indicate that the prevalence of smokeless tobacco use among males aged 18–24 years increased from 2.2 percent in 1970 to 8.9 percent in 1987 and declined slightly to 8.4 percent in 1991 (Giovino et al. 1994). Based on CDC's Youth Risk Behavior Survey, the prevalence of past-month smokeless tobacco use remained at about 20 percent among high school males during most of the 1990s (CDC 1992; Kann et al. 1995). Recent data indicate that smokeless tobacco use may be starting to decline among high school males (CDC 1998).

More vigorous steps are clearly required to prevent young people from beginning to use tobacco products. This chapter considers the effect of educational programs in such prevention. Throughout the discussion, the term "education" is used to encompass the range of activities that impart knowledge, alter perceptions, and modify behavior.

Reasons Young People Smoke

The public health importance of smoking among young people has generated a substantial amount of research on why they take up the habit. The results of these efforts have provided several consistent insights that have been reviewed in detail and summarized in recent reports (Lynch and Bonnie 1994; USDHHS 1994).

Development of tobacco addiction is a staged process that requires several years to progress from initiation to acquisition of an established habit (Leventhal and Cleary 1980; McCarthy 1985; see also Flay 1993).

The initial stages are consistently associated with a well-defined group of risk factors. Early adolescence (aged 11–15 years, or 6th–10th grades) is the period when people are most likely to try smoking for the first time. Especially at risk are adolescents whose parents or guardians smoke or have lower levels of income and education (USDHHS 1994).

Young people's perceptions of smoking behaviors in proximal and wider social environments are among the most powerful psychosocial forces influencing whether they begin to smoke (USDHHS 1994). Cigarette smoking among friends, peers, siblings, and others from the young person's immediate environment is consistently associated with smoking initiation. The influence of friends and peers seems to be especially powerful in the early stages of developing a smoking habit. Perceptions of the larger social environment also seem to have considerable influence on smoking decisions. Adolescents tend to overestimate the prevalence of smoking among people their own age and among adults. Such perceptions—and in general, susceptibility to becoming a smoker—are likely to be strongly influenced by the effects of advertising (Evans et al. 1995). Young people who perceive high levels of smoking among their peers and who report that peers are more likely to approve of cigarette smoking are more likely to become smokers themselves.

These external influences are likely supported or opposed by internal, personal factors. The personal factors most often associated with smoking initiation include the young person's belief that cigarette smoking is linked with positive functions, such as having a positive social image and bonding with a peer group. Among young women, smoking may be viewed as a means of weight control (French et al. 1994). Adoption of such perceptions may reflect, in part, the influence of a larger social environment in which smoking is presented through local and mass media as an adventurous and glamorous adult behavior. Thus, smoking provides some young people a perceived transition from childhood to adulthood (USDHHS 1994).

These findings, summarized in the 1994 Surgeon General's report *Preventing Tobacco Use Among Young People*, strongly suggest that tobacco use is socially learned by children and adolescents and that it tends to have socially relevant meanings for them (USDHHS 1994). Smoking prevention programs should thus address the most salient psychosocial dimensions that can influence a young person to not begin smoking. These dimensions include enabling the young to cope with direct social pressure to smoke from their friends and peers and correcting or preventing misperceptions about the social effects and short-term

health consequences of smoking, about peers' and adults' attitudes toward smoking, and about smoking prevalence.

Educational Models for Smoking Prevention

During the past two decades, several different theoretical orientations and program objectives have emerged for educational approaches to smoking prevention. Several changes have influenced these events: research and evaluation results that highlighted the ineffectiveness of the models used in earlier programs, the accumulation of consistent research characterizing the process of smoking initiation, advances in theories of human behavior, and promising results obtained from initial tests of newer educational models. Another important change is the expansion from relatively simple strategies and educational techniques to more complex plans that use multiple educational channels. Complex sociobehavioral problems are thus being addressed with more intensive educational strategies.

The earliest group (mostly from the 1960s and 1970s) of evaluated programs designed to prevent adolescents from beginning to smoke was based on an information deficit model (USDHHS 1994). This approach assumed that adolescents, as rational creatures, would refrain from cigarette smoking if they were supplied with adequate information demonstrating that this habit causes serious harm to the body. The educational techniques associated with these programs included lectures, demonstrations, films, posters, and books intended to raise levels of awareness and comprehension of health effects. Many programs based solely on this objective did increase knowledge among children and adolescents, as intended, but the programs were consistently found to be ineffective in dissuading young people from smoking (Goodstadt 1978; Thompson 1978; Kinder et al. 1980; Schaps et al. 1980, 1981). Although this approach alone was clearly inadequate, information about the health and social consequences of smoking was retained as an important component of later developments in smoking prevention education.

The limitations of this approach led to efforts in the 1970s to identify a more complex set of personal factors related to cigarette smoking by young people. Once these factors were identified, educational programs could be developed to try to modify them. Studies conducted during these years often observed that the use of cigarettes was associated with negative or antisocial patterns of adolescent behavior (USDHHS 1994). Educators interpreted these patterns as reflecting reduced levels of perceived self-worth and poor attitudes toward family, school, and community; these factors were hypothesized to be the root causes of smoking initiation. Various educational strategies to address these broad educational targets included programs focused on clarifying values, building self-esteem, and developing general skills for decision making, communication, and assertiveness.

Such efforts to prevent smoking initiation by helping young people develop stronger intrapersonal resources and general social competence have been collectively referred to as the affective education model. Evaluations of these programs, however, demonstrated that they were not much more effective in reducing cigarette smoking among young people than programs based on the information deficit model (Schaps et al. 1981; Durell and Bukoski 1984; Hansen 1992). The affective education strategy did mark the beginning of promising trends in designing education programs to prevent smoking: many programs began more directly incorporating results from research about factors found to influence smoking initiation and began including more powerful theoretical models of behavior change.

By the mid-1970s, results of analytic and theoretical research began to highlight a complex set of psychosocial factors associated with smoking initiation. Numerous studies had consistently found that smoking experimentation by the young was associated with peer smoking, smoking by others in the immediate social environment, and other social and psychological factors (USDHHS 1994). Although the resulting psychosocial intervention programs were developed through several different conceptual perspectives, they tended to share a core set of components that compose what is generally called the social influences model (USDHHS 1991). This model focuses on the development of social skills to resist social influences that encourage smoking.

The initial efforts to design programs based on these findings used a public health model: the problem was conceptualized as a social contagion in which the habit spread through a population by passing from one person to another. This concept directed program efforts toward strengthening the resistance of nonsmoking adolescents to the behavior of their smoking peers. For example, Evans and colleagues (1978) at the University of Houston used methods derived from communications and social learning theories to try "inoculating" young people against peer influences to smoke cigarettes; the study group of adolescents was

shown videotaped models of credible peers who successfully resisted such influences (McGuire 1964).

This approach was developed further in small-scale studies that added other objectives and used other educational technologies (Botvin et al. 1980; McAlister et al. 1980; Perry et al. 1980). The appeal of the overall conceptual approach and the generally positive results of this initial group of studies stimulated a sustained evolution of the approach through several stages of development; the result was a generally recognized social influences model for school-based programs to prevent smoking (Flay 1985).

The main goal of this approach was to equip younger adolescents with specific skills and other resources that would help them resist direct and indirect social influences to try smoking cigarettes. The specific objectives usually included having the young person learn the short-term negative social and health consequences of smoking and the advantages of remaining a nonsmoker; learn that a relatively small proportion of young people and adults are regular smokers; recognize the social influences in the immediate environment and from the wider community and culture that promote smoking; and develop specific skills for managing direct social pressures from friends and peers, as well as indirect pressures from adult modeling, the mass media, and tobacco industry marketing. Although representing a significant departure from previous approaches, this model retained the provision of information on the negative shortterm consequences of smoking (from the information deficit model) and continued to emphasize the development of social competencies (from the affective education model).

Social influences strategies have typically been applied through school-based programs for students in sixth through eighth grades (primarily during early adolescence). These programs have taken various formats, used different delivery methods, and been offered to diverse student populations.

By the mid-1980s, detailed analyses of research results indicated that social influences programs were consistently more effective than programs based on the information deficit or affective education models in preventing cigarette smoking (Tobler 1986, 1992; Rundall and Bruvold 1988; Hansen 1992; Bruvold 1993). Some reviewers, however, wondered whether this evidence was strong enough to justify developing public policies that would make these school-based programs a large-scale, key component of policies to prevent tobacco use (Flay 1985; Cleary et al. 1988; Kozlowski et al. 1989).

Concern focused on the quality of the effects achieved, the quality of the evaluation research that provided the evidence, and the generalizability of the programs. The programs' effects reported up to the mid-1980s were not consistently achieved, were of short duration, and tended to be small. For example, Drug Abuse Resistance Education (D.A.R.E.), a drug resistance program that included but was not primarily focused on tobacco use, has been in wide use since the mid-1980s. A recent meta-analysis of published and unpublished results concluded that the program's effect on tobacco use was small at best (Ennett et al. 1994). Limitations in evaluation methods—such as outcome measurement, attrition effects, consistency between assignment and analysis units, and completeness of reported effects on total populations—precluded drawing clear conclusions about program effectiveness. These reviewers also were concerned that the programs might be too complex to be carried out in most schools by most classroom teachers. Since 1990, many of these questions have been addressed by research on these educational strategies (Graham et al. 1991).

Recent Research on Educational Strategies for Smoking Prevention

Most early research programs on smoking prevention were located exclusively in school settings. Schools provide direct access to target populations and have a mission consistent with smoking prevention education. Schools, however, have some inherent limitations that reduce their usefulness as exclusive

channels for such education; the obvious one is that school programs cannot reach individuals who leave school. This section reviews shorter-term and longer-term studies of the effects of school-based smoking prevention programs (Table 3.1). The section also reviews studies of prevention programs that have tried to

enhance such programs by combining them with educational activities directed toward young people through parents, community programs, and the mass media or by combining them with programs that targeted multiple substances.

Shorter-Term Follow-Up of School-Based Programs

The group of studies summarized in this subsection evaluated programs that were based, with few exceptions, exclusively on educational experiences provided in school classrooms. These studies generally have addressed methodological problems commonly found in earlier evaluations of smoking prevention efforts. Improvements include use of biochemical measures to enhance the accuracy of selfreported smoking behavior, attention to validity issues related to attrition, and improved consistency between units of assignment to treatment and units of analysis. Most of this initial group of studies also improved on earlier reports by using more diverse study populations to test these programs and by following participants into the first year of high school to assess smoking prevention effects at an intermediate stage of adolescent development. The studies described and analyzed in this subsection thus represent the current state of the art in the evaluation of school-based smoking prevention.

Project Towards No Tobacco Use

Project Towards No Tobacco Use (Project TNT) was designed to assess the relative effectiveness of three main components of most smoking prevention programs based on the social influences model (Sussman et al. 1993b, 1995). The investigators developed separate classroom curricula to address each of these components (Sussman 1991; Sussman et al. 1993a). The first curriculum provided social skills to help students more easily refuse direct offers of cigarettes from peers; the second provided methods to counteract the impact of indirect pressures to smoke cigarettes, such as smoking (real or perceived) by peers or adults, tobacco industry advertising, and exaggerated notions of the actual prevalence of smoking among peers and adults; and the third improved knowledge of the short-term and long-term negative effects of smoking. A fourth curriculum addressed all three of these areas and was similar to the social influences model used with many other school-based smoking prevention programs. Each curriculum included 10 lessons designed for seventh-grade students. The curricula were delivered on 10 consecutive school days by trained health educators employed by the project. A control group received the standard curriculum.

The study included seventh graders from 48 junior high schools in 27 southern California school districts. Students from 8 schools were assigned to receive one each of the four curricula; students from the remaining 16 schools were assigned to receive the standard education program provided by their schools. These populations were relatively diverse: about 40 percent were from minority ethnic groups. Student reports of smoking behavior were measured immediately after the curricula were completed in the seventh grade (n = 6,716) and one year later in the eighth grade (n = 7,052).

Analyses of these data indicated that the curriculum that combined all three main objectives drawn from the social influences model achieved the lowest increase in weekly smoking prevalence (defined as smoking one or more cigarettes per week); this increase was 64 percent lower than the increase in the control group. The curricula that focused on indirect pressures to smoke cigarettes and on negative consequences of smoking also were significantly more effective than the control condition. The curriculum that focused on refusal skills did not yield results significantly different from the comparison condition. Changes in psychosocial mediators of program effects were consistent with these results (Sussman et al. 1993a). Similar effects were obtained for smokeless tobacco use. A two-year follow-up survey, completed when the participating students were in ninth grade, showed that the combined curriculum continued to have a significant impact on weekly smoking rates after these students entered high school (Dent et al. 1995).

Know Your Body

The Know Your Body (KYB) program, a school-based effort to reduce risk factors for chronic disease among young people, addressed cigarette smoking status, dietary behaviors, and physical fitness through curricula for fourth- through ninth-grade students (Walter 1989; Walter and Wynder 1989). Program components included parent education and periodic student health examinations. Designed to meet the rapidly changing educational needs of young people in this age group, the six-year curriculum progressed from a focus on knowledge and beliefs to a focus on decision-making skills (Walter and Wynder 1989). In the fourth and fifth grades, the curriculum's component on smoking prevention concentrated on students'

Table 3.1. School-based and multifaceted educational strategies

Project name	Educational methods				
School-based educational strategies with shorter-term follow-up					
Project TNT (Towards No Tobacco Use)	2 years; 10 class sessions delivered by project staff in grade 7				
Know Your Body	6 years; multiple risk factor curriculum delivered weekly by classroom teachers in grades 4–9, plus parent education				
SHOUT (Students Helping Others Understand Tobacco)	3 years; 18 class sessions in grades 7–8 delivered by project staff, plus telephone and mail contact in grade 9				
School-based educational strategies with longer-term follow-up					
Life Skills Training Program	3 years; 30 class sessions delivered by teachers in grades 7–9				
Minnesota Smoking Prevention Program	1 year; 5 class sessions in grade 7 delivered by teachers and peers				
Waterloo Smoking Projects	3 years; 11 class sessions delivered by project staff in grades 6–8				
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Project ALERT	2 years; 11 class sessions delivered by teachers and peers in grades 7–8				
Multifaceted educational strategies					
Class of 1989 Study (Minnesota Heart Health Program)	5 years; 17 class sessions delivered by teachers and peers in grades 7–9, plus related school courses and activities and very intensive community education directed toward adults				
Midwestern Prevention Project	3 years; 15 class sessions delivered by teachers and peers in grades 6–7 or 7–8, plus parent education and participation in school curriculum, informational media, and community organization				
University of Vermont School and Mass Media Project	4 years; 15 class sessions in grades 5–8 or 6–9 or 7–10 delivered by teachers, plus 540 television and 350 radio spot broadcasts each year				

Design	Results*	Comment
5 conditions tested in 48 schools (n = 6,716)	64% less weekly smoking for full intervention group by end of grade 8 and 55% by end of grade 9	Very large short-term effect achieved by moderately intensive school program
2 conditions in 15 schools (n = 911)	73% less smoking by end of grade 9	Very large short-term effect achieved by very intensive school program with parent education
2 conditions in 22 schools (n = 3,655)	33% less monthly smoking by end of grade 9	Large short-term effect achieved by intensive school program supplemented with other contacts
3 conditions tested in 56 schools $(n = 5,954)$	18% less weekly smoking observed at grade 12	Large sustained effects achieved by very intensive school program
4 conditions tested in 18 schools $(n = 7,030)$	Program effects at grades 8 and 9 but not at grade 12	No long-term effects of less-intensive school program
2 conditions tested in 22 schools (n = 654)	Program effects at grades 8 and 9 but not at grade 12	No long-term effects of moderately intensive school program
3 conditions tested in 30 schools $(n = 6,527)$	Program effects less at grades 8 and not at grade 12	No long-term effects of moderately intensive school program
2 conditions tested in 13 schools ($n = 2,401$)	39% less weekly smoking by end of grade 12	Large sustained effects achieved by intensive school programs supported by intensive commu- nity programs
2 conditions tested in 42 schools $(n = 5,065)$	32% less monthly smoking after 1 year; 19% less monthly smoking by end of grades 9–10	Large short-term effects achieved by intensive school program sup- ported by parent education, mass media, and community programs
2 conditions tested in 50 schools (n = $5,458$)	40% less weekly smoking by end of grades 8–10; 31% less weekly smoking at end of grades 10–12	Large sustained effects achieved by intensive school program combined with intensive mass media intervention

^{*}Results are reported relative to a comparison group.

health beliefs about smoking. Social influences, both direct and indirect, on decisions about smoking were addressed in the sixth through eighth grades. Psychological influences, such as stress and self-image, were addressed in the ninth grade.

The classroom program was delivered by the students' usual classroom teachers, who had been trained by project staff. The overall curriculum required about two hours per week throughout the school year. If the curriculum gave equal attention to each of the three targeted behavioral areas, the smoking component would include about 24 hours of class time per year over six years. The parent education component of the program included participation in students' homework from the curriculum, attendance at school meetings about the program, receipt of program newsletters, and self-assessment of risk factors for chronic disease.

The program was initially tested with students attending the fourth grade in 15 elementary schools from suburban communities near New York City (Walter et al. 1989). Students in eight schools received the KYB educational program, and students in the remaining schools received only measurement activities from the study. The follow-up survey in the ninth grade included 593 students (65 percent) from the original study cohort.

Analyses of these data showed that students who had received the program were significantly less likely than students not receiving the program to smoke cigarettes (verified through salivary cotinine measures). Smoking prevalence in the ninth grade was 73 percent lower among students who had received the program. This smoking prevention effect was stronger among boys than among girls. Favorable changes in health knowledge, dietary behavior, blood cholesterol, and obesity were also observed (Walter et al. 1988; Walter and Wynder 1989).

Project SHOUT

The Students Helping Others Understand Tobacco (SHOUT) project was designed to assess the effectiveness of a prevention program delivered to seventh through ninth graders by trained college undergraduates through classroom activities and telephone and mail support (Elder et al. 1993b). The program began with 10 class sessions distributed throughout the seventh-grade school year. Components focused on pressures to smoke, refusal skills, negative social and health consequences of smoking, decision making, and commitment to nonsmoking. In the eighth

grade, eight classroom sessions reviewed refusal skills and engaged students in community action projects, such as encouraging others to quit, writing letters about tobacco issues to mass media organizations and tobacco firms, and debating issues about tobacco use. Throughout the ninth grade, when students had transferred into secondary school, the college undergraduates trained by the program staff made four supportive telephone calls to each participant; 69 percent of participants were reached at least once (Elder et al. 1994a). Also during the ninth grade, five newsletters were mailed to students and two to their parents.

This program was initially tested in 22 southern California schools. Students from 12 schools received the SHOUT program, and students from the remaining schools did not. About 45 percent of the students were from minority ethnic groups. The effectiveness of the program was assessed through classroom and mail surveys conducted at the end of each of the three years. The ninth-grade survey included 2,668 members (73 percent) of the original study cohort.

By the end of the ninth grade, the prevalence of monthly smoking (defined as smoking one or more cigarettes per month) was about 33 percent lower among students who had received the program than among those who had not. The relative difference in the two groups' reported smoking increased each year and was statistically significant at the end of the ninth grade. The results at the end of the ninth grade were particularly encouraging, because program contact (via telephone calls and newsletters) was less costly. It was not possible to assess whether program effects had accumulated during the seventh and eighth grades. Results for ethnic subgroups were consistent with these overall results but were not always statistically significant. Similar effects for ninth graders were obtained for weekly cigarette smoking and for smokeless tobacco use. Assessments of cigarette refusal skills among students receiving and not receiving the program indicated that the program had positive effects on this mediator of smoking initiation at the end of the seventh grade but not subsequently (Elder et al. 1993a, 1994b). As was found with Project TNT, the results of the SHOUT program did not in general support a strong link between refusal skills and smoking behavior. In an extension of this program, newsletters and supportive telephone calls were offered again in 11th grade to a subset of the original intervention group. Results of an additional follow-up survey suggested positive effects of providing continued smoking avoidance support to students throughout the secondary school years (Eckhardt et al. 1997).

Longer-Term Follow-Up of School-Based Programs

The preceding group of studies did not address whether the observed prevention effects were permanent or whether they simply represented delays in smoking initiation from middle school to later high school years. Because few people begin smoking after high school, programs that prevent young people from smoking throughout the high school years are likely to prevent young people from ever becoming regular smokers.

Several studies of school-based programs to prevent smoking have followed participating students into the later years of high school to assess the durability of effects several years after the programs were implemented.

Life Skills Training Program

The Life Skills Training (LST) Program was designed to help adolescents develop a wide spectrum of personal and social skills, including those related to preventing cigarette smoking and the use of alcohol and other drugs (Botvin et al. 1990a). The core program consists of 12 curriculum units designed to be taught in 15 class periods to seventh graders. The problem-specific components of the LST Program are similar to those included in smoking prevention programs focused more directly on the social influences model. These components include offering practice in assertively resisting peer pressure to smoke and providing information about the negative short-term social consequences of cigarette use, the decreasing social acceptability of use, and the actual prevalence of use among adolescents and adults. Other program components address the development of generic personal and social competencies, such as communication skills and ways to develop personal relationships.

One of the notable strengths of this program is the relatively large number of separate trials reported by the investigators. The largest trial was conducted among students attending 56 suburban and rural schools in three geographic regions of New York (Botvin et al. 1990a). Students in 34 schools received the smoking prevention program, and students from the remaining schools did not. The smoking prevention program included the full 15-session LST Program in the seventh grade, followed by a 10-session booster program in the eighth grade and a 5-session booster in the ninth grade. These programs were delivered by the students' usual classroom teachers, who had been trained either through group workshops followed

by monitoring, feedback, and reinforcement of implementation procedures or through use of a training videotape. This study thus tested whether program effectiveness could be maintained while using low-cost methods for disseminating the program to large numbers of schools, teachers, and students.

Analyses of reports from the 4,466 students surveyed at the end of the ninth grade (75 percent of the original cohort) showed that the prevalence of cigarette smoking was significantly lower among students who had received the LST Program than among those who had not. The relative difference in the smoking scores was about 10 percent. Results were similar for both teacher training conditions. The analyses indicated that most of the knowledge, attitude, and skill variables that were targeted as mediators of effects showed significant changes consistent with program objectives. Program recipients also had significantly lower levels of marijuana use and alcohol intoxication.

In a long-term follow-up of the LST Program, data were collected from school, telephone, and mailed surveys administered six years after the initial 56 public schools had been randomized to treatment and control conditions (Botvin et al. 1995). The 3,597 predominantly white, 12th-grade students sampled represented 60.4 percent of the initial 7th-grade sample. Among all students included in the 12th-grade follow-up, weekly cigarette smoking was reported by about 22 percent of those receiving the intervention and by 27 percent of those in the comparison condition, representing an 18-percent relative reduction in smoking prevalence. For the subset of students receiving a reasonably complete version of the program, the relative reduction in smoking prevalence was 26 percent. The study is unique in demonstrating effects of a prevention program that lasted through high school. The generalizability of these results to other populations and school settings is an important area for exploration.

Similar support for the effectiveness of the LST Program has been obtained from shorter-term studies of variations in implementation procedures and study populations. These studies have provided evidence for the effectiveness of booster sessions after the initial program delivery (Botvin et al. 1983) and have compared the use of peers and teachers as program facilitators (Botvin et al. 1990b). Other studies have replicated the short-term effectiveness of the program with African American and Hispanic adolescents (Botvin et al. 1989a,b, 1992). Components of the program also appear to have had positive effects when implemented outside the context of a research project (Bruvold 1990). These multiple tests of one approach to school-based smoking prevention provide a

well-rounded picture of the potential effectiveness of various approaches. The results also demonstrate that relatively intensive programs that address the core objectives of the social influences model in the context of a larger curriculum can reduce smoking prevalence in diverse target populations and school settings when the curriculum maintains a reasonable level of integrity to the program design.

Minnesota Smoking Prevention Program

Two replications of a smoking prevention program based on the social influences model were combined into a single study of long-term effects, the Minnesota Smoking Prevention Program (Arkin et al. 1981; Murray et al. 1984). The core program contained units that identified social pressures to smoke, offered practice in skills to resist direct social pressures, provided information about actual levels of smoking among peers and adults, and provided information about the negative short-term social and physiological consequences of smoking. These objectives were addressed in five class periods delivered throughout the seventh grade; no additional educational components were offered in later grades. Both replications of the program compared the relative effectiveness of same-age peer leaders and adult leaders.

The two studies included 7,030 seventh-grade students participating in baseline surveys in 18 suburban Minnesota schools. In the first study, students received a social influences program led by adults or by peers or received an adult-led program of similar length on the long-term health consequences of smoking. In the second study, conducted a year later, seventh-grade students from the same 18 schools received the adult-led or peer-led social influences program, the adult-led health consequences program, or no specific smoking prevention program.

Results from the first study indicated that among students who were nonsmokers at the start of seventh grade, those who received the peer-led smoking prevention program were significantly less likely than those who received the adult-led programs to have tried smoking by the end of the eighth grade; similar results were seen for students who at the start had already tried smoking (Murray et al. 1984). Results from the second study indicated that at the end of the eighth grade, students who were initially nonsmokers and who received any of the test programs were significantly less likely than similar students from the schools receiving no program to have tried smoking (Murray et al. 1987). In the first study, differences among treatment groups had diminished by the ninth grade and

were not statistically significant. In the second study, students who had initially tried smoking and who received the peer-led programs had a significantly lower smoking prevalence than students receiving the adult-led health consequences program (Murray et al. 1987). Modest effects of a peer-led program were detected in an 11th-grade follow-up conducted for the second study (Murray et al. 1988).

The investigators surveyed members of the original study cohorts when the first study participants were one year beyond high school and the second study participants were in the 12th grade (Murray et al. 1989). Those still attending school in their original districts participated in a classroom survey, and others were interviewed by telephone; participation exceeded 90 percent in both studies. Responses indicated that the programs had no lasting differential effects on smoking behavior.

Waterloo Smoking Projects

The Waterloo Smoking Projects (WSP) in Canada tested a social influences program designed to follow students from the sixth through eighth grades. The program included three main components common to social influences curricula (Best et al. 1984). The first component provided information on negative consequences of smoking, on smoking prevalences in the general population, and on social influences to smoke. The second component provided practice in skills to resist direct social pressures to smoke. The third component focused on decision making and public commitment to not smoke. These topics were delivered in six sessions during the first three months of the sixth grade. Information about social influences was reviewed in two booster sessions later in the sixth grade. Two additional booster sessions in the seventh grade and one in the eighth grade featured student presentations and discussions about smoking pressures and decisions. All sessions were presented by graduate students who were members of the project staff.

The evaluation design for this study provided methodologically stronger evidence for potential longer-term effects than previous follow-up studies of school-based programs. The WSP was tested with students from 22 schools in two school districts in southwestern Ontario (Flay et al. 1985). Students from half the schools received the program, and students from the other half did not. The schools were located in urban, suburban, and rural areas. The study sample included 654 students tested at the sixth-grade baseline classroom survey.

At the end of the seventh grade, 18 months after the baseline survey, results were reported for the 498 students (76 percent) who had been present for all cross-sectional analyses at each time point. The analyses showed reduced experimentation with smoking in the entire target population receiving the program and reduced consumption among students who were regular smokers before involvement in the program (Flay et al. 1985). Longitudinal analyses showed significantly less smoking among program recipients who had already tried smoking before starting the program. Psychosocial mediators, such as knowledge and perceived control, showed changes throughout the target population that were consistent with program objectives (Flay et al. 1983).

Results at the end of the eighth grade were reported for the 439 students (67 percent) who had participated in all six school surveys administered through that time (Best et al. 1984). These analyses indicated that the program significantly reduced the amount of experimental smoking among the subgroup that at the baseline survey had reported never smoking. Effects that had been detected at the end of the seventh grade among students with more smoking experience were still apparent but no longer statistically significant.

The project surveyed original cohort members at the 12th grade by classroom survey, mailed questionnaire, and telephone interview. This effort yielded long-term follow-up data for 560 members (86 percent) of the original study cohort (Flay et al. 1989). There were no program effects at the 12th grade for any smoking level in the overall study sample or for any subgroups defined by initial level of risk.

Project ALERT

The Adolescent Learning Experiences in Resistance Training (ALERT) school program was based on a social influences model that included many features common to this type of program (Ellickson et al. 1993a). The overall goal was to provide young people with the motivation and skills needed to avoid substance use, including alcohol and marijuana as well as cigarettes. The motivational component focused on reducing barriers to resisting social pressures, such as normative beliefs that most young people and adults smoke, that this behavior is widely acceptable and approved, and that smoking has positive physical and social consequences. The skill component focused on practicing skills to resist direct social pressures to smoke. Eight sessions covering these objectives were delivered one week apart during the seventh grade; three booster sessions reviewed the main points during the eighth grade.

This program was tested with students from 30 schools in eight school districts located in urban, sub-urban, and rural communities of California and Oregon (Ellickson and Bell 1990). In the initial school survey, about 33 percent of these students were from minority ethnic groups. Students in 20 schools received the ALERT curriculum, and students in the other 10 schools did not. In 10 of the program schools, the curriculum was delivered by classroom teachers alone; in the other 10 program schools, teachers were assisted by older peer leaders recruited from nearby high schools.

The initial assessment of this program was reported for follow-up school surveys completed 15 months after the baseline survey. After substantial follow-up effort, about 60 percent of the baseline cohort of 6,527 students were included in these reports (Ellickson and Bell 1990). Among students in the treatment group who had experimented with smoking before the program, smoking was reduced by about 20 percent. Among students who had never smoked, however, the program did not achieve a statistically significant reduction. Psychosocial risk factors targeted by the program, including beliefs about the consequences of use and perceived norms for cigarette smoking, showed changes consistent with program objectives (Ellickson et al. 1993a). These findings were generally consistent across school districts in various geographic regions with differing ethnic and socioeconomic profiles; the results were not affected by whether an older peer assisted in delivering the program.

An additional follow-up of these students was reported at the ninth grade, two years after the baseline survey (Bell et al. 1993). These analyses included about 75 percent of the baseline sample. Earlier effects on psychosocial risk factors persisted, but program effects on cigarette smoking and other substance use behaviors had disappeared at this time (one year after the end of the program).

A final follow-up survey was completed in the 12th grade, five years after the baseline survey and four years after completion of the program; 57 percent of the baseline sample were included in these analyses (Ellickson et al. 1993b). By the end of high school, the program had no detectable effect on cigarette smoking or other substance use behaviors; most program effects on cognitive risk factors had also disappeared by this time. Similar to the other longer-term follow-up studies, these outcomes indicated that program effects eroded rapidly when the program ended and that no effects on smoking behavior or related beliefs were detectable at a later time.

Summary of Recent School-Based Research Studies

These reports reflect a high level of consistency in approaches taken to prevent smoking initiation and in the results obtained. All studies used some form of multiple-session school curriculum that was based on the social influences model and was delivered through classroom activities beginning in the sixth or seventh grade; all included a similar set of core curriculum components; and all reported achieving significant differences in smoking behaviors for one year or more after the program was initiated. For most programs, significant differences were reported through the ninth grade (the first year of high school and more than two years after program initiation).

Some specific features of these results strengthen the case for the effectiveness of school-based social influences curricula. The magnitude and scope of the effects achieved across studies were generally more impressive than those reported by earlier studies. The size of the reduction in smoking achieved at the eighth and ninth grades and the duration of these effects were larger than those of the short-term follow-up studies. Most of these studies also reported substantial effects on theory-based psychosocial mediators of cigarette smoking that were targeted for change by the programs, such as relevant knowledge, attitudes, skills, and perceived norms. These results thus indicated important and persistent effects (at least for several years) across a wide range of outcomes anticipated by the theoretical approach. As discussed later in this section, however, the effects did not persist in the longer term.

Programs that were successful in achieving prevention effects through the ninth grade tended to include a larger number of educational contacts with students over a longer time period than most earlier programs. For example, Project ALERT included 11 class sessions over two years; SHOUT included 18 class sessions, four telephone contacts, and five newsletters over three years; the LST Program included 30 class sessions over three grades; and the KYB program included an even larger number of class sessions over six school years. These relatively intensive programs successfully deterred young people from smoking cigarettes and using other substances during the periods that these curricula were provided. Comparable programs with smaller numbers of contacts over a more limited time have reported achieving a less sustained effect on smoking initiation (Biglan et al. 1987; Ary et al. 1990). These observations suggest a doseresponse relationship between how much the students are exposed to the social influences program and how effective the program is in preventing students from smoking. These results suggest that larger numbers of educational contacts over a longer period of time may yield larger and more enduring smoking prevention effects. This conclusion is strongly supported by the long-term reductions in cigarette smoking prevalence achieved by the relatively intensive LST Program.

The results were also obtained within a wide range of curriculum formats. Some of the recent social influences programs have tried to reduce the prevalence of several substance use behaviors often linked in the behavioral development of young people. These programs have included efforts within the same curriculum to prevent the use of smokeless tobacco, marijuana, and alcohol, as well as cigarettes. Including several substances in the program objectives, as might often be the case in ordinary school programs to prevent substance abuse, does not appear to have reduced the potential effectiveness of these programs in reducing cigarette smoking. In several cases, the positive effects on smoking behavior were also observed for other substance use behaviors. Similarly, social influences programs have been successful in diminishing smoking behavior when they have been incorporated in a larger health education program that successfully addressed other health behaviors, such as diet and physical activity. The success of programs under this broad diversity of curriculum formats increases confidence in the theoretical relevance and generalizability of this approach.

These studies also tested the social influences model under various implementation conditions. Successful programs were reported from a diverse group of geographic areas and with urban, suburban, and rural populations. A much wider mix of ethnic student populations has been involved in these than in earlier studies. Some studies reviewed here have reported favorable program effects for African American and Hispanic adolescents; similar programs have demonstrated positive effects for American Indian adolescents (Schinke et al. 1988, 1994; Moncher and Schinke 1994). Successful programs also used various personnel to deliver the programs. These included programs delivered by students' usual classroom teachers with or without intensive training, programs delivered with and without the assistance of peer leaders, programs delivered by college undergraduate or graduate students, and programs delivered by professional staff members of the research team. These diverse characteristics of successful programs further support the generalizability of the social influences model.

The more recent studies can be interpreted with much greater confidence than was possible with the pioneering studies reviewed a decade ago because of improvements in study design, measurement, and data analysis methods. Internal validity has been improved by including larger numbers of schools and students in study samples to enable investigators to account for school-level effects on smoking behavior (Murray and Hannan 1990). This approach also has improved external validity by providing for tests of programs with more diverse populations and placing program activities farther from the direct control of the chief investigators. In general, these reports have thus provided stronger demonstrations than were previously available of the benefits of social influences programs over other school health education programs for preventing smoking. The reports also provide greater assurances that the results obtained could be achieved in many types of classrooms if this curriculum approach was implemented with a reasonable level of fidelity.

The primary limitation of this promising record of success is its generally short-lived nature. Three of the studies that followed participants through the 12th grade consistently found that effects had faded over the high school years. The fourth, the LST Program, demonstrated a statistically significant impact through the 12th grade (Botvin et al. 1995). Thus, although the majority of programs based on the social influences model did not permanently protect young people from pressures or desire to begin smoking, the evidence shows that all of these programs successfully delayed this initiation for several years and that the most intensive of these programs reduced smoking prevalence through the end of high school. These results demonstrate that larger-scale implementation of intensive interventions based on this model can achieve long-term reductions in cigarette smoking among young people.

Further suggestions for overcoming this duration limitation may be drawn from these recent school-based studies. The studies provide evidence not only for the importance of overall program intensity, or the amount of exposure to the program (discussed earlier), but also for the effectiveness of programs that target a relatively broad array of educational modalities for smoking prevention. The LST Program addresses a spectrum of developmental concerns in addition to using a core unit on resistance to social influences that promote smoking; this curriculum has been shown to be effective with a wide range of populations. The KYB program achieved smoking prevention effects with a curriculum that was embedded in a larger program to change health behaviors. The SHOUT

program included classroom-based community action and advocacy components in addition to conventional units based directly on the social influences model. Such broader approaches within school settings thus seem to be effective in addressing the diversity of smoking prevention needs among adolescents.

This perspective receives additional support from a series of studies that have tried to identify more precisely the strengths of the social influences model by testing main components separately. The design of the Project TNT program evaluation provided a direct comparison between the effects of four curricula focused on skills training for resisting peer pressures, on social norms about the prevalence and acceptability of smoking, on knowledge of the negative consequences of smoking, or on a combination of the three elements. Contrary to theory-based expectations, the social skills curriculum did not perform as well as the social norms or negative consequences curriculum; the combined curriculum had the best results (Sussman et al. 1993b). A similar study found that a curriculum based on correcting erroneous normative perceptions was more effective than a curriculum on training in resistance skills; the results also suggested that a combined curriculum addressing a variety of educational needs about social influences on smoking was more effective than curricula focused on individual components of the model (Hansen and Graham 1991).

These studies thus indicate that attempts to reduce the scope of smoking prevention programs to skills training alone are likely to be ineffective. Although school programs are well suited to provide skills training through direct modeling and practice, as well as to convey knowledge about the consequences of smoking, they may not be as well equipped to influence young people's perceptions of the prevalence and acceptability of cigarette smoking among their wider peer group and adult society. As is discussed in the next section, more complex and intensive programs combining interventions within and outside of schools may be needed to overcome the powerful prosmoking cultural images fostered by the larger social environment.

Research on Multifaceted Programs

Another group of recent studies has expanded the traditional school-based scope of educational methods to prevent smoking. To counteract the multiple sources of social influences that promote smoking initiation, these projects enlist the positive influences of parents, community organizations, and the mass media in addition to offering strong school programs based on the social influences model. Relatively few examples of this new direction for smoking prevention efforts have been reported. Educational objectives for these programs have generally been developed directly from programs that have school-based components only, but specific strategies reflect various approaches, as might be expected when new techniques are being developed. Results provide good evidence that these multifaceted educational programs can achieve substantial smoking prevention effects that persist throughout the high school years more consistently than programs based only in schools.

Minnesota Heart Health Program: Class of 1989 Study

The Class of 1989 Study of the Minnesota Heart Health Program (MHHP) tested the efficacy of a school-based smoking prevention program conducted in the context of a wide range of associated school and community programs designed to improve health behaviors. These programs focused collectively on the overall goal of reducing the risk of cardiovascular disease among the adults of the targeted communities (Perry et al. 1992).

Smoking prevention programs were provided in the seventh through ninth grades. The main component of this multifaceted effort was based on the Minnesota Smoking Prevention Program (discussed in the previous section), which was one of the early successful designs for a social influences program (Perry and Jessor 1985). The Class of 1989 Study used a sevensession program delivered in weekly sessions during the seventh grade by peer leaders assisted by teachers (Perry et al. 1986). This program was followed by a two-session unit in the eighth grade that addressed smoking and exercise and by an eight-session unit in the ninth grade to prevent smoking and drug abuse. Similar curriculum units on eating and exercise behaviors were added to the school curriculum after the smoking prevention unit in the seventh grade (Perry et al. 1988).

These classroom components were supported in school by the development of health councils through which students participated in other projects related to the overall community program theme of cardiovascular risk reduction. Altogether, the students in the Class of 1989 Study participated in five years of educational programs that were provided through their schools and were focused on smoking and other health behaviors.

The school-based educational components were complemented and supported over the entire program period by community education and organization activities intended to reduce three cardiovascular risk factors—cigarette smoking, high levels of serum cholesterol, and elevated blood pressure—in adults of the targeted communities (Mittelmark et al. 1986; Perry et al. 1992; Luepker et al. 1994). The activities included individual risk factor screening and education, which was received by more than 60 percent of all adults; direct education sessions that were conducted in various community settings, which engaged more than 30 percent of all adults; food labeling education in grocery stores and restaurants; intensive mass media education; continued education of health professionals; and community organization to engage citizens, health professionals, and community leaders in developing and carrying out annual community education plans. Although the MHHP did not demonstrate a significant impact on adults (Luepker et al. 1994), a set curriculum and face-to-face training were found to increase the participation of teachers (Perry et al. 1990a).

The effect of these interventions on the smoking behavior of the targeted students was assessed through an evaluation design in which students from one community received these direct and indirect interventions and students from a matching community did not (Perry et al. 1992). At baseline, the target population consisted of all sixth graders attending the 13 elementary schools in these two communities. Longitudinal analyses at each annual follow-up considered students who had been present since the baseline surveys. The 12th-grade survey included 45 percent of the original cohort of 2,401 students. Cross-sectional analyses included all students participating in each survey.

Cohort analyses comparing weekly smoking prevalence and amount of smoking showed that students in the two communities did not differ significantly at the sixth-grade survey, which was administered before exposure to any substantial amount of program activities. Significant differences appeared at the seventh-grade survey, which was administered after completion of the core components of the smoking prevention program. Weekly smoking prevalence was about 40 percent lower in the treatment community cohort. Similar effects were found in the cross-sectional analyses. These significant differences were maintained through the 12th-grade survey, three years after the end of direct smoking prevention education and one year after the end of general community education.

This study was one of the first demonstrations in the United States that the effects of educational programs to prevent smoking could be maintained through late adolescence—and thus, theoretically, through life. Longer-term community programs supporting these school-based components appeared to play a key role in maintaining positive effects.

Midwestern Prevention Project

The Midwestern Prevention Project (MPP), a three-year school-based program for preventing substance use, was supported by several community interventions explicitly designed for this purpose (Pentz et al. 1989a). The school program consisted of 10 classroom sessions in the sixth or seventh grade (depending on the year of transition into middle school) and is the same as that reported by Hansen and Graham (1991). These sessions emphasized the negative consequences of cigarette, alcohol, and marijuana use; corrected misperceptions on actual levels of use among peers and adults; discussed direct and indirect pressures to use substances; practiced skills to resist pressures for substance use; and obtained public commitments to avoid substance use. These activities were presented by classroom teachers with the assistance of peer leaders. Ten homework sessions that involved parents' participation accompanied the school program. These sessions emphasized clarifying family rules on substance use, practicing techniques for avoiding substance use, and learning ways to counteract media and community influences to use substances. The mass media component of this program occurred throughout all three years of program effort and was equally available to program and control group students. Media messages focused on news coverage of program activities through newspaper articles, brief television news segments, and radio and television talk show interviews with project staff.

During the second year of the program (occurring in either the seventh or the eighth grade) for the target cohort, a five-session classroom booster program was combined with homework designed to keep parents actively engaged in prevention efforts (Pentz et al. 1989b). School administrators, parents, and students also planned and presented a parent education evening featuring communication skills and school policies on substance use (Rohrbach et al. 1995). During the third year of the program, community leaders received training in organizing task forces to prevent substance use. This program component, like the media component, was equally capable of influencing students in the program or the control group (Johnson et al. 1990).

The overall program was tested in 42 schools from eight communities in the Kansas City metropolitan area. About 21 percent of the students from these sixth- and seventh-grade target groups were from minority ethnic groups. Students from the target grades in these schools were assigned to the school and parent components (24 schools) or to a delayed-treatment control condition (18 schools). All students and parents were exposed to the mass media components and were potentially exposed to the effects of the community organization component beginning with the third program year. Effects were evaluated by using a one-third sample of the large sixth- and seventh-grade target group. This study sample was obtained through baseline surveys of all targeted students in 16 schools and through a one-fourth sample from the remaining schools (total n = 5,065).

Follow-up surveys combined sequential cross-sectional surveys, including all students present at a survey point, and longitudinal surveys of a subset of baseline cohort members. The one-year follow-up sample included 5,008 members of the target population, who were then in the seventh and eighth grades. Monthly cigarette use was about 32 percent lower among students who had received the combined school, parent, and mass media programs than among students who had received the mass media information only. Similar effects were observed among the subset of students tracked longitudinally (Dwyer et al. 1989).

Additional classroom surveys were completed with 3,875 students two years after baseline, when the students were in the eighth and ninth grades (Pentz et al. 1989b). Significant program effects on monthly and weekly smoking prevalence were maintained from the one-year follow-up, although the magnitude of the differences between program and control students was smaller. Similar results were obtained from the panel of students measured longitudinally (Pentz et al. 1989c).

The longitudinal panel from the original sample was followed up into the 9th and 10th grades (Johnson et al. 1990). The baseline sample included 1,607 sixth-and seventh-grade students, of whom 1,105 (69 percent) provided complete data at both baseline and the three-year follow-up. Analyses indicated a significant treatment effect for monthly cigarette smoking. Students receiving the entire program reported about 19 percent less monthly smoking than students who received only the mass media and community organization components.

University of Vermont School and Mass Media Project

The University of Vermont School and Mass Media Project (VSMM) evaluated the effects of supplementing a school-based smoking prevention curriculum with intensive mass media campaigns carefully targeted to the needs of adolescents. Both the school and the mass media programs shared a set of objectives consistent with the social influences model. These common objectives stated that adolescents exposed to the programs would perceive fewer advantages of smoking, perceive more disadvantages of smoking, acquire social skills to resist peer pressures to smoke, and perceive that most people their age do not smoke (Worden et al. 1988). Other objectives concerned with smoking cessation and awareness of tobacco industry marketing to young people were introduced as the target group matured.

The school program included grade-specific lesson plans and teaching materials, and classroom teachers received annual training. Curriculum content covered key elements of the social influences model, such as short-term social and health consequences, awareness of social pressures to smoke, skills for coping with peer pressures and other social pressures, and decision-making skills related to smoking behavior (Flynn et al. 1995). The three-grade study cohort received this program for four years, in either the 5th–8th grades, 6th–9th grades, or 7th–10th grades. The program required four class sessions for the units in the 5th–8th grades and three class sessions for the units in the 9th and 10th grades.

The mass media campaigns used the common objectives and data from high-risk young people in six predefined age and sex groups. High-risk students were defined as those who had previous smoking experience or who knew at least two people in their immediate social environment who smoked, such as parents, siblings, or friends. High-risk girls and boys from three age groups participated in diagnostic research activities on two occasions during the study to provide information needed to tailor the mass media campaign to their needs (Worden et al. 1988). These data were used to develop pilot mass media spots, which were assessed by small samples of high-risk students.

Mass media advertisements that clearly addressed the common educational objectives and were attractive to their intended target groups were produced for broadcast as 30- and 60-second television and radio spots. Spots targeted to the six specific target groups were broadcast on programs that school survey data had indicated were popular among these

groups; 36 television and 17 radio spots were produced. An average of 190 television broadcasts, 350 cable television broadcasts, and 350 radio broadcasts of these spots was purchased per year for four years in each target community.

The evaluation design included four geographically separate but demographically matched metropolitan areas from three states (Flynn et al. 1992). Students in two communities received the mass media and school programs for four years. Students in the other two communities received only the school programs during these four years. The initial cohort included all students from the fourth through sixth grades from 50 elementary and middle schools; more than 99 percent of these students (n = 5,458) participated in the first school survey. Interventions and annual follow-up surveys were conducted for the next four years, beginning at the 5th-7th grades in the 1985-1986 school year and ending at the 8th–10th grades. A classroom and telephone follow-up survey attempted to reach all original cohort members during the 10th-12th grades.

Results after four years of the program concentrated on the 47 percent of the original cohort who were fully exposed to the program components (n = 2,540). These analyses indicated that significant hypothesized differences in mediators of program effects occurred in the media-school communities beginning at the end of the second program year and that the amount and prevalence of cigarette smoking were significantly reduced at the beginning of the third program year (Flynn et al. 1992; Worden et al. 1996). By the end of the four-year program period, alternative measures of smoking prevalence and intensity indicated that students in the media-school communities reported 34–41 percent less smoking than students in the schoolonly communities. Two years later, when the study cohort was in the 10th-12th grades, differences between smoking prevalences in the two groups continued to be statistically significant and of similar magnitude (Flynn et al. 1994). Among students who were at high risk for smoking in grades 4-6, further analyses showed that these interventions produced significant differences in weekly smoking prevalence at grades 10-12 (Flynn et al. 1997). Cost-effectiveness analyses indicated that the cost per student smoker averted as a result of these interventions was about \$754 in 1996 dollars, and the cost per life year gained was about \$696 (Secker-Walker et al. 1997).

These findings show that carefully targeted mass media campaigns can add to school programs a substantial and enduring effect on smoking prevention when the program efforts are sufficiently intensive and the educational objectives for these two channels are closely coordinated. These interventions did not include a substantial program component directed toward parents or other adults in the community. The results provide powerful evidence of the influence of mass media messages on health behavior decisions made by young people.

Observations on Research on Multifaceted Educational Programs

These studies are notable because they all represent efforts to extend the impact of school programs by enlisting the influence, preferably throughout adolescence, of other powerful forces in the lives of young people and because their effects more consistently exceed those achieved by programs involving only the school (Table 3.1). This notion has added importance in view of the competition for curricular time within schools. The studies that were able to follow up study participants into the later high school years have provided the best evidence thus far that program effects can be extended when educational or other prevention strategies include multiple components and take place over longer terms. Because few people begin smoking after high school, these results suggest that long-term multifaceted programs can prevent significant proportions of young people from smoking not only during their junior and senior high school years but also for the rest of their lives.

The interventions used in these three studies were based on a common core of approaches. The main shared theme was that a strong school program was necessary to achieve substantial effects. The school component of the MHHP included 17 class sessions explicitly directed toward smoking prevention objectives over three school years; the MPP school program included 15 class sessions over two school years, as well as other school-based student activities; and the VSMM included 14-16 class sessions over four school years. The intensity of these school programs was similar to the intensity of successful school-only programs and approached that recommended by experts (Glynn 1989; CDC 1994b). A related theme was use of the social influences model in designing programs. The research groups that developed the MHHP and the MPP included investigators who were key contributors to the development of this model for school-based programs. The design of the VSMM program components also closely followed this model.

The third shared theme for these studies was their focus on entire communities. The MHHP was provided to, and evaluated in, all schools in a single

moderate-sized community and was supported by communitywide mass media and organizational programs. Some components of the MPP were provided to students, parents, and community members in an entire large metropolitan area. The VSMM was provided to adolescents in two entire moderate-size metropolitan areas, and the same large groups were the focus of targeted media campaigns. The educational messages of the school-only programs, in contrast, generally did not reach beyond the walls of the selected school. Directing messages to entire communities of adults and adolescents may have increased the capacity of multifaceted studies to influence adolescents' normative perceptions of the prevalence and acceptability of cigarette smoking.

The importance of the school component was emphasized by results of a study conducted within the context of the Stanford Five-City Project. This study shared with the MHHP the goal of reducing cardiovascular risk factors in entire adult populations and shared many features of the programs for adults (Farquhar et al. 1990). The adolescent smoking feature of this study assessed whether reductions in cigarette smoking among adults (Fortmann et al. 1993) were reflected among adolescents. A seven-session smoking prevention program was provided to adolescents in 7th and 8th grades during the fourth program year (Telch et al. 1982; Winkleby et al. 1993), and a four-session cessation unit was provided to half of the 10th-grade classes (Killen et al. 1988). The effect of this combination of programs was assessed through cross-sectional population surveys conducted over a 10-year period. No statistically significant differences in smoking prevalence were detected among participants aged 12–15, 16–19, or 20–24 years.

The duration of the community programs in the MHHP was one year less than that of the Stanford study. The school programs in the MHHP, however, were much more intensive and of longer duration. Although differences in evaluation methods preclude direct comparisons, results suggested that the MHHP's substantial impact on the smoking behavior of adolescents in the Class of 1989 Study depended on the presence of a strong school-based program that was enhanced by the supportive community environment in which it was conducted. The Stanford study's lack of effects on adolescents suggested that intensive, communitywide programs to reduce health risks among adults would not be sufficient to change adolescent smoking unless these programs were combined with more intensive school programs. These contrasting results affirm that a strong school program is important to the success of educational strategies for prevention.

The MHHP community activities were not specifically designed as smoking prevention programs; they were directed toward adults and addressed several cardiovascular risk factors in addition to smoking. These efforts to reduce adolescent smoking may have resulted because young people were directly exposed to community program messages and appeals intended for adults, school programs had heightened intensity from being conducted in communities focused on developing healthy behaviors, or parents stimulated by the community programs gave greater attention to adolescent health behaviors. The intensity, pervasiveness, and duration of the community program may also have affected the general norms of the community on health behavior, which in turn may have influenced young people to decide against start-

Similar results were obtained by another youth smoking prevention study conducted in the context of pervasive community cardiovascular risk reduction campaigns. The North Karelia Youth Project in Finland included a school program with three sessions in grade seven, five sessions in grade eight, and two sessions in grade nine (Vartiainen et al. 1998). Intensive community programs on cardiovascular risk reduction were conducted for adults, including community organization and mass communication campaigns for cigarette smoking cessation, during the years the school program was delivered. Significant differences in cigarette smoking prevalence between young people in the intervention and comparison areas were found at each follow-up survey through age 21. At age 28, significant differences in smoking prevalence were found among those who were nonsmokers at the baseline survey, in seventh grade. These results provide strong support for the findings of the MHHP Class of 1989 Study and emphasize the potential impact on youth smoking of combining school and community programs.

The community component of the MPP was explicitly designed to complement the school program to prevent substance use. Program activities that occurred outside the classroom were more focused on parents' behaviors than is usually found in research studies on smoking prevention. These activities included 10 homework exercises in the first program year and a wide range of family norm-setting activities; similar exercises accompanied the second year of the school curriculum. Parents helped plan and present a parent education evening in participating schools in the second year and participated in community organization activities in the third year.

The only program components to directly reach or involve the wider community were the media messages and community organization activities. The latter component was not introduced until the third program year and may not have had much effect on students' smoking behaviors. Because parents, then, were the principal focus of educational efforts outside the classroom, the MPP effects were likely achieved mainly through strong and consistent parental support of the objectives of this school-based program. The media messages may also have influenced adolescents' perceptions of peer, family, and community smoking norms.

Results of the MPP, the MHHP, and the North Karelia Youth Project thus offer the possible common interpretation that the programs' effects depended on strong school programs supported by community programs that may have affected students in two ways: through substantially increased efforts by parents and through young people's perceiving that smoking is not normative. Although parental components similar to the MPP homework assignments have been included in some school-only smoking prevention programs, the full scope of parent-oriented efforts used by the MPP in support of the school curriculum has not been tested previously. Further exploration of combined school and parent programs may be a promising avenue for future educational research studies. Similarly, these results highlight the importance of program components designed to influence adolescents' normative perceptions.

The VSMM shared with the MPP and the MHHP the general strategy of supplementing a relatively strong school-based smoking prevention program with other forms of intervention but differed in several respects. The combined school and mass media program in the VSMM was directed toward the target adolescents, and no adult participation was anticipated outside of the classroom. The project's resources thus were applied to influencing adolescents' smoking behaviors directly through changes in the students' beliefs, skills, and perceived norms.

The VSMM also differed in focusing on use of the mass media as a sole supplement to the school program. This design provided a reasonably clear indication that the magnitude and duration of a relatively strong school curriculum to prevent smoking could be significantly increased by a mass media component that concentrated exclusively on the target audience of adolescents.

Three other large-scale tests of mass media approaches to smoking prevention have been reported. One study conducted in North Carolina tested three

mass media campaigns that were not combined with school-based programs (Bauman et al. 1988). The media campaigns included radio spots on the expected consequences of smoking, a similar radio campaign that featured a smoking prevention contest, and the radio and contest components with television spots added. The messages were broadcast during three four-week periods at levels intended to reach 75 percent of the target audience four times during each period. Each campaign was conducted in two metropolitan areas; four other communities served as control areas. Adolescents aged 12-14 years were interviewed through household surveys at baseline (n = 2,102); 78 percent of them were followed up 11–17 months later. Results indicated that the campaigns had effects on the recipients' knowledge of the consequences of smoking and other mediators but not on cigarette smoking behavior (Bauman et al. 1991).

In the Television, School, and Family Smoking Prevention and Cessation Project (TVSFP), Flay and colleagues (1988, 1995) tested a mass media supplement to a school program. The study design was similar to that used in the MPP. The main study was conducted in a single metropolitan area. The mass media component was generally available to members of the community, and the school program was offered only to members of the main treatment group. The main research question thus addressed whether a school program combined with a mass media campaign had a stronger effect than the mass media campaign alone. The school curriculum included 10 classroom sessions delivered by trained health educators during the seventh grade. The media component included segments that ran for two months in evening television news shows that were linked to the classroom sessions. Students in the main intervention conditions were asked to view these segments with their parents and to complete related homework activities together. Seventh-grade students from 47 schools participated in the study; they were surveyed during the seventh, eighth, and ninth grades. Program effects were observed in the follow-up surveys for mediating variables but not for smoking behavior.

More promising results have been reported for a three-year mass media campaign on youth smoking in Norway (Hafstad et al. 1997). This campaign used the novel approach of creating messages intended to stimulate antismoking interactions among young people through use of provocative messages that presented starkly negative images of adolescent smokers. Unlike other mass media approaches, these messages were presented as movie and newspaper advertisements and posters, as well as through broadcast

media channels. Messages were broadcast or placed at a relatively high level of intensity over one three-week period each year for three years. Message themes were varied each year. The impact of these campaigns was evaluated over three years by comparing baseline and follow-up survey results among a cohort of 11,033 young people aged 14 and 15 years for one intervention county and one control county. Results showed that young people from the intervention county were less likely to start smoking and more likely to stop smoking at the follow-up survey. This study demonstrates the potential impact of relatively intensive, highly targeted mass media smoking prevention campaigns that are not combined with any other type of smoking prevention intervention.

Results of these studies using mass media as a primary educational strategy suggested that better outcomes were associated with more intensive, multifaceted program efforts on social influences. The TVSFP intervention included a substantial school curriculum for the seventh grade but did not include further sessions in later grades. The mass media campaign included a maximum of 10 exposures over a two-month period. The North Carolina study did not include a direct component for interpersonal education; the media component for this study did not directly address social influences on adolescent smoking and was delivered over a total period of three months. These program efforts contrast sharply with the three-year Norwegian media campaign and the 14to 16-session school program combined with a mass media campaign delivered over four years in the VSMM.

Because only relatively brief individual messages about cigarette smoking can be delivered to adolescents through the mass media, it is reasonable to hypothesize that behavioral effects can be achieved only when the media spots run frequently and over many months. Other evidence discussed here indicates that these types of media campaigns are most likely to be effective when combined with some form of coordinated interpersonal education, such as schoolbased smoking prevention programs. The VSMM results thus align with those of the MHHP and MPP in supporting the importance of school programs. The VSMM also directly targeted normative perceptions in its school and media components and demonstrated positive changes in these mediators of adolescents' smoking behaviors.

Several guidelines for designing future educational efforts to prevent smoking can be drawn from this review of three successful multifaceted programs. The central role of school programs in smoking prevention education was affirmed by the results of all three studies. The MHHP and the MPP results both suggested the power of influencing adolescents' perceptions of cigarette smoking norms through community programs that enhance the effect of school programs; the MPP results demonstrated the effectiveness of parents' participation as a specific strategy for enhancing school prevention programs; and the VSMM demonstrated that long-term mass media campaigns targeted to adolescents' beliefs, skills, and

perceived norms could enhance the effect of school programs.

On a cautionary note, the theoretical and demonstrated ability of these programs to alter the smoking behavior of young people must be viewed in the larger context of their practicality. As noted earlier, the ability to disseminate such programs has been a matter of active public health engagement. The following section examines the current status of such dissemination.

Diffusing Programs to Prevent Tobacco Use

In the mid-1990s, several surveys were undertaken to assess the extent to which national guidelines for tobacco prevention in schools (CDC 1994b) were being implemented. One of these, the School Health Policies and Programs Study (SHPPS), queried state and local education districts directly about their adherence to guidelines (Collins et al. 1995). A second survey used health department tobacco coordinators as the primary information source about tobacco prevention programs in schools (J.K. Worden and B.S. Flynn, Tobacco use prevention education in the United States, 1994, unpublished data, September 1995).

National Guidelines

According to the CDC's "Guidelines for School Health Programs to Prevent Tobacco Use and Addiction" (CDC 1994b), all schools should, for developmentally appropriate ages, provide instruction about the short-term and long-term negative physiological and social consequences of tobacco use, about social influences on tobacco use, about peer norms regarding tobacco use, and about refusal skills. Local school districts and schools are advised to "review these concepts in accordance with student needs and educational policies to determine in which grades students should receive particular instruction" (CDC 1994b, p. 9). The guidelines recommend that students in kindergarten through the 12th grade receive curricula for preventing tobacco use. Because tobacco use often begins in the 6th-8th grades (USDHHS 1994), more intensive instructional programs should be provided in these grades, and students should receive annual prevention education thereafter through the 12th grade. The guidelines also recommend that programs include support from families, support from community organizations, tobacco-related policies, and advertising campaigns for preventing smoking, because school-based efforts appear to be enhanced by complementary programs in the community. Finally, an ongoing assessment should monitor whether an adequate tobacco education program is being maintained.

School Health Policies and Programs Study

The SHPPS survey, in a follow-up to a similar survey conducted by the American School Health Association in 1989, examined state-, district-, school-, and classroom-level data (Collins et al. 1995). SHPPS examined specific instruction provided in six critical areas: intentional and unintentional injury, alcohol and other drug use, tobacco use, sexual behaviors, dietary patterns, and physical activity. The education agencies in all 50 states and the District of Columbia, a national sample of 413 school districts, a national sample of 607 middle/junior and senior high schools, and 1,040 randomly selected health education teachers were surveyed. State and district data were collected with selfadministered questionnaires mailed to the person most knowledgeable about or responsible for each component of the school health program. School and classroom data were collected through on-site personal interviews with lead health education and classroom teachers. The multiple levels of data collection were necessitated by the embedded tradition of local control in determining educational requirements and content of instruction. The data from SHPPS are most clearly assessed by their relationship to the CDC guidelines.

Guideline: All schools should develop and enforce a school policy on tobacco use. Policies should prohibit tobacco use by all students, staff, and visitors during school-related activity.

Almost two-thirds of schools had smoke-free building policies in place in 1994, though significantly fewer (37 percent) had prohibited the use of tobacco products by all persons on school property, in school vehicles, and at school-sponsored functions away from the school site. Most schools (83 percent) prohibited tobacco use by athletes and coaches during schoolsponsored events, and most (89 percent) provided written copies of the policy to students, staff, and parents. Schools were significantly more likely to have used exclusively punitive consequences (58 percent) in response to the most recent violation of their school's tobacco use policy than exclusively remedial consequences (2 percent) or a combination of punitive and remedial consequences (30 percent); few (8 percent) invoked attendance at a tobacco use prevention program as remediation for violations. Only 30 percent of schools offered tobacco cessation services in or through the school.

Guideline: All schools should provide tobacco prevention education in kindergarten through 12th grade. The instruction should be especially intensive in middle and junior high school and reinforced in high school.

In 1994, tobacco use prevention education was required in 37 states (72 percent) and in 83 percent of school districts. At the school level, 91 percent of middle/junior high schools and 82 percent of senior high schools included tobacco use prevention education in a required course. However, only 55 percent of middle/junior high school teachers and 47 percent of senior high school teachers of health education reported tobacco use prevention as a "major" topic in their courses. Of the middle/junior and senior high school teachers who included tobacco use prevention education as a major topic, only 21 percent spent six or more class periods on the topic.

Guideline: Schools should provide instruction about the immediate and long-term consequences of tobacco use, about social norms regarding tobacco use and the reasons why adolescents say they smoke, and about social influences that promote tobacco use. Schools should provide behavioral skills for resisting social influences that promote tobacco use.

Of the approximately 50 percent of teachers who taught tobacco use prevention as a major topic, 74 percent taught both short- and long-term effects of cigarette smoking. Fewer (61 percent) taught both

short- and long-term effects associated with using smokeless tobacco. Although 61 percent of teachers addressed group attitudes (i.e., social norms) about tobacco use, only 42 percent taught about the actual amount of smoking and tobacco use among adolescents and adults. Less than half (48 percent) of this group of teachers provided instruction about "healthy alternatives" to tobacco use. Sixty-eight percent included instruction on social influences. Most teachers taught behavioral and social skills, though it is unclear if these skills were taught specifically within the context of tobacco use prevention education. For example, 89 percent of teachers taught decision-making skills, 87 percent taught skills for resisting social pressures, 81 percent taught communication skills, and 78 percent taught goal-setting skills.

Guideline: Improve curriculum implementation and overall program effectiveness.

In 1994, 82 percent of states had offered inservice training on teaching tobacco use prevention during the past two years. However, only 24 percent of school districts had offered in-service training on tobacco use prevention. Consequently, it is not surprising that only 9 percent of teachers of health education received training on tobacco use prevention education during the same time period. Although state-level training is typically designed for district staff, district-level training is the most common source of training for teachers. Increased training opportunities for teachers are needed to improve the effectiveness of tobacco use prevention education.

The 1994 SHPPS data were analyzed to examine the extent to which U.S. schools were implementing the CDC's "Guidelines for School Health Programs to Prevent Tobacco Use and Addiction" (Crossett et al. 1999). Although data do not exist in SHPPS that specifically assess adherence to each of the six recommended program areas, three criteria were selected that reflect a "comprehensive" approach to tobacco use prevention (Crossett et al. 1999): (1) a tobacco-free policy consistent with CDC guidelines, (2) at least one teacher who taught tobacco as a major topic and covered four essential content areas (short-term health effects, groups' attitudes toward tobacco, social influences, and life/refusal skills), and (3) access to tobacco cessation services for students. Only 4 percent of middle schools, junior high schools, and high schools nationwide met all three criteria. Twenty-six percent met two of the three criteria, and 41 percent met one of the three. More than one-fourth of schools (29 percent) met none of the three criteria. This analysis is limited, because not all of the CDC guideline recommendations could be measured directly by SHPPS. Nevertheless, these findings indicated that very few schools were fully implementing the CDC recommendations in 1994.

Schools are faced with many competing demands for instruction and classroom content. Currently, most of this nation's schools are providing students with some basic tobacco use prevention education. However, the recent increases in tobacco use prevalence among youth and the overwhelming documentation of the health consequences of tobacco addiction emphasize the need for improvement in what schools are doing to reduce tobacco use and nicotine addiction among their students, faculty, and staff.

A State-Based Assessment

To estimate current program activity in smoking prevention education across the United States, tobacco control coordinators in all 50 states and the District of Columbia were asked to participate in a survey (Worden and Flynn, unpublished data; unless otherwise noted, cited data in this section are derived from this survey). The position of tobacco control coordinator was established to oversee tobacco control and education efforts in each state health department, through either the American Stop Smoking Intervention Study (ASSIST) program of the National Cancer Institute (NCI) (Shopland 1993) or the Initiatives to Mobilize for the Prevention and Control of Tobacco Use (IMPACT) program of the CDC (USDHHS 1995). The survey was conducted between December 1994 and March 1995. The tobacco control coordinators were asked to describe any educational programs to prevent tobacco use—including school, community, and mass media activities—that were being implemented in their state during 1994 and to send written descriptions or examples of materials used in these programs. This survey differed from SHPPS in its primary reliance on health department rather than education department personnel and in the absence of a multilevel sampling approach. The state-based survey, on the other hand, focused more on the types of materials used.

Basic Curriculum

The state-based survey determined that school systems were generally left to create their own tobacco use prevention programs or to decide which of several available commercial programs would be implemented. Examples such as Here's Looking At You,

2000 or the LST Program (Bosworth and Sailes 1993; Glynn 1994) were mentioned by a few of the states. A number of states had implemented some school-based educational programs on tobacco use that were supplemental to statewide school curricula. Among the supplementary programs, the most popular was Teens As Teachers (American Nonsmokers' Rights Foundation 1994). Reported in 10 states, this program trains older high school youth to discuss with younger students the physiological and social consequences of tobacco use. The older youth also may convey the accurate norm that most young people do not use tobacco. Six states reported using the Tar Wars program, in which medical professionals discuss the consequences of tobacco use with junior high school students (Tar Wars 1995). Save a Sweet Heart, a program that emphasizes social influences on tobacco use for junior high school and high school youth (American Heart Association 1989), was reported in three states. Sporadic use was reported for several other programs, including Growing Healthy®; Teenage Health Teaching Modules, a version of D.A.R.E. that includes tobacco use prevention; the Minnesota Smoking Prevention Program; and a curriculum developed at the University of Vermont (Bosworth and Sailes 1993; Gerstain and Green 1993; Glynn 1994). In several states, either a voluntary health agency or a community or school group originated its own supplement to a school program.

Supplemental Programs

During 1994, two states—Massachusetts and California (see Chapter 7)—were particularly active in developing and implementing supplemental programs (i.e., in addition to statewide curricula) using mass media in smoking prevention. Although smoking prevention was one of several aims of the generic media campaigns funded through tobacco tax revenues in each state, the topic was clearly emphasized in a set of media spots specifically targeting youth in 1994 in each state. The Massachusetts campaign was comprehensive; seven messages addressed various topics suggested in the CDC guidelines (Massachusetts Department of Public Health 1994). The 1994 California campaign used seven television spots and six radio spots to describe the physiological consequences of smoking. Using humorous vignettes, the campaign identified toxic substances in cigarette smoke, such as arsenic, formaldehyde, ammonia, methane, and dichlorodiphenyltrichloroethane (DDT).

On a smaller scale, supplemental efforts with comprehensive coverage also occurred in West Virginia and in Denver, Colorado. In West Virginia, through a contest sponsored by the American Cancer Society, four winning scripts for radio spots on smokeless to-bacco use and on environmental tobacco smoke were selected from more than 300 entries from students in kindergarten through the 12th grade. The spots were broadcast on 22 stations and included several topics, although the only one related to the CDC guidelines concerned the physiological consequences of tobacco use. In Denver, a three-month billboard campaign promoted the theme "Smoking Doesn't Add Up," which suggested the financial consequences of tobacco use (Colorado ASSIST Alliance 1994).

Programs Including Families

Only two states reported large-scale supplemental programs that included families: New Jersey in its community grants programs and Oregon in a program entitled Parenting for a Positive Future. Three other states reported using the Unpuffables program, which requires parents' participation and includes the topics of social influences and refusal skills (Perry et al. 1990b). It should be noted, however, that this estimate of parental involvement is likely to be low, since districts and schools, which vary considerably in the degree to which they involve parents in school activities, were not queried directly.

Community Programs

In general, virtually no states reported community organization programs dedicated to supplementing educational programs to prevent tobacco use. Several programs—including the Kids Against Tobacco program, which involved 5,000 young people in northwestern Louisiana—combined tobacco education and advocacy, but the main emphasis was on inspiring young people to advocate against tobacco use.

Combined Activities

At the time of the Worden and Flynn survey, only Pennsylvania reported combining a mandated school curriculum with supplemental school, community, and mass media programs in an educational strategy to prevent tobacco use. The statewide Youth Against Tobacco program was sponsored by the state's health and education departments along with the American Cancer Society and the Pennsylvania Medical Society. These sponsors asked community organizations throughout the state to participate in the program, which ran from 1992 through 1995. More than 175,000 young people in 47 counties participated with local

Boy Scouts and Girl Scouts, Boys' & Girls' Clubs, health organizations, Students Against Driving Drunk, D.A.R.E., and other groups. Community events included the 1994 Farm Show, in which 8,444 young people pledged not to smoke. The 1994 mass media program included a rap radio message aired by 223 stations in January and 280 stations in June. Declaring it "not cool" to smoke, the message described the social consequences of smoking (Pennsylvania Department of Health 1992).

Monitoring Program Objectives

Only Vermont reported having a system in place to annually assess school program activity. Act 51 stipulates that schools in Vermont annually report the number of schools implementing a curriculum. In 1994, 219 schools reported using the Here's Looking At You, 2000 program, 25 used the LST Program, and 19 used other programs (Glynn 1994). Arkansas, Indiana, Missouri, Pennsylvania, and Rhode Island were able to report the estimated number of students receiving specific programs run by voluntary agencies or local school districts. For example, Indiana reported that 15 percent of its students received the Growing Healthy program.

Interpreting the Diffusion Process

Because of the methodological differences, the results of SHPPS cannot be compared directly with those of the state-based survey conducted by Worden and Flynn. In particular, it is likely that the latter underestimated the type and amount of tobacco use prevention activity that may have been occurring on the local level. The two surveys concurred, however, in their overall assessment: considerable progress has been made, but comprehensive school health education can be improved in some areas, including tobacco use prevention. SHPPS, which focused on multiple activity levels, concluded that few schools met all the major criteria provided in the CDC guidelines (CDC 1994a; Crossett et al. 1999). As a result of its focus, the state-based survey concluded that optimal use had not yet been made of the available research on multichannel methods for maximizing the impact of school health education programs for tobacco use prevention.

Thus, the review of reported program activity in 1994 indicated that we are far from attaining an ideal, national level of educational programs to prevent tobacco use. By one set of criteria, only 4 percent of the middle, junior, and high schools in this nation were

meeting three criteria of a comprehensive tobacco use prevention program in 1994 (Crossett et al. 1999). Several reasons have been offered for this shortcoming at the time. One reason is that the year 1994 fell between two periods that may have been more active. The first period was the late 1980s and early 1990s, when the states of Minnesota and California were implementing large-scale campaigns to reduce tobacco use that were financed by tax revenues from cigarette sales. For a brief time, Michigan also developed mass media spots for preventing smoking among adolescents. Resources for these efforts apparently shrank (Begay et al. 1993), and the campaigns faded by 1994. A second period, which follows the 1994 activities reported here, arguably began with the 1994 publication of the Surgeon General's report Preventing Tobacco Use Among Young People (USDHHS 1994). That report seems to have stimulated development of a new set of guidelines. In addition, by this time all states had received support to coordinate their education and policy efforts to reduce tobacco use. This support came through the ASSIST program, which began such activities as early as 1991, and through the IMPACT program, which supplemented ASSIST coverage. Therefore, 1994 may represent an interregnum in the enthusiasm for tobacco prevention education. This view is supported by the events of the late 1990s. The major legal and legislative activities (see Chapter 5) were instrumental in mobilizing several states to intensify multichannel efforts at tobacco prevention (described in detail in Chapter 7).

A second reason is that there has been little evidence that the community-based approaches to prevent tobacco use that have been shown to be effective in controlled research studies have been adapted effectively to statewide use. Two states, California and Minnesota, have attempted some evaluation of community-based programs to prevent smoking on a statewide scale. In both cases, marketing research techniques similar to those described as diagnostic and formative research in the VSMM (Worden et al. 1988, 1996) were applied in developing mass media campaigns. Several creative messages for preventing smoking were developed in each state, but the number of messages dedicated to young people was limited; exposure also was limited, because paid advertising slots were allocated to target groups of adults as well as youths (Kizer et al. 1990; Minnesota Department of Health 1991).

Although awareness of each of these campaigns appeared to be high among adolescents, there was no reduction in smoking behavior (Murray et al. 1994; Pierce et al. 1994; Popham et al. 1994). Part of the

difficulty may have been the absence of a sufficiently strong school-based program having similar educational objectives. It is also possible that, with funds divided to reach many targeted groups, the media could not be concentrated sufficiently on smoking prevention among youth to have a measurable effect.

A third reason is that programs implemented on a day-by-day basis over the years often lack the essential ingredients for success that were evident when they were created and evaluated by researchers. To be effective, programs should be taught as designed (Rohrbach et al. 1993). For many curricula, teachers require training—if not to encourage adoption of the program, then at least to ensure that the curriculum is correctly and completely delivered (Perry et al. 1990a; Smith et al. 1993). Many teachers are resistant to training (Brink et al. 1991), and teachers who smoke may be particularly uncomfortable with a curriculum that discourages smoking. Such resistance may not affect the quality of a brief, single-pronged program format, such as the Smoke Free Class of 2000, but may jeopardize the integrity of more long-term and comprehensive curricula. It also has been found that a school system's decision to use a curriculum is simply not enough to ensure successful implementation; teachers should be brought in at the earliest stages of adoption (Rohrbach et al. 1993). Teachers and school administrators with prior experience in tobacco use prevention education should be involved in orienting and inspiring other teachers, who will then be more likely to deliver the curriculum faithfully and effectively (Smith et al. 1993). Successful implementation also depends on the size of the school organization; smaller organizations are more likely to adopt new programs quickly, whereas larger organizations are more likely to maintain a program once it is adopted (McCormick et al. 1995).

A fourth reason is that there appears to be a shortage of linking agents, who have been found to be essential for maintaining educational programs to prevent tobacco use (Dijkstra et al. 1993) and have been recommended in several diffusion studies (Brink et al. 1991; Goodman et al. 1992; Rohrbach et al. 1993). Linking agents are persons or groups that have a strong incentive for maintaining a program and promoting its continuation by consistently and faithfully coordinating all of the necessary resources for implementation. Potential candidates for local linking agents are school health teachers, principals, volunteers, and health professionals; each could ensure that school curricula include a strong component for preventing tobacco use, much as local voluntary agencies have supported the Smoke Free Class of 2000 effort (Brink et al. 1991). These individuals, working through a coalition, could also coordinate community program efforts involving families, community organizations, and mass media.

On a state level, the natural linking agents would be the tobacco control coordinators, who could work through coalitions or other state agencies to accomplish several long-term, comprehensive aims: (1) establish legislation mandating school-based tobacco use prevention with guidelines specifying effective curricula; (2) establish a curriculum training program, through the state education department, that would involve school administrators and teachers in the ongoing implementation of school-based curricula to prevent tobacco use; (3) establish a monitoring and support system to determine the penetration and quality of programs throughout the school system and improve instruction with ongoing teacher training; (4) work with parents' groups and volunteer organizations to support the school program; and (5) work with interested citizens to place media messages that support each of the content areas recommended by the CDC guidelines.

On a national level, linking agents could be agencies, such as the NCI or the CDC, that could support local and state efforts to reduce tobacco use with funding and continued coordination, such as by regularly convening state coordinators to share program ideas. These national linking agents might focus their diffusion efforts on using the mass media, because youth in different markets respond equally well to media-based messages for preventing tobacco use (Flynn et al. 1992). Considerable opportunity exists

for enhanced diffusion of programs that have demonstrated effectiveness (Parcel et al. 1989a,b, 1995; O'Hara et al. 1991; Brink et al. 1995; Parcel 1995; McCormick and Tompkins 1998; Siegel and Biener 2000). As an example of such diffusions, the CDC's Division of Adolescent and School Health initiated the Research to Classroom project. Through this project, CDC identified programs with credible evidence of effectiveness in reducing health risk behaviors among young people. So far, CDC has identified curricula for sexuality and tobacco use prevention. The CDC staff review electronic databases, literature reviews, meta-analyses, and reports to identify evaluation studies that meet the criteria for consideration in the Research to Classroom project. Two external panels, one of evaluation experts and the other of program experts, review the curricula and their evaluations. If both panels recommend adoption of the curriculum, based on attainment of identified criteria, CDC designates the curriculum as a Program that Works. The Research to Classroom project identified Project Towards No Tobacco Use and Life Skills Training as appropriate tobacco use prevention curricula. Research to Classroom also provides information and training on these curricula for interested educators from state and local education agencies, departments of health, and national nongovernmental organizations. The CDC identifies and disseminates information on Programs that Work to help inform local and state choices. The choice to adopt a curriculum ultimately rests with local decision makers and must address community standards and needs.

Conclusions

- 1. Educational strategies, conducted in conjunction with community- and media-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents.
- 2. Although most U.S. schools have tobacco use prevention policies and programs in place, current practice is not optimal.
- 3. More consistent implementation of effective educational strategies to prevent tobacco use will require continuing efforts to build strong, multiyear prevention units into school health education curricula and expanded efforts to make use of the influence of parents, the mass media, and other community resources.

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Introduction

Preventing tobacco addiction among young people and promoting abstinence among current smokers are the final common denominators for public health strategies to reduce smoking prevalence. Although prevention efforts are increasingly regarded as the most promising long-term approach for reducing tobacco use (Lynch and Bonnie 1994; U.S. Department of Health and Human Services [USDHHS] 1994), about 1.2 million youths become regular smokers each year in the United States—adding to the millions of adult smokers who are candidates for addiction management (Leventhal et al. 1991; Centers for Disease Control and Prevention [CDC] 1998; see "Trends in Tobacco Use Among Young People" in Chapter 3). Effective treatments do exist for smoking cessation, and they are available for both the clinical and the public health context (Fiore et al. 1996). These treatments compose an important modality in the effort to eradicate tobacco use. Many of the adverse health effects of tobacco use are reversible by cessation (USDHHS 1989)—a fact important to the millions of adults who already smoke, as well as to the large numbers of young people who continue to take up smoking.

Since the 1964 release of the first Surgeon General's report on the health consequences of smoking, the prevalence of cigarette smoking among adults in the United States has decreased by 41 percent, falling from 42.2 percent in 1965 to 24.7 percent in 1997 (Giovino et al. 1994; CDC 1999a). Although these data represent significant progress in the public health campaign against tobacco use, the steady decline of 0.5 percentage points per year observed from 1965 to 1985 has lessened in recent years. In 1997, approximately 48 million adult Americans smoked; the prevalence was higher among men (27.6 percent) than among women (22.1 percent) and among American Indians and Alaska Natives (34.1 percent) than among blacks (26.7 percent), whites (25.3 percent), Hispanics (20.4 percent), or Asian Americans and Pacific Islanders (16.9) percent) (Table 4.1). Smoking prevalence was also lower among college graduates (11.6 percent) than among high school dropouts (35.4 percent) and higher among those below the poverty level (33.3 percent) than above it (24.6 percent) (CDC 1999a). Since smoking prevalence did not decline at a more rapid rate than that observed in the past few years, the *Healthy* People 2000 goal of an adult smoking prevalence of 15 percent or less by the year 2000 (USDHHS 1991) was not met. Unless smoking prevalence declines at a more rapid rate than that observed in the past, we will not achieve the *Healthy People 2010* goal of an adult smoking prevalence of 12 percent or less by the year 2010 (USDHHS 2000).

Considered over the time frame of the last 30 years, however, smoking cessation has increased dramatically. Self-reported data from 1997 suggest that almost 50 percent (44 million) of people who have ever smoked have successfully quit smoking (Thomas and Larsen 1993). In 1991, the earliest year for which socioeconomic data are available, the prevalence of smoking cessation was greater among male, white, older, more educated, and wealthier persons (Table 4.2) (Giovino et al. 1994). An encouraging finding from the 1993 National Health Interview Survey was that most (70 percent) current adult smokers were interested in quitting. Such interest was higher among women, African Americans, and younger persons (Thomas and Larsen 1993).

Cessation represents a desired end result to what is usually a lengthy, demanding, and often frustrating undertaking. Data on cessation should be interpreted in light of the fact that for every successful attempt to quit using tobacco, many more attempts fail. Although millions of Americans say they want to quit smoking, studies suggest that only about 6 percent of persons who try to quit smoking at any given time are successful for more than one month (CDC 1993a). Research into tobacco cessation seeks tools that will translate the desire to quit into prolonged abstinence from tobacco. Such treatments hold a greater potential for immediate public health returns than do prevention methods, and cessation treatments may also be cost-effective (see "Cost-Effectiveness" later in this chapter).

In the course of this chapter, the terms "smoking cessation" and "management of tobacco addiction" are used interchangeably. Though the former is the more familiar, the latter better conveys a more rigorous and systematized approach to a complex addiction behavior. Value judgments on the impact of a particular modality should be interpreted within a qualitative system for judging costs and benefits. A small impact may be viewed favorably if achieved with minimal intervention. More intense intervention may have a larger impact, but may not be justified by the resources it requires.

Table 4.1. Percentage of adults aged ≥18 years who were current cigarette smokers,* by sex, race/ethnicity, education, age, and poverty status—United States, National Health Interview Survey, 1997

	Men (n = 15,361)		Women $(n = 20,455)$		Total (n = 35,816)	
Characteristic	%	(95% CI ⁺)	%	(95% CI)	%	(95% CI)
Race/Ethnicity [‡]						
White, non-Hispanic	27.4	(± 1.0)	23.3	(± 0.8)	25.3	(± 0.7)
Black, non-Hispanic	32.1	(± 2.4)	22.4	(± 1.7)	26.7	(± 1.4)
Hispanic	26.2	(± 2.1)	14.3	(± 1.4)	20.4	(± 1.4)
American Indian/Alaska Native§	37.9	(± 13.7)	31.3	(± 8.8)	34.1	(± 7.7)
Asian American/Pacific Islander	21.6	(± 4.4)	12.4	(± 3.5)	16.9	(± 2.7)
Education (years) [∆]						
≤8	29.9	(± 3.0)	15.1	(± 2.2)	22.5	(± 1.9)
9–11	41.3	(± 3.1)	30.5	(± 2.4)	35.4	(± 2.0)
12	31.8	(± 1.7)	25.7	(± 1.3)	28.4	(± 1.0)
13–15	27.4	(± 1.7)	23.1	(± 1.4)	25.1	(± 1.1)
≥16	13.0	(± 1.2)	10.1	(± 1.0)	11.6	(± 0.8)
Age (years)						
18–24	31.7	(± 2.8)	25.7	(± 2.4)	28.7	(± 1.9)
25–44	31.2	(± 1.3)	26.1	(± 1.1)	28.6	(± 0.8)
45–64	27.6	(± 1.5)	21.5	(± 1.3)	24.4	(± 1.0)
≥65	12.8	(± 1.4)	11.5	(± 1.1)	12.0	(± 0.9)
Poverty status¶						
At or above	27.3	(± 1.0)	21.8	(± 0.8)	24.6	(± 0.7)
Below	38.7	(± 2.8)	29.8	(± 1.9)	33.3	(± 1.7)
Unknown	23.4	(± 2.0)	18.2	(± 1.5)	20.5	(± 1.2)
Total	27.6	(± 0.9)	22.1	(± 0.7)	24.7	(± 0.6)

^{*}Persons who reported having smoked at least 100 cigarettes during their lifetime and who reported currently smoking every day or some days. Excludes 300 respondents with unknown smoking status.

Source: Centers for Disease Control and Prevention 1999a.

^{†95%} confidence interval.

[‡]Excludes 74 respondents of unknown, multiple, and other racial/ethnic categories.

[§]Wide variances on estimates reflect the small sample sizes.

 $[\]Delta$ Persons aged \geq 25 years. Excludes 305 respondents with unknown years of education.

Published 1996 poverty thresholds from the Bureau of the Census are used in these calculations.

Table 4.2. Percentage of adults* who abstained from smoking cigarettes in the previous year, by sex, race/ethnicity, age, education, and poverty status—United States, National Health Interview Survey, 1991[†]

Characteristic		Abstinence for ≥1 day		Maintenance among abstainers		Maintenance [‡] among all persons who were daily smokers 1 year earlier*	
	%	(95% CI§)	%	(95% CI)	%	(95% CI)	
Sex							
Male	42.6	(40.8-44.4)	13.8	(12.0-15.6)	5.8	(5.0-6.6)	
Female	41.5	(40.0–43.0)	13.7	(12.0-15.4)	5.6	(4.9-6.3)	
Race/Ethnicity							
White $^{\Delta}$	40.3	(39.0-41.6)	14.0	(12.6-15.4)	5.6	(5.0-6.2)	
Black∆	48.7	(45.2–52.2)	7.9	(5.1-10.7)	3.8	(2.4-5.2)	
Hispanic	52.1	(46.4–57.8)	16.3	(10.3-22.2)	8.5	(5.2-11.8)	
American Indian/	53.3	(39.7-67.0)		NA^{\P}		NA^{\P}	
Alaska Native		,					
Asian American/	45.0	(33.7-56.3)		NA^{\P}		NA^{\P}	
Pacific Islander							
Age (years)							
18–24	56.7	(52.9-60.5)	14.0	(9.9-18.1)	7.9	(5.6-10.3)	
25–44	43.4	(41.8-45.0)	12.7	(11.0-14.4)	5.4	(4.7-6.1)	
45–64	36.1	(33.9 - 38.3)	14.1	(11.4-16.8)	5.0	(4.0-6.0)	
≥65	35.7	(32.2–39.2)	19.4	(14.6-24.2)	6.8	(5.1-8.5)	
Education (years)							
<12	36.5	(34.1 - 38.9)	12.9	(10.2-15.6)	4.7	(3.7-5.7)	
12	42.5	(40.8–44.2)	12.8	(10.9–14.7)	5.3	(4.5-6.1)	
13–15	46.9	(44.2–49.6)	14.3	(11.4–17.2)	6.6	(5.2-8.0)	
≥16	45.9	(42.5–49.3)	18.8	(14.9–22.7)	8.5	(7.0-10.0)	
Poverty status**							
At or above	42.7	(41.4-44.0)	14.8	(13.4-16.3)	6.2	(5.6-6.8)	
Below	42.9	(39.5–46.3)	7.5	(4.7-10.3)	3.2	(2.0-4.4)	
Unknown	35.2	(31.2–39.2)	12.6	(8.3–16.9)	4.4	(2.9-6.0)	
Total	42.1	(40.9–43.3)	13.8	(12.5–15.1)	5.7	(5.2–6.3)	

^{*}Persons aged ≥18 years who reported having smoked at least 100 cigarettes in their lifetime and smoked cigarettes daily 1 year earlier and who provided information of their current smoking status.

Source: National Center for Health Statistics, public use data tape, 1991.

[†]Sample size = 9,703; race/ethnicity variable excludes 34 respondents of other, unknown, or multiple race; education variable excludes 24 respondents of unknown education level.

[‡]Abstinence from smoking cigarettes for at least 1 month at the time of the survey. Excludes 92 respondents who were abstinent from cigarettes for <1 month or for whom duration of abstinence was unknown.

[§]Confidence interval.

[∆]Excludes persons of Hispanic origin.

[¶]Sample sizes too small to derive reliable estimate.

^{**}Poverty statistics are based on definitions developed by the Social Security Administration, which includes a set of income thresholds that vary by family size and composition.

Methods for Managing Nicotine Addiction

Historically, the great majority of smokers (more than 90 percent) who successfully quit smoking did so "on their own"—that is, without the assistance of formal cessation programs (USDHHS 1989; Fiore et al. 1990). With the advent of new treatments, including pharmaceuticals, more smokers (20 percent) are using some form of assistance when trying to quit (Zhu et al. 2000). The success rate among this large group of unassisted quitters is half that observed for those who use some form of assistance. Although more than 1 million smokers quit each year, 75–80 percent relapse within six months (Carmody 1992). Those who quit may relapse at any time (even after a period of years), and a substantial portion of quitters go through cycles of quitting and relapse (Cohen et al. 1989a). Given this complex context in which the natural history of smoking occurs (an important leitmotif in the management of tobacco addiction), it is difficult to assign a single number to the proportion who quit on their own. Nonetheless, in the current environment of declining prevalence, the end result of this cyclic process, and of all the interventional efforts brought to bear on it, is that each year about 3–5 percent of smokers quit for a year, for longer, or for good.

The success of smoking cessation methods should be evaluated in terms of both process and outcome measures. Process measures are designed to assess those variables that are affected by treatments and that influence outcomes. Ideally, process measures should target the specific change mechanisms that treatments are intended to influence. For instance, if a treatment is intended to provide smokers with coping skills, process measures might assess a patient's ability to anticipate and generate appropriate responses to stresses. If a treatment is intended to promote cessation by reducing withdrawal symptoms, then a withdrawal symptom scale might be used as a process measure. Clinically significant outcome measures include attempts at quitting and abstinence success. Withdrawal symptom severity and concomitants of cessation attempts, such as weight gain, may be viewed as outcomes as well.

Some of the efficacy evaluations reported here incorporate the results of published meta-analyses. Meta-analysis is a statistical technique that assesses the impact of a variable (or, in this context, a treatment) across a set of related investigations (Dickersin and Berlin 1992). Meta-analyses may present a more

objective assessment of accumulated research findings than do traditional narrative reviews (e.g., Cooper and Rosenthal 1980) and can be useful for identifying study or treatment characteristics that are associated with differences in study outcomes (Dickersin and Berlin 1992). Meta-analyses of smoking cessation treatments have used different techniques for estimating the size of treatment effects. The precise methods used to calculate and pool these estimates vary (for detailed descriptions, see Fleiss 1981 and Cooper and Hedges 1994). In both meta-analyses and individual studies, the most frequently encountered measures are the odds ratio (an estimate of the relative risk for the outcome in control versus treatment groups) and some form of effect size (difference in effect between treatment and control groups).

Self-Help Manuals

Because of the size of the population who try quitting on their own, the broad dissemination of materials that can help them in their efforts—without requiring them to participate in a formal cessation program—may be a potent strategy at the national level for decreasing the prevalence of smoking (Glynn et al. 1990a; Curry 1993). A wide array of self-help strategies has been developed for smoking cessation (Curry 1993). This section discusses the efficacy of written manuals, the most extensively investigated self-help materials (Curry 1993). The discussion is limited to studies of such manuals distributed to relatively small populations of smokers. Self-help materials delivered to large populations are discussed later in the chapter in association with nonprint messages and programs (self-help or supervised) included in mass media and community-based efforts.

Efficacy

In a review of the research literature on self-help manuals, the median long-term prevalence of cessation associated with manual-based interventions was about 5 percent (Curry 1993). This proportion is lower than those of face-to-face cessation programs (Schwartz 1987; Lichtenstein and Glasgow 1992; Lando 1993). Furthermore, recent evidence suggests that self-help manuals, when used by themselves, may produce negligible

increases in long-term cessation (Gritz et al. 1992; Petersen et al. 1992; Gomel et al. 1993; Fiore et al. 2000).

Because self-help manuals can be distributed, at low cost, to very large numbers of smokers, even relatively small cessation success could translate into large numbers of successful quitters. Since 30-40 percent of smokers each year make a serious effort to quit, selfhelp aids could have a vast influence on public health (Hatziandreu et al. 1990; CDC 1993b, 1999b). The available evidence suggests that self-help manuals work better for smokers who are less dependent on nicotine, more motivated, and more confident of quitting (Curry 1993), but the relationship between motivation and success is complex. Less addicted smokers may be less likely to seek formal treatment (Fiore et al. 1990; Zhu et al. 2000) and are therefore an apt audience for self-help manuals. More addicted smokers are more likely to seek formal self-help programs (Wagner et al. 1990) but may be less successful in quitting (Schoenbach et al. 1992). Thus, in view of both their uncertain effectiveness and their potential to be cost-effective, it is important to determine whether self-help manuals have a consistent, albeit small, benefit.

Although many self-help manuals have been developed, there is little evidence that they differ in their effectiveness (Cummings et al. 1988; Glynn et al. 1990a; Curry 1993). Accordingly, an Expert Advisory Panel convened by the National Cancer Institute (NCI) has recommended that public health professionals try to increase the availability of existing manuals rather than refine them or develop new ones (Glynn et al. 1990a). The committee also concluded that if new materials are deemed necessary, they should, at a minimum, contain the following components: (1) information about the social and health effects of smoking; (2) specific strategies and exercises for quitting; and (3) specific strategies and exercises to avoid relapse and, in the event of relapse, to try quitting again (Glynn et al. 1990a).

Manuals tailored to special populations of smokers, such as pregnant women, older adults, African Americans, and Hispanics, have been developed and tested (Windsor et al. 1985; Glynn et al. 1990b; Davis et al. 1992; USDHHS 1998). Although manuals targeted to specific populations have not had consistently greater success than generic manuals at helping members of relevant populations quit (Curry 1993; Rimer et al. 1994), such manuals have the potential to reach smokers missed by traditional materials (Curry 1993).

It appears that combining multiple types of self-help materials (manuals, videotapes, etc.) does not improve long-term cessation rates. A meta-analysis of 21 studies using multiple types of self-help without person-to-person contact found no significant difference

between multiple types of self-help and no self-help at all (Fiore et al. 2000).

Reading level has been increasingly recognized as an important attribute of self-help manuals. Since the early 1970s, trends in smoking prevalence have been different for those with differing levels of educational attainment (Pierce et al. 1989). Smoking prevalence has dropped sharply among persons with a college education (10.1 percentage points between 1974 and 1985) but has declined only marginally among high school dropouts (2.1 percentage points during the same period). Concerns about literacy have led to the recommendation that self-help materials for smoking cessation be written at no more than a seventh-grade reading level (Glynn et al. 1990a), although this level may be too high in some situations.

Adjuncts to self-help manuals, such as telephone counseling (Orleans et al. 1991; Curry et al. 1992; Lando et al. 1992), hot lines (Ossip-Klein et al. 1991), and personalized feedback (Curry et al. 1991; Prochaska et al. 1993), have also been evaluated. These adjunctive interventions have met with varying success (Curry 1993). For example, self-help treatments that include nicotine gum as well as smoking cessation manuals have not had greater long-term efficacy than the manuals alone (Harackiewicz et al. 1988; Killen et al. 1990b). Computer-generated personalized feedback (Curry et al. 1991) and telephone outreach, however, have improved cessation success (Orleans et al. 1991; Lando et al. 1992; Prochaska et al. 1993; Strecher et al. 1994). At present, research suggests that such adjuvants materially improve the effectiveness of self-help manuals.

Adjunctive interventions that require financial and personnel resources, however, may undercut the potential population impact of self-help interventions. The addition of other components to self-help manuals may also mark the point at which the self-help modality merges with more formal assistance, which, as mentioned earlier, have not appealed to as large a population of smokers motivated to quit. But at least one such treatment, proactive telephone counseling (as opposed to reactive approaches, such as help lines smokers must call), appears to be effective when used as an adjuvant (Fisher et al. 1993).

Relevant Process Measures

Most studies of self-help manuals lack process measures, and the specific measures used across studies vary considerably (Curry 1993). Two distinct process measures, manual reading and manual use, have been assessed in some studies of self-help manuals for smoking cessation. Reading measures simply ask smokers whether they read most or all of the manual. Use measures assess the extent to which smokers performed the specific exercises recommended in the manual. In theory, persons who actually read a manual or practice manual-recommended exercises should be more successful than those who merely possess a manual. Curry (1993) concluded that although reading has sometimes been related to program success, use has been more consistently related to improved outcomes. Further work is needed to determine with some certainty whether the information conveyed by the manuals, rather than nonspecific motivational effects, is responsible for their efficacy.

Summary

Although self-help manuals have had only modest and inconsistent success at helping smokers quit, manuals can be easily distributed to the vast population of smokers who try to quit on their own each year. Adjuvant behavioral interventions, particularly proactive telephone counseling, may increase the effect of self-help materials. Process measures are not routinely incorporated into self-help investigations, but the available process data suggest that persons who not only have a self-help manual but also perform the exercises recommended in the manual are more likely to quit smoking.

Minimal Clinical Interventions

Minimal clinical interventions are those that can be delivered briefly to smokers by health care professionals during the course of a regular health care encounter. These strategies may be as simple as advising smokers to quit, or they may be as complex as using computers to tailor the intervention to the individual smokers. Minimal clinical interventions could have a great influence at a national level on smoking cessation, but they have been underused. Findings from a 1985 (Ockene et al. 1987), a 1991 (CDC 1993b), and a 1992 national survey (Tomar et al. 1996) suggest that nearly 70 percent of American smokers (nearly 36 million) make at least one outpatient health care visit each year; however, only 40-52 percent of the smokers in the surveys reported that during the preceding year they had been advised by a health care professional to quit smoking. In a separate study, 48.8 percent of 2,710 current smokers had been advised by their physician to stop smoking or to smoke less (Frank et al. 1991). More than 50 percent of adult smokers in the United States saw a dentist in 1992, but fewer than 25 percent of those who saw a dentist in the preceding year reported that the dentist had advised them to quit smoking (Tomar et al. 1996). Among adult users of smokeless tobacco, 18 percent reported that they had ever been advised by a dentist and 15 percent had ever been advised by a physician to quit (Tomar et al. 1996).

Many clinicians may believe that they are not equipped to help smokers quit (Wells et al. 1984; Glynn 1988) or that a physician can help a smoker quit (Ockene et al. 1988a). Training programs for clinicians have been developed to address this problem (Ockene et al. 1988b; Cummings et al. 1989a,b; Duncan et al. 1991; Manley et al. 1991; Strecher et al. 1991); however, data suggest that simply training clinicians may not be effective (Dietrich et al. 1992; Carney et al. 1995; Klein et al. 1995). However, implementing reminder systems in the clinic has been shown to triple clinician intervention with smokers (Fiore et al. 1996, 2000). Some evidence suggests that the delivery of these minimal clinical interventions is becoming more common (Gilpin et al. 1992).

Surveys suggest that smokers who are white, female, older, better educated, or ill, or who smoke more cigarettes per day are more likely than others to receive clinical advice to quit (Ockene et al. 1987; Frank et al. 1991; Gilpin et al. 1992; CDC 1993b). At present, clinicians apparently do not ensure that all of their patients who smoke receive cessation advice and assistance, in part because of structural and policy issues (such as reimbursement) related to medical care delivery. Nonetheless, such efforts might be more common if clinicians were trained to view smoking as a chronic disease, marked by periods of remission and relapse, rather than as an acute disorder (Fiore and Baker 1995).

Researchers have shown that institutional changes can increase the systematic delivery of minimal clinical interventions for smoking cessation. For example, brief physician training, availability of nicotine gum, and patient chart stickers documenting smoking status can increase the amount of time physicians spend in cessation counseling and increase successful cessation by a factor of 2 to 6 (Cohen et al. 1989b; Ockene et al. 1991). One proposed change is to expand patient vital signs to include an assessment of tobacco use (Fiore 1991). This simple institutional change has been shown to increase markedly the proportion of patients who report that their health care providers asked and counseled them about smoking cessation (Fiore et al. 1995; Robinson et al. 1995).

Finally, institutional changes are critical for prompting more clinicians to play a role in smoking cessation. Currently, clinicians are only sporadically reimbursed for clinical and pharmacologic treatments to help patients quit smoking (Group Health Association of America, Inc. 1993; Schauffler and Parkinson 1993). Appropriate reimbursement may be essential to ensuring greater clinical attention to tobacco addiction (Schauffler and Parkinson 1993; Fiore and Baker 1995; Kaplan et al. 1995).

The Public Health Service-sponsored Clinical Practice Guideline *Treating Tobacco Use and Dependence* has recommended that health care professionals use the "five A's" to help their patients quit smoking: (1) *ask* about smoking, (2) *advise* all smokers to quit, (3) *address* willingness to make a quit attempt,

(4) assist patients who want to quit, and (5) arrange follow-up visits (Manley et al. 1991; Glynn and Manley 1993; Orleans et al. 1993; Houston et al. 1994; Fiore et al. 2000). These recommendations, based on a comprehensive review of the empirical literature, constitute a proscriptive algorithm for clinical interventions (see the text box).

Additional follow-up visits, at increasing intervals, with patients who continue not to smoke have been associated with greater long-term abstinence (Kottke et al. 1988; Wilson et al. 1988; Orleans et al. 1991). Patients who have relapsed should be helped to quit again at follow-up visits and subsequent visits.

The Five A's

To help their patients quit smoking, clinicians can use the "five A's" approach: (1) ask patients about smoking, (2) advise all smokers to quit, (3) assess willingness to make a quit attempt, (4) assist those who want to quit, and (5) arrange follow-up visits with those trying to quit (Glynn and Manley 1993). These brief clinician interventions, which are described in this text box, can be completed within two to three minutes at each visit and have been associated with a cessation prevalence of 5 percent (Glynn 1988) to 8 percent (Kottke et al. 1988).

All patients seen in a primary care setting should be routinely *asked* about their smoking status. One means of institutionalizing the identification of smokers is to expand the vital signs to include smoking status (Fiore 1991). Another means is to use stickers or other markers to clearly identify charts and prompt clinicians to help their patients who smoke quit (Cohen et al. 1989b; Ockene et al. 1991).

All patients who smoke should be *advised* to quit. This advice should be clearly stated and personalized. After giving this advice, clinicians should *assess* whether smokers desire to quit at the present time. Clinicians should provide motivational materials and messages to those not willing to quit. These patients should be asked about smoking and advised to quit at all subsequent visits.

Clinicians should *assist* patients who want to quit. The clinician should work together with the patient to set a date to quit (preferably within two weeks of the clinic visit) and should provide the

patient with practical advice about how to quit and self-help materials.

Clinicians should determine whether the patient is likely to require adjunctive help and whether the patient is a candidate for pharmacotherapy. Pharmacotherapy should be considered for all patients motivated to make a quit attempt, except in the presence of specific contraindications (Fiore et al. 2000). The choice may take into account previous patient experience, preferences, and other factors (see "Pharmacologic Interventions," later in this chapter). Clinicians should also present other treatment options to their patients who want to quit. In particular, patients should be made aware of community cessation resources (such as those offered by the American Cancer Society and the American Lung Association) and of intensive clinical interventions (see "Intensive Clinical Interventions," later in this chapter) available in the community. The primary care clinician, however, should continue to monitor and assist those patients who elect to undergo intensive treatments.

Clinicians should *arrange* for a follow-up visit to discuss smoking cessation within two weeks of the chosen date to quit. Researchers have documented that scheduling follow-up visits or making follow-up telephone calls improves cessation success (Kottke et al. 1988; Wilson et al. 1988; Ockene et al. 1991, 1992; Orleans et al. 1991). Follow-up visits should be arranged whether the patient has been referred to another clinic or treated by the primary care clinician.

Modifications in treatment, including a discussion of more intensive efforts, should be considered for relapsing patients at each iteration.

An area of current active research in minimal interventions is the use of computer-tailored messages for individual smokers who want to quit. Computer software that approximates deductive or inductive human reasoning has been proposed as an efficient and cost-effective mechanism for this modality (Velicer et al. 1993). In a large trial of one such system, interactive computer reports plus individualized manuals produced higher current abstinence (20 percent) and prolonged abstinence (11 percent) than did standard manuals, individualized manuals alone, or personalized counselor calls (Prochaska et al. 1993). Similarly, analyses of two separate controlled trials found that computer-tailored letters generated significantly greater cessation proportions in groups receiving them than in control groups (Strecher et al. 1994). Although these mechanisms have not been extensively evaluated, they are a promising avenue for further investigation.

Efficacy

Kottke and colleagues (1988) performed a metaanalysis of 39 smoking cessation trials conducted in medical practice settings. Most of these trials involved relatively minimal interventions, but some more intensive treatments were included. Participants had a mean of 4.8 (standard deviation = ± 4.4) contacts with these clinic-based programs. The major conclusion of this analysis was that success increased with the number of intervention modalities employed, the number of health care professionals involved in the effort, and the number of follow-up assessments. Duration of follow-up (as opposed to number of follow-ups) was not predictive of success. Using diverse techniques may be a key characteristic of successful clinic-based smoking cessation programs (Fiore et al. 2000). A successful program might be one in which face-to-face counseling or advice is given; dates for quitting are set; pamphlets are distributed; reminders by telephone are made; smokers are advised and counseled on quitting by physicians, nurses, and other health professionals; and multiple clinic visits or telephone calls are made after the smoker's quitting day. In the metaanalysis by Kottke and colleagues (1988), cessation assistance delivered by nonphysicians tended to be slightly more effective than that performed by physicians, but a more recent meta-analysis (Fiore et al. 2000) found no difference in effectiveness between physicians and nonphysicians. Both individual and group counseling was effective (Fiore et al. 2000).

The meta-analysis by Kottke and colleagues (1988) also suggested, however, that complex interventions are not necessary for clinic-based success. Compared with smokers who received no assistance, smokers who received help consisting of advice only or brief counseling had a 13.1-percentage point increase in cessation 6 months after treatment and a 3.8-percentage point increase after 12 months. Comparable estimates for smokers whose only treatment was to receive written self-help materials from health care professionals were 1.6 percent at 6 months and 2.0 percent at 12 months. The impact of brief intervention is illustrated in one study by Russell and colleagues (1979), who found that providing advice in a primary care setting produced a biochemically confirmed increase in abstinence of 3.3 percentage points; when smokers were told they would be followed up and when self-help materials were distributed in conjunction with the advice, the resulting one-year increase in abstinence was 5.1 percentage points.

Trials postdating the meta-analysis of Kottke and colleagues (1988) have also indicated that brief clinical interventions have a small but reliable impact on smoking cessation success (Cummings et al. 1989a; Risser and Belcher 1990; Taylor et al. 1990; Ockene et al. 1991, 1994; Weissfeld and Holloway 1991; Hollis et al. 1993; Strecher et al. 1994). A meta-analysis of seven studies found that physician advice to quit increases cessation by 30 percent (Fiore et al. 2000). The consistency of these findings over a considerable time span and in multiple settings lends credence to the usefulness of minimal interventions.

Smokeless tobacco use may be particularly amenable to minimal clinical interventions, especially in dental office settings. Oral lesions caused by smokeless tobacco are quite common among users of these products (Ernster et al. 1990; Tomar et al. 1997) and provide the opportunity for the dentist to point out the direct adverse health effects of smokeless tobacco. Several trials have examined the efficacy of minimal clinical interventions in smokeless tobacco cessation.

In a randomized trial conducted in a dental health maintenance office clinic to test a minimal clinical intervention, Stevens and colleagues (1995) reported significantly higher smokeless tobacco quit rates in the intervention group than in the usual-care group at both 3 months (32.2 vs. 21.3 percent) and 12 months (33.5 vs. 24.5 percent). In a randomized clinical trial conducted in private dental offices, Severson and colleagues (1998) also found that a minimal intervention significantly increased smokeless tobacco quit rates in the intervention group compared with rates in the usual-care group at 3 months (17.8 vs. 8.8

percent) and 12 months (10.2 vs. 3.3 percent). A minimal intervention trial for smokeless tobacco use among college athletes, which included dental examinations to demonstrate oral lesions, 15–20 minutes of counseling by dental hygienists, and follow-up telephone calls, found that three-month biochemically assayed quit rates were 24 percent in the intervention group and 16 percent in the control group (Masouredis et al. 1997).

Relevant Process Measures

Although minimal clinical interventions provide smokers with some practical advice about quitting, their primary purpose is to increase smokers' motivation to quit. Specific process measures—such as measures of this motivation—are seldom incorporated into minimal clinical interventions. The nonspecific measures some investigators use do not associate clinical success with changes (such as greater awareness of disease risk or enhanced belief in one's ability to quit). Nonetheless, the available evidence suggests that minimal clinical interventions can enhance smokers' desire and intention to quit (Russell et al. 1979), decrease the number of cigarettes smoked per day (Folsom and Grimm 1987), and increase the number of attempts to quit smoking (Folsom and Grimm 1987; Cummings et al. 1989b; Strecher et al. 1991). In addition, patients have reported that physicians trained to perform more intensive interventions are more helpful than physicians without such training (Ockene et al. 1991).

Summary

Substantial evidence suggests that minimal clinical interventions (e.g., a health care provider's repeated advice to quit) foster smoking cessation and that the more multifactorial or intensive interventions produce the best outcomes. These findings highlight the importance of cessation assistance by clinicians, who have a unique access to more than 70 percent of smokers each year. Moreover, minimal clinical interventions have been found to be effective in increasing smokers' motivation to quit and are cost-effective (see "Cost-Effectiveness," later in this chapter). However, research has not clarified fully the specific elements of minimal interventions that are most important to clinical success nor the specific types of changes they produce in smokers that lead to abstinence.

Intensive Clinical Interventions

Intensive clinical interventions (sometimes called "formal" or "organized" cessation treatments) are multisession counseling programs involving extensive contact between a health care provider and a smoker. The value of intensive interventions has been questioned because they are more expensive and reach fewer smokers than self-help and minimal clinical interventions do (Chapman 1985). However, more intensive interventions continue to attract interest because they are more successful at helping people quit smoking (Schwartz 1987). Despite their comparatively high cost, they are cost-effective (Elixhauser 1990), and they may be especially well-suited for treating the most addicted smokers (Lichtenstein and Glasgow 1992; Orleans 1993).

Intensive clinical interventions may be characterized by structure and content. Structural variables include providers' credentials and training; individual, telephone, or group format; session length; total number of sessions; and duration of follow-up. Relatively little research into intensive treatments has been designed to assess the effects of different structural variables (Lichtenstein and Glasgow 1992). Increased patient contact results in better outcomes (Lando 1981; Decker and Evans 1989; Lichtenstein and Glasgow 1992; Fiore et al. 2000). In a meta-analysis of research on the nicotine patch (Fiore et al. 1994c), researchers found that the following counseling features were associated with significant increases in six-month abstinence rates: counseling being a main reason for clinician-patient contact, at least weekly clinicianpatient meetings during the first 4 weeks of treatment, and more than six clinician-patient meetings in the first 12 weeks of treatment. A more recent meta-analysis that was not restricted to nicotine patch studies (Fiore et al. 2000) found that quitting success increased with increasing contact time (up to 90 minutes of total contact) and that there was a dose-response relationship between number of sessions and treatment efficacy (Fiore et al. 2000). Thirty to 90 minutes of total counseling and four or more sessions were two to three times more effective in producing long-term smoking cessation than no contact controls. This research supports the notion that in general, as the intensity of clinician-patient counseling increases, so does the longterm effectiveness of treatment.

Because so little information is available on how structural variables affect intensive treatment outcomes, this section concentrates on a review of content variables. Content refers to the specific information, materials, and techniques to which smokers are exposed during the course of treatment. The various contents of intensive smoking cessation interventions are not easy to evaluate, partly because the methodological quality of clinical trials tends to differ across content areas. For example, trials of relatively unorthodox treatments, such as acupuncture and hypnosis, tend to use shorter follow-up periods than assessments of efforts involving pharmacologic and behavioral treatments (Schwartz 1987; Ter Riet et al. 1990); inflated efficacy estimates may thus result for unorthodox treatments. These methodological concerns are handled here by limiting the review primarily to studies reporting outcomes with at least five months of follow-up.

Another problem in evaluating the content of intensive interventions is that the evolution of treatments over the past 40 years prevents a cumulative assessment of specific intensive interventions. Moreover, changing research interests and methodologies make it difficult to integrate findings from over the entire period. For instance, pharmacotherapies have changed greatly during this period and are now incorporated routinely into intensive treatments. In addition, treatment response may be affected by changes in the nature of the smoking population; for instance, compared with 40 years ago, a higher proportion of today's smokers are women. Methodological and statistical changes have also altered the nature of the studies themselves: sample sizes are larger to increase statistical power, and biochemical confirmation of abstinence is now routine, as is the application of the "intent to treat" principle in analyses. Because of these refinements, early cessation research is now often neglected, perhaps because it is difficult to integrate with newer work. On the other hand, some apparently effective methods, such as rapid smoking, have often not been evaluated by newer methods. The older literature on such strategies is included selectively in this review.

A related problem, complicating the interpretation of relatively recent research, arises from what Lichtenstein and Glasgow (1992) have referred to as a shift from a "clinical" to a "public health" (p. 518) orientation among smoking cessation researchers. This shift has resulted in a dearth of theory-driven research into intensive interventions. In fact, one observer has suggested that the long-term research trajectory favors modifying established models over applying innovation in the basic approach to treatment (Shiffman 1993b). Recent emphasis on public health has also produced a research climate that favors the evaluation of treatment packages and minimal interventions over treatment components (Lichtenstein and Glasgow 1992). One reason for this shift is the high cost and

large sample sizes required to evaluate individual components. Thus clinical trials rarely allow assessment of a given treatment's independent contribution. Smoking cessation trials now tend to combine specific treatment components into multicomponent interventions. Moreover, within the same study, not only may groups receive different treatment packages but the packages may differ in their structural components.

Finally, the question of selection bias remains a challenge to interpreting the literature on intensive interventions. Investigators typically recruit highly motivated volunteers to serve as subjects, because the efficacy of intensive interventions can be tested only if the patients under study actually receive the entire treatment. Efficacy estimates derived from this atypical population may not be appropriate for making predictions about the larger population of smokers. The principal types of intensive interventions must be evaluated in the context of these limitations stemming from the nature of the available evidence.

Problem Solving/Skills Training

Various strategies try to impart to smokers the knowledge and skills necessary to cope with cessation that is, both to attain and to maintain abstinence when confronted with withdrawal symptoms or the temptation to smoke (Marlatt and Gordon 1985; Curry and McBride 1994). This approach (hereafter referred to as problem solving/skills training) springs from the observation that most relapse efforts seem to be associated with a finite number of factors, such as alcohol use, negative affect (e.g., depression), and the presence of others smoking (Shiffman 1982; Baer and Lichtenstein 1988; Brandon et al. 1990). Problem solving/skills training tries to help people who have recently quit smoking anticipate these "high-risk" situations and learn to cope with them when they arise. Such interventions also train participants to cope with withdrawal symptoms, replace positive reinforcements they had linked to smoking, and meet other challenges that might be encountered during or after an attempt to quit smoking.

General problem solving/skills training targets challenges that occur early in the quitting process (e.g., withdrawal discomfort). Because newly abstinent smokers often return to regular smoking (Curry and McBride 1994), one specialized type of intervention teaches skills to help the former smoker maintain abstinence (Marlatt and Gordon 1985). These interventions also train former smokers to prevent any relapse from becoming a long-term return to smoking. Former smokers are encouraged to view relapses as a normal

part of the quitting process rather than as an indication of failure (Curry et al. 1988).

Another type of problem solving/skills training focuses on coping with the immediate negative affects of quitting smoking. The growing body of research on dysphoria (feeling unhappy or unwell) after smoking cessation (Glassman et al. 1988; Covey et al. 1990; Brandon 1994; Hall et al. 1994) suggests that strategies that help smokers who have just quit resist negative moods may be particularly successful (Shiffman 1993b). However, a recent meta-analysis (Fiore et al. 2000) did not find that interventions that targeted negative affect improved cessation rates. These interventions were used with the general population as well as smokers with a history of depression. It is possible that the results might be more positive if the studies were restricted to high-risk populations.

Efficacy

Because nearly every state-of-the-art smoking cessation program contains elements of problem solving/skills training (Curry and McBride 1994), the technique is difficult to assess as an individual treatment. Some investigators have failed to uncover evidence that this technique increases cessation success relative to comparison groups (Curry et al. 1988; Emmons et al. 1988; Omenn et al. 1988; Minneker-Hügel et al. 1992; Zelman et al. 1992). Other studies have found beneficial effects, but these benefits have often been modest and have come only through protracted treatment (Hall et al. 1984b; Davis and Glaros 1986; Goldstein et al. 1989; Stevens and Hollis 1989). Even in studies that report success in long-term abstinence through skills training, the overall relapse curves for treatment subjects have paralleled those for comparison groups (Glasgow and Lichtenstein 1987; Goldstein et al. 1989; Stevens and Hollis 1989; Mermelstein et al. 1992; Minneker-Hügel et al. 1992; Gruder et al. 1993). A recent metaanalysis (Fiore et al. 2000) of 104 studies, however, reported that problem solving/skills training increased quitting success by 50 percent. Some evidence suggests that problem solving/skills training may be particularly useful for female smokers (Curry et al. 1988), those who smoke fewer cigarettes (Hall et al. 1984b), those who smoke to cope with emotional stress (O'Connor and Stravynski 1982), and those who are less prone to negative affect (Zelman et al. 1992).

Although multicomponent skills-training programs have sometimes included information about managing the dysphoria associated with smoking cessation (Tiffany et al. 1986; Kristeller et al. 1993), relevant behavioral interventions have only recently

begun (Hall et al. 1994). Initial results suggest that such strategies are promising, but these findings require replication and extension.

In sum, the evidence on problem solving/skills training suggests a beneficial impact (Fiore et al. 2000). Such training can offer practical strategies about quitting and inculcate desired coping skills.

Relevant Process Measures

Skills training rests heavily on two assumptions: (1) coping skills will help former smokers remain abstinent in the face of temptation, and (2) smokers can be taught these skills. Some cross-sectional research (Shiffman 1984) and skills-training intervention trials (Hall et al. 1984b; Davis and Glaros 1986; Zelman et al. 1992) have suggested that coping strategies help avert relapse. The available evidence also indicates that patients given skills training acquire coping skills (Hall et al. 1984b; Davis and Glaros 1986; Zelman et al. 1992), and there is evidence that the level of skill acquisition predicts long-term abstinence (Zelman et al. 1992). Although the results of one trial suggest that coping skills are not retained for very long (Davis and Glaros 1986), consistent self-monitoring of smoking during treatment is associated with longer-term maintenance (Kamarck and Lichtenstein 1988); this finding suggests the importance of behavioral characteristics that foster maintenance.

One of the goals of skills training is to encourage relapsed former smokers to renew their efforts to quit smoking. Curry and colleagues (1988) found evidence that smokers who had received skills training were more likely to try quitting again if they relapsed.

Rapid Smoking

Rapid-smoking strategies typically require that smokers inhale deeply from a cigarette about every six seconds until they become nauseated. In theory, this aversive conditioning transforms the subject's perception of smoking from a pleasurable activity into an unpleasant one, thereby making it easier for smokers to give up cigarettes.

Medical complications produced by rapid smoking can include elevations in heart rate, blood pressure, and carboxyhemoglobin blood levels as well as electrocardiogram abnormalities (Horan et al. 1977). Because of these potential problems, candidates for rapid smoking should be selected carefully (Lichtenstein and Glasgow 1977). Older persons and persons with cardiovascular or pulmonary conditions are generally excluded from rapid-smoking strategies,

but some evidence suggests that rapid smoking can be conducted with these persons if appropriate precautions are taken (Hall et al. 1984a).

Efficacy

The 1988 Surgeon General's report on smoking and health (USDHHS 1988) reviewed the literature on rapid smoking and reached two conclusions: (1) although its effectiveness is variable when used alone, rapid smoking yields moderately high long-term abstinence success (40 percent of subjects were abstinent 6–12 months after treatment) when incorporated in multicomponent behavioral interventions, and (2) auxiliary treatment factors, such as patient expectations, patient-therapist rapport, and admonitions not to smoke between sessions, can influence how successful rapid-smoking strategies are. Few rapid-smoking trials have appeared since the 1988 report.

The mid-1980s advent of pharmacologic treatments for smoking cessation greatly reduced research interest in rapid smoking. Pharmacologic aids, such as nicotine gum, appear as efficacious as rapid smoking (Zelman et al. 1992) and are probably more acceptable to smokers and program administrators. Nonetheless, the doubling of long-term success associated with rapid smoking (Fiore et al. 2000) suggests that it may remain an option for smokers who are unable to quit through other methods and for whom such aversive conditioning is acceptable.

Relevant Process Measures

Rapid smoking is intended to produce aversive conditioned responses to stimuli associated with smoking (USDHHS 1988). The technique reliably produces tachycardiac responses to cigarettes, and the magnitude of these responses is directly related to treatment outcome (Tiffany et al. 1986; Zelman et al. 1992). More easily observable variables, such as the number of cigarettes smoked during a rapid-smoking session or the degree of nausea reported by patients, have not been shown to be consistently related to outcome (USDHHS 1988).

Other Aversive-Smoking Strategies

Three other techniques intended to produce aversion to cigarettes have been investigated: satiation therapy, rapid puffing, and focused smoking. Concern over the safety of rapid smoking (Horan et al. 1977) was partly responsible for investigation of these alternative aversion techniques. Some evidence suggests that they are less unpleasant and less risky than rapid smoking (Glasgow et al. 1981; Tiffany et al. 1986).

Satiation therapy requires that patients smoke many more cigarettes per day than they normally do, usually about twice as many (Best et al. 1978). Rapid puffing is similar to rapid smoking, but patients are instructed not to inhale cigarette smoke (Tiffany et al. 1986). Focused smoking requires patients to smoke for an extended period of time at a normal rate while concentrating on the negative sensations smoking produces (Lowe et al. 1980).

Efficacy

Satiation therapy alone produces relatively little cessation success (15 percent at one year) (Lando 1982), but the technique may be more effective when incorporated into multicomponent programs (USDHHS 1988). Focused smoking and rapid puffing produce long-term abstinence rates that are equivalent to, or slightly lower than, those produced by rapid smoking (USDHHS 1988; Fiore et al. 2000). Because these techniques do not appear to result in significant tachycardiac responses (USDHHS 1988), their efficacy is probably accounted for by mechanisms other than aversive conditioning.

Cue Exposure

Cue exposure therapy is based on the premise that smokers become conditioned to certain cues or contextual signals correlated with smoking behavior. When persons who have recently quit smoking are exposed to these cues, they are motivated to begin smoking again (Rohsenow et al. 1990–91; Brandon et al. 1995). In cue exposure therapy, persons trying to quit smoking are repeatedly exposed to these signals in a therapeutic context in which smoking is prohibited; the resulting reduced association between smoking and previous cues is hypothesized to reduce some of the temptation for relapse that former smokers will face in the natural environment.

Because cue exposure therapy has produced promising results with other addictive disorders (Monti et al. 1993), several researchers have suggested that such strategies be developed for smoking cessation (Hodgson 1989; Heather and Bradley 1990). These strategies may be particularly important for women, whose responsiveness to nicotine replacement therapy appears to be less than that of men (Perkins 1996). Women may be less controlled by nicotine and more influenced by nonnicotine factors (sensory stimuli, environmental factors) (Perkins et al. 1999) and may therefore respond better than men to behavioral approaches.

Efficacy

Studies conducted to date that have evaluated cue exposure have failed to find significant differences in outcome between cue exposure and comparison interventions (Lowe et al. 1980; Raw and Russell 1980; Götestam and Melin 1983; Corty and McFall 1984). However, clinical research on cue exposure for smoking cessation is sparse, and interpretation of most existing trials is hampered by methodological flaws (Brandon et al. 1995).

Relevant Process Measures

Environmental associations with cigarette smoking can be strong enough to provoke the desire to smoke (Herman 1974; Rickard-Figueroa and Zeichner 1985; Tiffany and Hakenewerth 1991). These provoked responses may affect treatment outcome (Niaura et al. 1989). However, because cue reactivity has not been assessed in existing clinical trials of cue exposure therapy, it is impossible to determine whether such interventions extinguish motivational responses to smoking-related cues.

Nicotine Fading

Nicotine fading is based on the assumption that withdrawal symptoms will be lessened through a gradual reduction of nicotine intake (Foxx and Brown 1979; McGovern and Lando 1991). Nicotine fading can be accomplished either by progressively switching to brands of cigarettes yielding less nicotine or by using a series of graduated filters (McGovern and Lando 1991). Once the lowest nicotine level is reached, cessation is attempted. Nicotine fading should be distinguished from cigarette fading, in which the number of cigarettes smoked per day is gradually reduced. Cigarette fading has generally not been shown to be an effective smoking cessation technique; participants generally reach a level beyond which they find it difficult to reduce cigarette consumption (Lando 1993; Fiore et al. 2000).

Efficacy

Foxx and Brown (1979) reported that 4 of 10 subjects who tried nicotine fading had quit smoking at 18 months, but subsequent investigations have found more modest long-term results (usually around 20 percent) (Beaver et al. 1981; Lando and McGovern 1985; Burling et al. 1989). Some evidence suggests that nicotine fading can increase abstinence success independently within a larger smoking cessation program

(Burling et al. 1989). In a community setting where participants were allowed to select their treatment, about 25–30 percent of those who chose multicomponent interventions containing nicotine fading achieved long-term abstinence (Lando et al. 1990; Lando 1993). Brand switching and graduated filters have produced equivalent outcomes (McGovern and Lando 1991). Cinciripini and colleagues (1995) found that 44 percent of persons using a combined nicotine fading and skills-training package were abstinent from nicotine at one year, a proportion significantly higher than that produced by matched conditions.

Relevant Process Measures

Nicotine fading is presumed to exert its effects by gradually weaning smokers from nicotine, thereby reducing withdrawal symptoms. Reductions in nicotine intake and withdrawal indexes are thus the process measures of primary importance to nicotine fading. One early study suggests that nicotine fading reduces the severity of withdrawal symptoms (West et al. 1984a,b).

The process measure of reduced nicotine intake is problematic, because smokers' nicotine consumption seldom matches a given brand's machine-rated nicotine yields (McMorrow and Foxx 1983). Smokers are able to compensate for reduced nicotine yield by adjusting how they smoke—by inhaling more strongly, holding smoke in longer before exhaling, inhaling more frequently, or smoking the cigarette closer to its high-yield butt (Benowitz et al. 1983; Kozlowski et al. 1988). Smokers can also compensate for nicotine fading by blocking the air inlet holes on the filters that are used to decrease nicotine intake (McGovern and Lando 1991). The best available evidence indicates that although nicotine consumption is indeed reduced by nicotine fading, the extent of these reductions is smaller than would be expected (i.e., based on machine ratings); apparently, some compensatory smoking occurs (Lando 1993). For example, one study (McGovern and Lando 1991) compared two nicotine fading regimens, brand switching and graduated filter use, each of which was designed to reduce nicotine intake by 80 percent by the final stage. Each regimen significantly reduced nicotine consumption but by far less than 80 percent: brand switching reduced intake by 42.5 percent and graduated filters by 55.2 percent.

Lando and McGovern (1985) suggested that nicotine fading increases smokers' self-efficacy by providing them with a series of concrete steps that are mastered before cessation. Self-efficacy does increase during the fading process (McGovern and Lando 1991),

although no more than with comparison treatments (Burling et al. 1989). Moreover, increased self-efficacy has not been shown to predict treatment outcome for nicotine fading (McGovern and Lando 1991).

Motivational Rewards

Strategies that use motivational rewards are rooted in operant conditioning theory. These efforts are designed to provide reasons for remaining abstinent to smokers who have just quit—reasons more tangible and immediate than the important but delayed outcomes that typically motivate cessation attempts (e.g., improvements in health). In a typical motivational rewards intervention, the provider collects a deposit from each participant at the outset of treatment and refunds a portion of this sum at each follow-up assessment at which the participant demonstrates abstinence (Paxton 1983). Other variations of this technique have used nonmonetary rewards (Lando 1982), punished smokers for every cigarette smoked (Murray and Hobbs 1981), instructed participants to reward themselves for abstinence (Tiffany et al. 1986), and rewarded participants who had reduced their carbon monoxide levels (Stitzer and Bigelow 1985). Curry and colleagues (1991) used a theoretical framework that tested intrinsic motivation (personalized feedback) against extrinsic motivation (financial incentive). Abstinence at 3 and 12 months was two times higher in the intrinsically motivated groups.

Efficacy

When used alone, motivational rewards foster relatively high abstinence success in the short term, but these gains do not appear to be durable (Antonuccio et al. 1992). Participants often return to smoking after the term of the contract expires (Paxton 1980, 1981). Attempts to prolong abstinence by varying factors such as duration and frequency of reward have generally been unsuccessful (Paxton 1981, 1983). Multicomponent treatments using motivational rewards have sometimes fared better than comparison treatments, but these comparisons are generally confounded by other factors (Jason et al. 1990; Lando et al. 1990) and may lead to type II errors. A meta-analysis of 62 studies comparing components of behavioral controls found that motivational rewards (contingency contracting) did not significantly alter long-term cessation rates (Fiore et al. 2000). In the final results of the Minnesota Heart Health Program, the failure of community education methods (which included motivational rewards for smoking cessation) to produce results that exceeded secular trends is an important demonstration of the difficulties in evaluating such modalities (Lando et al. 1995).

Relevant Process Measures

The process measures most relevant to this strategy are presumably motivational; making rewards contingent on abstinence should increase a smoker's resolution to remain abstinent. However, motivational measures have been neglected in research on this intervention. Many programs require participants to administer their own rewards or punishments. Evaluations of these strategies should routinely assess how well participants take on this responsibility; to date, evaluations have not made this assessment.

Social Support

Social support interventions try to ease the smoking cessation process by enlisting the support of significant persons in smokers' lives (extratreatment social support) and by providing support from clinicians (intratreatment social support). Both strategies may range from intense and pervasive to relatively minimal and limited. Intensive extratreatment social support may train participants to elicit aid and support of family and friends, whereas training clinicians to communicate caring, concern, and encouragement increases intratreatment social support. Increasing the cohesiveness of smoking cessation groups can enhance both forms of social support (Hajek et al. 1985; Lando and McGovern 1991). At the basic level, the simple use of a group rather than an individual format can be viewed as a social support intervention.

Efficacy

Strategies that add social support to pharmacologic treatment appear to significantly increase longterm quit rates compared to treatments without social support, although some intensive interventions have reported mixed results (Glasgow et al. 1986; McIntyre-Kingsolver et al. 1986). A recent meta-analysis of 19 studies (Fiore et al. 2000) reported that interventions to increase social support in the smoker's environment increase long-term cessation by 50 percent. A metaanalysis of 50 studies (Fiore et al. 2000) reported that within-treatment social support increased cessation by 30 percent. The importance of intratreatment social support may well be reflected in the finding that individual and group counseling are both much more effective than no contact interventions (Kottke et al. 1988; Fiore et al. 1996).

Relevant Process Measures

Studies of intensive social support interventions have regularly included measures of smokers' perceived support. These investigations have found that the amount of support a smoker perceives is directly related to outcome (Malott et al. 1984; Glasgow et al. 1986; McIntyre-Kingsolver et al. 1986; Gruder et al. 1993), but the trials have typically failed to find evidence that the support itself has increased this perception (Malott et al. 1984; Glasgow et al. 1986). In one study that found social support intervention to be effective, the strategy was itself associated with an increase in received support (Gruder et al. 1993). Moreover, this increase in support was statistically related to the differential outcome. Because support measures have rarely been incorporated into the evaluation of group treatments for smoking cessation, little is known about whether group formats enhance perceived support and about what influence such support has on treatment outcome (Hajek et al. 1985).

Weight Control

Most people who quit smoking gain weight (Klesges et al. 1989), and this effect may be greater for women than for men (Williamson et al. 1991; Fant 1996). This effect has been hypothesized to result from nicotine's ability to modify various mechanisms in the central nervous system that regulate body weight (Schwid et al. 1992; Perkins 1993). Apprehension about weight gain may serve as a barrier to cessation attempts, especially among young women (Gritz et al. 1989). Cessation strategies that address this barrier have only recently begun to be assessed.

Efficacy

Two important trials have examined the contribution of a weight control component to a multicomponent smoking cessation program. One study (Hall et al. 1992) compared a specialized weight control program with both a nonspecific weight control program and a standard program. Patients in the specialized group learned behavioral self-management, reduced their caloric intake under the direction of a dietitian, and received an individualized activity plan from an exercise counselor. Patients in the nonspecific group attended several group sessions devoted to discussing weight-related issues. Results showed that participants in both of these weight control programs were less likely to be abstinent after one year (21 percent success for both groups combined) than participants treated with the standard protocol (35 percent success).

Another study (Pirie et al. 1992) examined the effects of adding nicotine gum, weight control counseling, both, or neither to a standardized smoking cessation program in a sample of women who had indicated that they were concerned about postcessation weight gain. After 12 months, the group that added nicotine gum to the standard program had much greater success (44.4 percent had quit smoking) than the groups that added weight control counseling to the standard package (27.8) percent success for the group that added weight control only and 27.6 percent success for the group that added both weight control and nicotine gum). However, the standard package alone was the least successful program (19.4 percent had quit smoking) and was viewed by participants as less appealing than the weight control component (Pirie et al. 1992).

A meta-analysis of six studies (Fiore et al. 2000) that looked at the effect of dieting and physical activity on smoking cessation did not find that these interventions increased cessation success. A recent single study (Marcus et al. 1999) found that vigorous physical activity increased quit rates.

Relevant Process Measures

Weight gain has not been a consistent predictor of smoking relapse (Gritz et al. 1989), and it has predicted abstinence as well (Hall et al. 1986; Gritz et al. 1989; Hughes et al. 1991b). Nonetheless, actual control of weight is an important process measure for weight control interventions—the primary purpose of which is relapse prevention—because they explicitly assume that preventing weight gain will boost abstinence rates (Hall et al. 1992; Pirie et al. 1992). Neither published trial of weight control interventions found differences in weight gain among abstinent subjects across treatment conditions (Hall et al. 1992; Pirie et al. 1992). One of the studies (Hall et al. 1992) found evidence for lower caloric intake in specialized weight control interventions, especially among women, but failed to find differences in activity levels across treatment conditions. In sum, despite the intuitive appeal of weight control interventions to promote smoking cessation, there is mixed evidence relating such interventions to cessation success (Fiore et al. 2000). Hall and colleagues (1992) suggested that such interventions may interfere with cessation. However, Marcus and colleagues (1999) found that a vigorous exercise intervention increased quit rates while contributing to weight management. Pharmacotherapies, including bupropion sustained release (SR) and nicotine gum, may help to delay weight gain after cessation (Emont and Cummings 1987; Doherty et al. 1996; Jorenby et al. 1999).

Hypnosis

Some smokers try hypnosis therapy to help them quit (Schwartz 1987). Strategies for hypnosis interventions include direct hypnotic suggestions to quit, suggestions intended to produce aversion to smoking, and training in self-hypnosis to reinforce formal treatment (Simon and Salzberg 1982).

Efficacy

The methodological shortcomings of hypnosis research make it difficult to estimate the value of this therapy for smoking cessation (Schwartz 1987). Reviewers have noted that, in general, hypnosis is not very effective when used alone, but it may be useful as part of a multicomponent intervention in which subjects see a therapist many times (Holroyd 1980; Schwartz 1987). In methodologically sound studies, hypnosis often fails to outperform comparison techniques, such as self-help strategies (Rabkin et al. 1984; Lambe et al. 1986). Hypnosis techniques may work best for the relatively small proportion of people highly susceptible to hypnosis (Barabasz et al. 1986; USDHHS 1988). Since the late 1980s, there have been only two trials of hypnosis in smoking cessation, with inconclusive results. Johnson and Karkut (1994) conducted an uncontrolled clinical trial of hypnosis plus aversion treatment and reported about 90 percent abstinence at three months. A similar uncontrolled study of 226 smokers reported a 23-percent abstinence at two years (Spiegel et al. 1993). A recent review of hypnosis by the Cochrane group (Abbot et al. 2000) found insufficient evidence to support hypnosis as a treatment for smoking cessation.

Relevant Process Measures

Appropriate process measures for studies of hypnosis are those that assess the various means of hypnotic induction and the motivational changes that are presumed to accrue from them. Because measures have rarely been collected, little is known about the mechanisms of hypnotic treatments for smoking cessation (Holroyd 1980; Schwartz 1987; USDHHS 1988).

Acupuncture

The typical acupuncture treatment for smoking cessation involves the insertion of needles or staples into the outer ear, but a number of other techniques have been investigated (Schwartz 1988). The most commonly cited rationale for using acupuncture is that it relieves the discomfort of nicotine withdrawal.

Efficacy

The available evidence suggests that acupuncture is no more effective in smoking cessation than placebo treatments (Schwartz 1987). For example, Schwartz (1988) reviewed eight studies in which acupuncture at a theoretically appropriate site was contrasted with acupuncture at a placebo site. Only one of these studies found greater success among participants undergoing the procedure with theoretically appropriate sites (MacHovec and Man 1978). A recent meta-analysis of five studies (Fiore et al. 2000) found that acupuncture was no more effective than placebo.

Relevant Process Measures

Acupuncture is commonly presumed to exert its effects by easing tobacco withdrawal. At present there is no evidence that acupuncture is capable of relieving withdrawal symptoms associated with smoking cessation (Clavel et al. 1987; Schwartz 1987; USDHHS 1988).

Summary of Intensive Clinical Interventions

Intensive programs serve an important function in the nation's efforts to reduce smoking, despite the resources the programs demand and the relatively small population of smokers who use them. Such programs may be particularly useful in treating smokers who find it most difficult to quit.

Because intensive smoking cessation programs differ in structure and content, evaluation is often hampered by variation in methodology and by a lack of research addressing specific treatment techniques. Because few studies have chosen to isolate single treatments, assessment of the effectiveness of specific approaches is difficult. Nonetheless, skills training, rapid smoking, and both intratreatment and extratreatment social support have been associated with successful smoking cessation. When such treatments are shown to be effective, they are usually part of a multifactorial intervention. Little clear evidence has implicated particular psychological, behavioral, or cognitive mechanisms as the agents of change. The specific impact of intensive interventions may be masked by the efficacy of several multicomponent programs, some of which have achieved cessation proportions of 30-50 percent (Lando 1993).

Thus, in their positive effect on smoking cessation and long-term abstinence rates (Kottke et al. 1988; Fiore et al. 1994a), intensive interventions seem little different from other forms of counseling or psychotherapy. With intensive interventions, as with counseling, it is difficult to attribute the efficacy to

specific characteristics of the interventions or to specific change mechanisms (Luborsky et al. 1975; Elkin et al. 1989).

Pharmacologic Interventions

At first look, nicotine replacement therapy appears to be the treatment of a disease with its cause. The rationale, however, is well established. Observations on the beneficial effects of nicotine replacement in abstinent smokers were first made in 1967 (Lucchesi et al. 1967), and the process has its medical precedent in the use of methadone for opiate dependence. Nicotine use, in the form of 10 or more cigarettes a day, provides continuous neuroexposure (Benowitz 1993). The resulting tolerance and physical dependence produce classic withdrawal symptoms (USDHHS 1988). As Benowitz (1993) has summarized, "Nicotine replacement therapy serves primarily to break the daily addiction cycle by relieving withdrawal symptoms, thereby facilitating behavioural modification that is necessary for permanent smoking cessation" (p. 158). However, as will be discussed later in this chapter, recent data suggest that nicotine replacement may be effective without behavioral support or counseling. A number of candidate delivery systems have now been extensively evaluated with clear and consistent results. In addition, nonnicotine pharmacotherapies for treatment of tobacco use are now available.

Nicotine Polacrilex

Nicotine polacrilex (nicotine gum) was approved by the Food and Drug Administration (FDA) for use as an aid to smoking cessation in a 2-mg dose in 1984 and in a 4-mg dose in 1994. The nicotine in the gum is bound to an ion-exchange resin. Chewing the gum liberates the nicotine, which is absorbed through the buccal mucosa. Currently, both doses of nicotine polacrilex are approved for use as over-the-counter preparations by adults. The package insert instructs patients to use the gum as needed with the constraint that they not exceed a daily dose of 20 pieces of 4-mg gum or 30 pieces of 2-mg gum.

Efficacy

With more than 50 studies on its efficacy, nicotine gum is the most extensively investigated pharmacologic treatment for smoking cessation. This body of research has been summarized by several major meta-analyses (Lam et al. 1987; Cepeda-Benito 1993; Silagy et al. 1994; Tang et al. 1994). The most recent

meta-analysis (Fiore et al. 2000) is summarized in Table 4.3. All meta-analyses found the gum to be effective in helping smokers quit.

Lam and colleagues (1987) performed a metaanalysis of nine randomized, controlled trials of the 2-mg nicotine gum. These authors performed separate analyses on the trials conducted in specialized smoking cessation clinics and on those conducted in general medical settings. In the specialized clinics, cessation success was greater with nicotine gum than with placebo gum. In general medical practice settings, however, nicotine gum was no more successful than placebo gum; both types of gum were more successful than usual care. The authors suggested that participants at the specialized cessation clinics had greater success because such participants may have been more motivated to quit and may have received more intensive adjuvant behavioral support than those at the generalized settings. The authors also speculated that patients who seek treatment in specialized clinics may be more physically dependent on nicotine and thus more likely to benefit from nicotine replacement than the average patient seen in a general medical clinic.

Cepeda-Benito (1993) performed a meta-analysis of 33 trials of the 2-mg gum. As in the review by Lam and colleagues (1987), the trials were categorized according to whether the adjuvant behavioral support was intensive or brief and according to whether the control group used placebo gum or no gum. Pooled estimates of efficacy were derived for short-term (0-8 weeks after treatment) and long-term (12 \pm 2 months) outcome measures within each category. Effect sizes were not systematically related to the type of control treatment used but were related to the intensity of behavioral support provided. When used in intensive interventions, the gum was associated with greater abstinence success than the control treatments at both long-term and short-term follow-up. When used in brief behavioral interventions, however, the gum outperformed the control interventions only at short-term follow-up. The author concluded that nicotine gum is an effective aid to smoking cessation but questioned its long-term value in the absence of adjuvant psychosocial support.

In the context of a larger review of available nicotine replacement therapies, Tang and colleagues (1994) performed a meta-analysis of 28 randomized, controlled trials of the 2-mg gum and 6 randomized, controlled trials of the 4-mg gum. The authors found that among participants recruited through advertisements to attend specialized cessation clinics, the 2-mg gum was associated with an 11-percent increase in success over control treatments. However, among

smokers who were directly invited to participate in a general smoking cessation trial conducted by a non-specialist physician, the 2-mg gum increased abstinence success by only 3 percentage points over control conditions. Consistent with the analysis by Lam and colleagues (1987), the authors suggested that these findings reflect (1) the greater motivation of the smokers who referred themselves (i.e., responded to advertisements instead of being directly invited), (2) the greater degree of nicotine dependence in the self-referred group, and (3) the more extensive encouragement and more detailed instructions provided by

therapists in the specialized settings in which the self-referred smokers were treated.

Six of the 28 trials of the 2-mg gum (Fagerström 1982, 1984; Jarvik and Schneider 1984; Areechon and Punnotock 1988; Hughes et al. 1989b; Jensen et al. 1990) reported abstinence success as a function of nicotine dependence as assessed by the Fagerström Tolerance Questionnaire (described later in this chapter). The authors aggregated these data and found that the 2-mg gum improved cessation success by 16 percentage points among smokers scoring high (indicating considerable nicotine dependence) on the

Table 4.3. Meta-analyses of efficacy (estimated odds ratio and abstinence rates) for seven pharmacotherapies used in tobacco dependence treatment

Pharmacotherapy	Number of study groups	Estimated odds ratio (95% CI*)	Estimated abstinence rate (95% CI)
	grany grants	(1011-11)	(**************************************
Bupropion SR [†] $(n = 2^{\ddagger})$	2	1.0	17.0
Placebo	2	1.0	17.3
Bupropion SR	4	2.1 (1.5, 3.0)	30.5 (23.2, 37.8)
Nicotine gum, $2 \text{ mg} (n = 13)$			
Placebo	16	1.0	17.1
Nicotine gum	18	1.5 (1.3, 1.8)	23.7 (20.6, 26.7)
Nicotine inhaler (n = 4)			
Placebo	4	1.0	10.5
Nicotine inhaler	4	2.5 (1.7, 3.6)	22.8 (16.4, 29.2)
Nicotine nasal spray (n = 3)			
Placebo	3	1.0	13.9
Nicotine spray	3	2.7 (1.8, 4.1)	30.5 (21.8, 39.2)
Transdermal nicotine			
(the nicotine patch) (n = 27)			
Placebo	28	1.0	10.0
Transdermal nicotine	32	1.9 (1.7, 2.2)	17.7 (16.0, 19.5)
Clonidine (n = 5)			
Placebo	6	1.0	13.9
Clonidine	8	2.1 (1.4, 3.2)	25.6 (17.7, 33.6)
Cicianic	Ü	(, o. <u>_</u>)	20.0 (17.17, 00.0)
Nortriptyline (n = 2)			
Placebo	3	1.0	11.7
Nortriptyline	3	3.2 (1.8, 5.7)	30.1 (18.1, 41.6)

^{*}Confidence interval.

Source: Fiore et al. 2000.

[†]SR = sustained release.

[‡]Number of studies.

questionnaire but produced only a 2-percentage point increase among smokers whose scores indicated low levels of nicotine dependence.

When data from the 4-mg gum trials (Puska et al. 1979; Kornitzer et al. 1987; Tønnesen et al. 1988a,b; Blöndal 1989; Hughes et al. 1990a) were aggregated, the influence of nicotine dependence paralleled that seen in trials using the lower dose. Among smokers highly dependent on nicotine, those who used the 4-mg gum had a 21-percent greater success at cessation than those using the 2-mg gum. In contrast, among smokers low in nicotine dependence, those who used the 4-mg gum had an 18-percent lower success than those using the 2-mg gum. Highly dependent participants using the 4-mg gum had a 35-percent greater success than those using the placebo gum, but this comparative improvement was only 5 percent greater among less dependent participants.

Tang and colleagues (1994) concluded that nicotine gum is an effective aid to smoking cessation and suggested that its efficacy is a direct function of the dependence of the smoker. On the basis of their review of other nicotine replacement therapies (including the nicotine patch), the authors concluded that the 4-mg gum is the most effective form of nicotine replacement for highly dependent smokers.

Silagy and colleagues (1994) examined 42 nicotine gum trials in their meta-analysis of nicotine replacement interventions. To compute effect sizes for each analysis, the authors combined data from the longest follow-up assessments (mainly 12 months) from available trials, regardless of gum dose or type of control treatment. Across all 42 trials, 42 percent of participants using nicotine gum quit smoking, whereas only 18 percent of participants in the control groups, who used either placebo gum or no gum, succeeded in quitting. The pooled odds ratio (OR) for the gumto-control comparison across all trials was 1.61 (95 percent confidence interval [CI], 1.46–1.78). Differences between gum and control conditions did not vary according to the intensity of adjuvant behavioral support.

Fiore and colleagues (1990) conducted a metaanalysis of 13 randomized controlled trials of 2-mg nicotine gum therapy with at least five months of follow-up (Table 4.3). Nicotine gum treatment was associated with a 50-percent increase in quit rates (23.7 percent quit rate vs. 17.1 percent) in the control group. There were too few studies done in the over-thecounter setting to allow meta-analysis of the over-thecounter effect of nicotine gum.

Taken together, these meta-analyses suggest that nicotine chewing gum is an effective aid to smoking cessation. This conclusion continues to be borne out as evidence continues to accumulate. In an ongoing project, Silagy and colleagues (1999) have been regularly searching medical databases for new nicotine replacement trials, recalculating effect sizes as new data sources are identified, and frequently publishing the updated meta-analyses. In the most recent edition of this meta-analysis, the pooled gum-to-control OR was estimated at 1.63. That in most settings nicotinecontaining gum is associated with greater cessation success than placebo gum suggests that the gum's efficacy is due to its pharmacologic properties. Some evidence indicates that the efficacy of the 2-mg gum depends on the presence of intensive adjuvant behavioral support. The meta-analysis by Silagy and colleagues (1994) suggests that nicotine gum may be beneficial even without intensive adjuvant therapy. In this analysis, however, because 2-mg and 4-mg gum studies are combined, definitive conclusions about the efficacy of either dose alone in the absence of behavioral support cannot be drawn. This finding underscores the importance of selecting those smokers for whom nicotine gum is likely to be beneficial. The available evidence suggests that traditional measures of nicotine dependence may be a useful basis for selecting gum candidates. Both doses of the gum appear to be of greater value to smokers who are more dependent on nicotine. The 4-mg gum may be particularly effective for the most dependent smokers.

Relevant Process Measures

Nicotine gum is presumed to exert its effects by replacing a portion of the nicotine that smokers usually obtain through smoking; in therapy, the gum ameliorates aversive tobacco withdrawal (Benowitz 1991; Hughes 1993). Some evidence suggests that nicotine gum reliably reduces some withdrawal symptoms.

Patients receiving the 2-mg nicotine gum have consistently reported having less total withdrawal discomfort than patients treated with placebo gum (Jarvis et al. 1982; Hughes et al. 1984, 1989a, 1991b; Gross and Stitzer 1989; Hatsukami et al. 1991). However, studies have found that withdrawal severity is not consistently related to smoking relapse (West 1992; Hughes 1993), and the withdrawal suppression produced by nicotine gum appears to be somewhat independent of its efficacy. Moreover, the suppression reported seems to accrue through the lessening of a relatively small subset of withdrawal symptoms (Hughes et al. 1990b). The 2-mg gum consistently alleviates symptoms such as

anxiety and irritability but does not appear to reliably ameliorate craving, hunger, sleep disturbance, or difficulty concentrating (West et al. 1984a,b; Gross and Stitzer 1989; Hughes et al. 1989a, 1990a; Hatsukami et al. 1991). One trial (Hughes et al. 1990a) has found that the 4-mg gum was no more effective than the 2-mg gum either in suppressing total withdrawal severity or in relieving any of the individual symptoms of withdrawal. Future research must explore whether these counterintuitive findings are a result of poor measurement of withdrawal severity or whether other mechanisms explain how nicotine gum produces clinical success (Hughes 1993).

Effect on Postcessation Change in Body Weight

Evidence suggests that the 2-mg gum is capable of delaying, but not preventing, postcessation weight gain. Early in the cessation process, smokers given the 2-mg gum tend to gain less weight than smokers treated with placebo gum (Gross et al. 1989). During this period, weight gain among the 2-mg gum users is inversely related to the amount of gum used (Emont and Cummings 1987; Fagerström 1987; Killen et al. 1990a; Nides et al. 1994). However, differences in weight gain between smokers using the 2-mg gum, using placebo gum, and using no gum (Gross et al. 1989; Nides et al. 1994) disappear when follow-up is conducted after gum therapy has ended.

Relatively little is known about the weight-related effects of the 4-mg gum. Early trials did not show it to diminish weight gain any more than either the 2-mg gum (Kornitzer et al. 1987; Tønnesen et al. 1988a) or the placebo gum (Puska et al. 1979; Tønnesen et al. 1988a). These trials, however, tended to use different weight measures and more distal end points than the typical trial with 2-mg gum, and one trial used a mixed-dose regimen (Tønnesen et al. 1988a). A more recent study, however, reported that nicotine gum suppressed weight gain with greater suppression occurring with the 4-mg dose (Doherty et al. 1996). Analysis of salivary cotinine showed that smokers who replaced a greater percentage of their baseline cotinine levels gained less weight.

Side Effects and Likelihood of Inappropriate Use

Common side effects reported by the 2-mg gum users include mouth soreness, hiccups, indigestion, jaw ache, and unpleasant taste (American Medical Association [AMA] 1993; Tang et al. 1994). Most of these symptoms are relatively mild and transient, and many can be resolved by correcting the user's chewing technique. Symptoms observed less frequently (in

less than 2 percent of patients) include irritability, lightheadedness, headache, excessive salivation, and anorexia (AMA 1993). Moreover, absorption of nicotine from the gum is highly dependent on the pH of the mouth (Henningfield et al. 1990). Because nicotine is inactivated by an acidic environment, patients are urged to refrain from eating or drinking anything but water for 30 minutes before using the gum. Approximately 10-25 percent of successful abstainers continue to use the gum for one year or longer (Hajek et al. 1988; Hughes 1988; Hughes et al. 1991a). Although discontinuance of use should be encouraged, continued use confers a substantial reduced health risk compared to a return to smoking. The 4-mg gum appears to have similar side effects, but it may produce slightly more dyspepsia and hiccuping than does the 2-mg gum (Tønnesen et al. 1988a,b).

Transdermal Nicotine

In 1991, the FDA approved the use of transdermal nicotine patches as an aid to smoking cessation. Nicotine patches contain a reservoir of nicotine that diffuses through the skin and into the wearer's bloodstream at a constant rate. Patients are usually instructed to apply one patch each day. Specific dosing regimen may vary.

All currently marketed brands are designed to deliver approximately 0.9 mg per hour of nicotine over the weaning period. Most are intended for 24-hour wear and deliver 21–22 mg of nicotine; one is intended for waking hours wear (16 hours per day) and delivers 15 mg of nicotine. Full-strength patches typically produce serum nicotine levels similar to trough levels of serum nicotine in moderate to heavy smokers (Mulligan et al. 1990). On July 3, 1996, the FDA approved the transdermal nicotine patch for over-thecounter sales at a dose of 15 mg for use as part of a comprehensive behavioral program of smoking cessation, although the FDA's proscription does not provide a clear statement of the constituents of such a program. Since that time, all varieties of nicotine patches have become available over the counter, some as "house brands."

Efficacy

Several meta-analyses of the efficacy of the nicotine patch have been published (Po 1993; Fiore et al. 1994c; Gourlay 1994; Silagy et al. 1994; Tang et al. 1994; Fiore et al. 2000). Each meta-analysis has concluded that the patch is an effective aid to smoking cessation.

Po (1993) combined data from 11 nicotine patch trials and found that persons using the nicotine patch had greater cessation success than persons using a placebo patch. This finding held for both short-term follow-up (3–10 weeks; combined OR = 3.10 [95 percent CI, 2.65–3.62]) and long-term follow-up (6–12 months; combined OR = 2.26 [95 percent CI, 1.80– 2.86]). Gourlay (1994) pooled the results of six trials and found that the nicotine patch produced greater cessation success than a placebo patch at all follow-up assessments (2–3 months, 6 months, and 12 months; all pooled ORs were between 2.2 and 2.4 [95 percent CI, 1.6–3.4]). Tang and colleagues (1994) conducted a meta-analysis of six patch trials. Overall, at long-term (12-month) follow-up, persons using nicotine patches had a 9-percent (6–13 percent) greater success at cessation than did persons using placebo patches. Nicotine patches were found to be more effective among self-referred subjects than among invited subjects and slightly more effective among smokers who were more dependent on nicotine. Silagy and colleagues (1994) combined data from nine patch trials and found that at long-term (12-month) follow-up, nicotine patches were associated with a combined OR of 2.07 (95 percent CI, 1.64-2.62) when compared with control conditions (placebo patches or no patch). Secondary analyses indicated that the patch's relative efficacy was not affected by the intensity of adjuvant support. Fiore and colleagues (1994c) examined 17 nicotine patch trials and found a combined OR of 2.6 (95 percent CI, 2.2–3.0) at the end of the treatment and 3.0 (95 percent CI, 2.4–3.7) at 12-month follow-up. More intensive adjuvant support was found to produce higher abstinence rates at six months (26.5 vs. 19.5 percent for low-intensity interventions) but did not increase the relative advantage of nicotine patches over placebo patches. The 16- and 24-hour patches were found to be equally effective. Neither weaning nor extending treatment beyond eight weeks was found to improve outcome. A recent meta-analysis (Fiore et al. 2000) of 27 studies reported that transdermal nicotine increased long-term cessation by 90 percent (Table 4.3). A metaanalysis of three studies reported that over-the-counter nicotine patch use increased successful long-term cessation by 80 percent (Fiore et al. 2000).

These meta-analyses strongly indicate that the nicotine patch is an effective aid to smoking cessation. This conclusion is buttressed by the findings of a continuing, regularly updated review of the existing research literature on transdermal nicotine (Silagy et al. 1999). In the most recent release of this evolving meta-analysis, Silagy and colleagues (1999) found a pooled patch-to-control OR of 1.84 (95 percent CI, 1.60–2.10). The data continue to suggest that 16- and 24-hour patches are equivalent in efficacy, that there is no advantage associated with weaning or tapering of patch

dose, and that the relative efficacy of the patch is fairly independent of the intensity of adjuvant therapy. Nicotine patches have been consistently found to outperform placebo patches regardless of dosing regimen and in a variety of investigational settings. For example, a study of "real-world" use of the patch—based on a follow-back of older persons who had filled patch prescriptions—produced a self-reported cessation proportion of 29 percent at six months (Orleans et al. 1994). The patch is more effective than placebo treatment when paired with only brief support, and it is associated with the higher long-term success when paired with more intensive counseling or behavioral interventions (Fiore et al. 1994b). Though the nicotine patch does increase success rates when used with minimal formal counseling, many nicotine patch clinical trials involve frequent follow-up assessments. Such contacts might boost success rates obtained with the patch. In support of this possibility, Jorenby and colleagues (1995b) found that the combination of nicotine patch treatment plus frequent assessments produced followup outcomes equivalent to the nicotine patch plus intensive behavioral therapy. Further assessment of this issue is important, as frequent follow-up contact does not usually accompany nicotine patch use outside of clinical trials (Cummings et al. 1994; Swartz et al. 1995). A meta-analysis of three studies of over-the-counter nicotine patches, however, indicated that patch therapy was superior to placebo (Fiore et al. 2000).

Effects on Discomfort of Nicotine Withdrawal

Some evidence suggests that the nicotine patch reduces overall measures of nicotine withdrawal discomfort (Daughton et al. 1991; Transdermal Nicotine Study Group 1991; Jorenby et al. 1996), but this finding has not been consistent (Abelin et al. 1989; Tønnesen et al. 1991; Merz et al. 1993). Use of the nicotine patch has been repeatedly found to reduce the craving for cigarettes (Abelin et al. 1989; Rose et al. 1990; Tønnesen et al. 1991; Transdermal Nicotine Study Group 1991; Merz et al. 1993; Sachs et al. 1993; Westman et al. 1993; Fiore et al. 1994b; Levin et al. 1994; Jorenby et al. 1996), but other symptoms of nicotine withdrawal are affected less reliably (Palmer et al. 1992). In a study designed to clarify the impact the patch has on withdrawal symptoms, the patch reliably reduced craving, anxiety, and irritability but did not alleviate depressed mood, restlessness, or sleep disruption (Jorenby et al. 1996). The authors noted that with or without the patch, most withdrawal symptoms disappeared within three to four weeks.

Effect on Postcessation Change in Body Weight

Nicotine patches can attenuate postcessation weight gain while they are in use (Abelin et al. 1989; Sachs et al. 1993; Jorenby et al. 1995a; Dale et al. 1998), but this short-term effect has not always been observed (Rose et al. 1990; Tønnesen et al. 1991; Transdermal Nicotine Study Group 1991; Fiore et al. 1994b). Moreover, studies that follow up effects after treatment has ended have not found that persons who used the nicotine patch gained less weight than those who used a placebo patch (Tønnesen et al. 1991).

Side Effects and Likelihood of Inappropriate Use

Most side effects of nicotine patch use are relatively mild; less than 5 percent of patients need to discontinue patch therapy because of side effects (Hughes and Glaser 1993). Minor skin irritation at the patch site is reported by 30–50 percent of patch users and can be relieved by moving the patch to another site. Insomnia is reported by 1–23 percent of patch users (AMA 1993). Comparatively rare side effects include headache, dizziness, fatigue, gastrointestinal distress, sweating, limb pain, and palpitations (Palmer et al. 1992). Studies have found little evidence that people will inappropriately use transdermal nicotine systems (Palmer et al. 1992; Hughes 1993; Jorenby et al. 1995b).

The risks associated with using the nicotine patch during pregnancy are largely unknown. Nicotine itself poses risks to the fetus, including neurotoxicity (Slotkin 1998), and pregnant women should first be encouraged to quit without pharmacotherapy. Because exposure to nicotine through maternal use of the patch probably poses less danger to the fetus than does continued maternal smoking (Hackman et al. 1999), however, nicotine replacement therapy may be indicated for pregnant women who are unable to quit smoking (Benowitz 1991; Lewis and Fiore 1994). However, if a decision is made to use nicotine replacement therapy during pregnancy, the physician should consider monitoring blood nicotine levels, using doses at the low end of the effective range, and choosing intermittent delivery systems (such as nicotine gum) (Fiore et al. 2000). The issue is under active investigation.

Continued smoking while using the patch may be a significant problem. In an observational study of self-reported patch use, almost one-half the respondents stated that they smoked while using the patch; 20 percent of the respondents did so every day (Orleans et al. 1994). A small number of adverse cardiovascular events were reported in patients who continued to smoke while using the patch. When these events received much attention from the popular press,

several analyses, including one by an FDA advisory committee, have documented no association between nicotine replacement therapy and cardiovascular events even in patients who continue to smoke intermittently (Working Group for the Study of Transdermal Nicotine in Patients with Coronary Artery Disease 1994; Joseph et al. 1996; Benowitz and Gourlay 1997; Mahmarian et al. 1997). Caution should be used, however, for patients with acute cardiovascular disease (immediately post-myocardial infarction or in the presence of serious arrhythmias or serious or accelerating angina pectoris).

Relevant Process Measures

Like nicotine gum, the nicotine patch is intended to reduce tobacco withdrawal symptoms (Palmer et al. 1992; Glover 1993b; Hughes and Glaser 1993). Although the nicotine patch appears to reduce withdrawal severity, particularly craving for cigarettes, withdrawal suppression may or may not be responsible for the patch's efficacy (Hughes 1993). For example, one trial failed to reveal reliable differences in withdrawal severity between persons using nicotine patches and those using placebo patches (Merz et al. 1993); the trial nevertheless found that participants who used the nicotine patch were nearly twice as likely to quit smoking. Another trial employing two doses of transdermal nicotine found that the higher-dose patch produced significantly greater cessation success than the lower-dose patch, even though both doses provided about the same amount of relief from withdrawal symptoms (Transdermal Nicotine Study Group 1991; Hughes 1993). Clearly, other potential mechanisms of the patch's action, as well as the action of nicotine replacement therapy in general, need to be explored.

Nicotine Nasal Spray

Nicotine nasal spray was approved for prescription use in the United States in March 1996. The spray consists of a pocket-sized bottle and pump assembly, which is fitted to a nozzle designed for insertion into the nose. Each metered spray delivers 0.5 mg of nicotine to the nasal mucosa. The recommended dose is 1 mg, or one 0.5-mg spray per nostril, as needed (Sutherland et al. 1992).

Efficacy

A number of clinical trials have assessed the efficacy of the nicotine nasal spray as an aid to smoking cessation. Sutherland and colleagues (1992) found that 26 percent of participants given nicotine nasal spray were abstinent after one year, compared with only 10 percent of participants given placebo. Hjalmarson and colleagues (1994) found similar results in a placebo-controlled trial; at one-year follow-up, abstinence rates were 27 percent and 15 percent, respectively, for participants given active spray or placebo. Schneider and colleagues (1995) again replicated this effect, finding continuous abstinence rates of 18 percent and 8 percent among participants given active or placebo spray. Another study (Blöndal et al. 1997) did not find a significant difference in abstinence rates between active spray and placebo groups at one year (25 vs. 17 percent); active spray was associated with higher abstinence rates at six months and earlier in this trial.

Recently, Blöndal and colleagues (1999) provided all participants in a second trial with active nicotine patches, then studied the incremental efficacy of adding nasal spray therapy to the patch regimen in a double-blind, placebo-controlled fashion. Results showed that participants given the active spray were more likely to be abstinent after one year than participants given placebo (27 vs. 11 percent). Participants given active spray had a higher rate of abstinence than participants given placebo a full six years after the start of treatment (16 vs. 9 percent), but this effect was only marginally significant. Taken together, the results of these studies suggest that nicotine nasal spray is an aid to smoking cessation. A meta-analysis by Silagy and colleagues (1999) reported a pooled spray-to-control OR of 2.27, and a recent meta-analysis (Fiore et al. 2000) reported an OR of 2.7 (30.5 percent long-term abstinence rate) (Table 4.3).

Effect on Discomfort of Nicotine Withdrawal

Evidence regarding the nicotine nasal spray's effects on nicotine withdrawal discomfort is sparse. The results of two studies suggest that the spray may be useful for coping with craving, but may not be effective in alleviating other withdrawal symptoms. One study (Sutherland et al. 1992) found that, compared with participants using placebo spray, participants treated with nicotine spray reported having less total withdrawal discomfort during the 48 hours immediately after smoking cessation and reported less craving for cigarettes during this period. After 48 hours, however, the two groups reported equivalent levels of withdrawal discomfort and craving. When craving did arise, the nicotine spray was consistently rated more effective than the placebo spray.

The other study (Hjalmarson et al. 1994) found that during the first 48 hours of smoking cessation,

users of nicotine spray reported somewhat less severe withdrawal discomfort than placebo users, but this effect was not statistically significant. The severity of craving was found to be similar across both groups, but the nicotine spray was more helpful in quelling craving than the placebo spray was. Other clinical trials have not reported comparisons between active and placebo spray groups with regard to withdrawal measures (e.g., Schneider et al. 1995; Blöndal et al. 1999).

Effect on Postcessation Change in Body Weight

The limited evidence available suggests that the nicotine nasal spray may be capable of delaying, but not preventing, postcessation weight gain. In one of the trials (Sutherland et al. 1992), participants were allowed to use the spray they were assigned for as long as one year. Weight effects in that study differed as a function of duration of spray use: abstinent subjects who had continued to use the nicotine spray for the entire year of the study had gained significantly less weight than subjects still using the placebo spray. However, change in body weight was equivalent for abstinent patients who had stopped using either type of spray during the year.

Another study (Hjalmarson et al. 1994) failed to find any statistically significant differences in weight gain between participants using nicotine spray and those using placebo spray. The authors observed, however, that participants still using nicotine spray at the 12-month follow-up tended to gain less weight than both participants continuing to use a placebo spray and participants who had stopped using the nicotine spray before that time.

Side Effects and Likelihood of Inappropriate Use

Unpleasant side effects are common with the nasal spray. Between 75 and 100 percent of nasal spray users reported experiencing irritant effects, such as runny nose, sneezing, throat irritation, nasal irritation, watering eyes, and coughing (Sutherland et al. 1992; Hjalmarson et al. 1994; Schneider et al. 1995). Some authors have reported that these sensory irritation effects are actually viewed as desirable by many smokers and have suggested that they may help bridge the gap between cigarette smoking and nicotine replacement (Glover 1993a; Schneider 1993). Less common side effects, present in 15–25 percent of users, include nausea, sweating, headache, dizziness, and cold hands and feet.

Because the spray rapidly delivers nicotine to the user, the potential for inappropriate use (e.g., using more often or at a higher dose than recommended) is

high. The results of both clinical trials lend some credence to these speculations. Sutherland and colleagues (1992) found that 43 percent of abstinent study participants who had been given the nicotine spray chose to continue using it for the entire year of the study; moreover, mean plasma nicotine concentrations increased over the follow-up period among participants who continued to use the spray. Participants in the trial conducted by Hjalmarson and colleagues (1994) were explicitly encouraged to begin weaning themselves from the spray (whether nicotine or placebo) after three months. Nonetheless, 30 percent of abstinent participants who had been given the nicotine spray continued to use it after one year. Schneider and colleagues (1995) required that participants in their trial use the spray daily for six weeks, then allowed participants to use spray for up to six months postcessation as needed. Thirty-two percent of participants given active spray continued using it daily for six months, compared with 13 percent of participants given placebo. The authors also reported that some continuous abstainers assigned to active spray reported being concerned that they were dependent upon the spray at six months postcessation. However, a substantial proportion of these individuals remained abstinent many months after drug weaning.

Relevant Process Measures

Nicotine nasal spray, like other nicotine replacement products, is intended to aid smoking cessation by relieving withdrawal symptoms. Although the spray has been found effective in promoting cessation, its circumscribed impact on total withdrawal severity suggests that withdrawal relief is not itself responsible for the spray's usefulness. The spray's documented ability to alleviate craving may be what makes it an effective smoking cessation treatment. More research is needed to advance definitive conclusions about the spray's mechanism of action.

Nicotine Inhaler

In May 1997, the FDA approved the nicotine inhaler for prescription use. The inhaler consists of a plastic tube, about the size of a cigarette, that contains a plug impregnated with nicotine. Menthol is added to the plug to reduce throat irritation. Smokers are instructed to puff on the inhaler as they would on a cigarette. An average puff delivers approximately $13 \, \mu g$ of nicotine (about $1/80 \, th$ the amount of nicotine contained in an average cigarette puff), which is absorbed primarily by the buccal route (Glover 1993a;

Tønnesen et al. 1993). Each inhaler contains enough nicotine for approximately 300 puffs. Smokers are instructed to use between 6 and 16 inhalers per day.

Efficacy

A handful of published trials have examined the efficacy of the nicotine inhaler as an aid to smoking cessation. Tønnesen and colleagues (1993) found that 17 percent of participants randomized to active inhalers had quit smoking at six months, compared with 8 percent of participants given placebo. Corresponding rates at one year were 15 vs. 5 percent. Schneider and colleagues (1996) found active-placebo abstinence rates of 17 vs. 9 percent and 13 vs. 8 percent at six months and one year, respectively. These differences were not significant in the Schneider trial, although active inhalers were superior to placebo at all follow-ups through three months postcessation. Hjalmarson and colleagues (1997) found continuous abstinence rates of 35 percent and 28 percent for active inhaler users at 6 and 12 months, compared with 19 percent and 18 percent, respectively, among placebo users. Active-placebo comparisons were statistically significant at all followups in this trial. The most recent edition of a regularly updated meta-analysis of nicotine replacement products (Silagy et al. 1999) found an inhaler-to-control pooled OR of 2.08, and another recent meta-analysis of four studies (Fiore et al. 2000) reported a pooled OR of 2.5 (Table 4.3).

Taken together, the results suggest that the nicotine inhaler is an effective aid to smoking cessation. However, the findings of Schneider and colleagues (1996) suggest that the inhaler may be most useful for producing initial abstinence and that additional interventions may be needed to prevent relapse among users of the inhaler.

Effects on Discomfort of Nicotine Withdrawal

Limited information is available regarding the effects of the nicotine inhaler on nicotine withdrawal symptoms. Two studies (Schneider et al. 1996; Hjalmarson et al. 1997) showed that active inhaler use was associated with decreased craving during the first several days of the quit attempt but not thereafter. Hjalmarson and colleagues (1997) assessed a wide array of withdrawal symptoms across the cessation attempt, but did not find any effects of active inhalers on these other than the fleeting effects on craving. However, this may have been influenced by a floor effect, as mean withdrawal scores were very low in both groups across all assessments.

Side Effects and Likelihood of Inappropriate Use

The most common side effects associated with inhaler use are throat irritation and coughing. These are reported by between 20 to 50 percent of active inhaler users and are less common among placebo inhaler users (Tønnesen et al. 1993; Schneider et al. 1996; Hjalmarson et al. 1997). Other less common side effects include nausea, bad taste in the mouth, dizziness, gastrointestinal disturbances, and oral burning or smarting. Few (0–9 percent) active inhaler users have withdrawn from clinical trials or stopped using the inhaler because of side effects. The potential for inappropriate use appears to be fairly low, with between 2 to 16 percent of active inhaler users continuing to use the device at six months postcessation in clinical trials allowing unrestricted inhaler use (Tønnesen et al. 1993; Schneider et al. 1996; Hjalmarson et al. 1997).

Effect on Postcessation Change in Body Weight

Two placebo-controlled inhaler trials have examined postcessation weight gain (Tønnesen et al. 1993; Hjalmarson et al. 1997). Neither study found evidence that active inhaler use prevented or reduced weight gain among successful quitters.

Relevant Process Measures

The nicotine inhaler is thought to act by relieving withdrawal symptoms (Glover 1993a; Leischow 1994), but little published evidence to date supports this contention. It is often suggested that the inhaler may be effective because it more closely resembles smoking than other pharmacotherapies do, replacing some of the orosensory and behavioral aspects of smoking (Glover 1993a; Tønnesen et al. 1993; Leischow 1994; Schneider et al. 1996; Hjalmarson et al. 1997).

Schneider and colleagues (1996) asked participants to rate their assigned inhalers relative to their usual brand of cigarettes in terms of sensory effects, preference, and satisfaction. Results showed that participants given the active inhaler rated their devices more highly than did participants given placebo. However, the absolute magnitude of the ratings revealed that the inhalers did not compare very favorably to cigarettes in either group. The mechanism of action of the nicotine inhaler would seem to require further scrutiny.

Bupropion

Bupropion is an atypical antidepressant that is believed to work by blocking neurotransmitter reuptake in noradrenergic and dopaminergic sites in the central nervous system (Ascher et al. 1995). Anecdotal reports of spontaneous smoking cessation in patients prescribed bupropion for depression, coupled with a growing appreciation of the importance of negative affect and clinical depression in smoking maintenance (Hall et al. 1994; Piasecki et al. 1997) have recently stimulated clinical investigations of a sustained-release bupropion preparation as an aid to smoking cessation. These investigations led to the approval of a smoking cessation indication for bupropion by the FDA in 1997. The typical dosing regimen for smoking cessation consists of 150 mg sustained-release bupropion per day for three days, followed by 150 mg twice a day thereafter. Therapy is initiated one to two weeks before the target quit date and is generally continued for three months.

Efficacy

Two large-scale clinical trials of bupropion's efficacy as a smoking cessation aid have been published to date. Hurt and colleagues (1997) compared three doses of bupropion (100 mg, 150 mg, and 300 mg) with placebo. Abstinence rates in the 150-mg and 300-mg groups were significantly higher than those of the placebo group at 12 months. All active treatment groups were found to have higher abstinence rates than the placebo group at earlier end points. Jorenby and colleagues (1999) studied active and placebo patches and active and placebo bupropion in a 2 x 2 factorial design. Abstinence rates after one year showed no difference between patch-only and placebo groups (16 percent and 15 percent, respectively). Both placebo and patch treatments were associated with higher abstinence rates when given with bupropion. Thirty percent of the bupropion-only group (150 mg twice a day) were abstinent at 12 months, whereas 36 percent of participants given active patches and bupropion were counted as abstinent.

A recent meta-analysis (Fiore et al. 2000) of two studies reported a pooled OR of 2.1 and an estimated abstinence rate of 30.5 percent (Table 4.3). Thus, the available evidence suggests that bupropion is an effective aid to smoking cessation, and that it may improve quit rates over those observed with conventional nicotine replacement therapies, although further studies will be needed to demonstrate such efficacy.

Effect on Discomfort of Nicotine Withdrawal

The evidence concerning bupropion's ability to suppress withdrawal symptoms is somewhat mixed. Hurt and colleagues (1997) found that their groups using 150 mg and 300 mg reported withdrawal

symptoms that were equivalent to those reported by placebo participants. Individuals assigned to the 100-mg group, however, reported withdrawal that was significantly worse than that among either the placebo group or the other bupropion groups. The authors suggested that this effect may have arisen because the 100-mg dose produced side effects similar to withdrawal symptoms but was not strong enough to reduce true withdrawal symptoms. Jorenby and colleagues (1999) found that all three groups receiving active treatments compared with the placebo group reported reduced withdrawal. The group given both active patches and active bupropion reported the most consistent withdrawal relief. Further research is needed to characterize the reliability and magnitude of bupropion effects on withdrawal symptoms.

Relevant Process Measures

Although nicotine replacement therapies are strongly predicated on the assumption that nicotine will relieve withdrawal symptoms, withdrawal relief represents only one of several rationales for using bupropion as a smoking cessation aid. One hypothesis is that bupropion may selectively reduce depressive symptoms after cessation. However, both trials mentioned previously excluded individuals with current major depression. Both clinical trials (Hurt et al. 1997; Jorenby et al. 1999) also included multiple assessments of postcessation depressive symptomatology, and neither found any differences among treatment groups on these measures. These findings suggest that bupropion does not work through its antidepressant effects per se in relatively healthy clinical trial participants.

Bupropion moderates dopaminergic activity in the central nervous system, and dopaminergic circuits are known to play a role in drug reinforcement (Nutt 1997). This raises the possibility that bupropion may exert its effects by replacing positive reinforcement associated with smoking (Hurt et al. 1997). To date, there is no evidence directly bearing on this hypothesis, and it is clear that this process is not easily studied in clinical trials. Laboratory-based pharmacokinetic and neuroimaging studies should be performed to explore this hypothesis.

Effects of Postcessation Change in Body Weight

Hurt and colleagues (1997) found evidence for a dose-response effect among continuous abstainers, suggesting that participants given the highest doses gained less weight after quitting. Moreover, the disparities between treatment groups in terms of weight

gain increased across time while medication was dispensed. At six-month follow-up, 17 weeks after participants went off the assigned medication, no differences in weight gain were observed. These comparisons were limited to a small subsample of continuous abstainers. In the Jorenby and colleagues (1999) trial, members of all active treatment groups tended to gain less weight than did placebo participants over the first seven weeks of cessation. Weight gain suppression was greatest for the combined patch-bupropion group. However, none of the groups differed in weight gain after seven weeks after quitting. Together, the results of these trials suggest that bupropion treatment may delay, but not prevent, postcessation weight gain.

Side Effects

In both clinical trials, two side effects were reported more commonly among participants given bupropion than among those given placebo. Dry mouth was reported by 10 to 15 percent of bupropion users, and insomnia was reported by about 30 to 40 percent of bupropion users. Bupropion may increase the risk of seizure and is thus contraindicated for individuals who are seizure prone, such as individuals with a history of alcoholism or alcohol abuse, eating disorder, seizure disorder, or using MAO inhibitors. No seizures were reported in either clinical trial, but participants with risk factors for seizure were excluded from each before enrollment.

Clonidine

Clonidine is a centrally acting α_2 -adrenergic agonist that dampens sympathetic nervous system activity. Clonidine is most commonly used in the management of hypertension; it has not been approved by the FDA as an aid to smoking cessation. Clonidine is available for prescription in oral and transdermal forms; both of these preparations have been investigated in smoking cessation trials. Smokers using clonidine as an aid to smoking cessation are generally started on the drug several days before quitting and are maintained on a fixed daily dose for several weeks.

Efficacy

Covey and Glassman (1991) conducted a metaanalysis of nine early trials of clonidine for smoking cessation. They found that persons given clonidine were more successful at quitting than those given a placebo (OR = 2.36). Five of the nine trials assessed outcome after the therapy was discontinued; only one (Glassman et al. 1988) showed a significant overall advantage for clonidine. Clonidine trials using adjunctive behavioral therapy were associated with greater relative success (OR = 4.2) than were trials in which treatment essentially consisted of dispensing the drug (OR = 1.7). Trials using transdermal clonidine produced somewhat greater relative success (OR = 3.2) than did trials using oral clonidine (OR = 2.2). The two trials that analyzed efficacy according to sex found clonidine to be much more effective, relative to placebo, among women (OR = 11.0) than among men (OR = 0.9). There is no obvious explanation for this finding.

Since the Covey and Glassman (1991) metaanalysis, several large-scale clonidine trials have appeared (Prochazka et al. 1992; Glassman et al. 1993; Hilleman et al. 1993; Niaura et al. 1996). These studies indicated a therapeutic effect for clonidine, with some evidence suggesting that clonidine was more effective among women (Glassman et al. 1993; Hilleman et al. 1993) and among those most dependent on nicotine (Glassman et al. 1993).

A recent meta-analysis (Fiore et al. 2000) of five clinical trials reported a pooled OR for long-term effectiveness of 2.1 (25.6 percent abstinence rate) (Table 4.3). In these studies, the clonidine dose ranged from 0.1 mg to 0.75 mg per day and was delivered either orally or transdermally. Because of the side effects, the lack of a specific dosing regimen, the problems with abrupt discontinuation of the drug, and the lack of FDA approval, clonidine has been recommended as a second-line agent for smoking cessation (Fiore et al. 2000).

Effect on Discomfort of Nicotine Withdrawal

An early report (Glassman et al. 1984) that clonidine could reduce tobacco withdrawal symptoms, especially craving, spurred the initial investigations of clonidine's usefulness in smoking cessation. Since that report, evidence for this effect has been mixed. Clonidine- and placebo-treated patients have had equivalent levels of withdrawal severity (Wei and Young 1988; Franks et al. 1989; Gourlay et al. 1994). Studies have fairly consistently found that clonidine diminishes the specific symptom of craving (Glassman et al. 1984; Ornish et al. 1988; Prochazka et al. 1992; Gourlay et al. 1994), and some studies have found some effects on withdrawal symptoms, such as anxiety and irritability (Ornish et al. 1988; Prochazka et al. 1992).

Side Effects

Unpleasant side effects are commonly associated with clonidine use (Gourlay et al. 1994), and as many

as 25 percent of patients may discontinue clonidine therapy because of them (Covey and Glassman 1991). The most frequently observed symptoms are dry mouth, fatigue, and dizziness. Local skin irritation is common with transdermal clonidine therapy. The incidence of side effects appears to be dose dependent (Gourlay et al. 1994). Care must also be taken to discontinue clonidine gradually to prevent rebound hypertension. No published clinical trials have assessed the effect of clonidine on postcessation weight gain.

Relevant Process Measures

Clonidine is presumed to exert its effects by ameliorating withdrawal discomfort (Glassman et al. 1984; Franks et al. 1989). Although a few studies have found that clonidine reduces withdrawal discomfort, findings from a well-designed, large-scale multicenter trial (Prochazka et al. 1992) have suggested that this effect does not necessarily lead to greater abstinence.

Nortriptyline

Nortriptyline is a tricyclic antidepressant that blocks reuptake of norepinephrine and serotonin. As with clonidine, smoking cessation is not an FDA-approved indication for nortriptyline; its primary indication is for the treatment of depressive symptoms. It is a prescription medication and is available in generic form. In smoking cessation studies conducted to date, treatment was initiated 2–4 weeks before the target quit date with gradual titration of dose.

Efficacy

Two studies have assessed the efficacy of nortriptyline for smoking cessation. Hall and colleagues (1998) conducted a 2 (nortriptyline vs. placebo) x 2 (history vs. no history of major depression) x 2 (cognitive behavioral vs. health education therapy) trial that produced a 24-percent sustained abstinence rate in nortriptyline users compared with 12 percent in the placebo group. There was no difference in cessation rates as a function of previous history of major depression. In a straight comparison of nortriptyline to placebo, Prochazka and colleagues (1998) found cessation rates at six months of 14 percent in participants given nortriptyline and 3 percent in participants given placebo. A meta-analysis (Fiore et al. 2000) of these two studies reported a pooled OR of 3.2 and a 30.1-percent abstinence rate (Table 4.3). Both studies provide clear evidence of nortriptyline's therapeutic effect.

Effect on Discomfort of Nicotine Withdrawal

The Hall and colleagues (1998) study assessed both nicotine withdrawal symptoms and negative affect in the first eight days following the target quit date. There were no significant differences between the drug therapy groups on nicotine withdrawal severity, suggesting that as with many of the other smoking cessation pharmacotherapies, withdrawal relief may not be the primary mechanism of action. The negative affect measure, however, increased in the first three days in the placebo group and declined in the nortriptyline group. This suggests that a negative affect assessment may be more sensitive to some of nortriptyline's therapeutic effects than a conventional nicotine withdrawal symptom scale.

Side Effects

Tricyclic antidepressants are known to produce a number of side effects, including sedation and various anticholinergic effects. In the smoking cessation studies, commonly reported side effects included dry mouth (64–74 percent), lightheadedness (49 percent), shaky hands (23 percent), and blurry vision (16 percent) (Hall et al. 1998; Prochazka et al. 1998).

Other Antidepressants and Anxiolytics

Investigators have begun to explore the potential use of other antidepressants and anxiolytics as pharmacologic aids to smoking cessation, because population-based epidemiologic samples have found that depression and anxiety are associated with cigarette smoking (Breslau et al. 1991; Kendler et al. 1993). Research has also shown that smokers with a history of depression are more likely to experience depressive symptoms (Covey et al. 1990) and to relapse after quitting (Glassman et al. 1988; Anda et al. 1990) than are smokers without such a history. Some anxiolytics (Glassman et al. 1984; Hilleman et al. 1992) have been shown to ameliorate symptoms of tobacco withdrawal, and preliminary smoking cessation trials using antidepressants (Edwards et al. 1989) and anxiolytics (Hilleman et al. 1994) have yielded encouraging results. Among the drugs that have been studied or hypothesized to be useful for smoking cessation are buspirone hydrochloride, doxepin hydrochloride, and fluoxetine hydrochloride. Although promising, this avenue of research is not yet developed enough to permit the multipart discussion given to other pharmacologic agents in this chapter.

Summary of Pharmacologic Interventions

Abundant evidence confirms that both nicotine gum and the nicotine patch are effective aids to smoking cessation. The efficacy of nicotine gum may depend on the amount of behavioral counseling with which it is paired. The 4-mg dose may be the better pharmacologic treatment for heavy smokers or for those highly dependent on nicotine. The nicotine patch appears to exert an effect independent of behavioral support, but absolute abstinence rates increase as more counseling is added to patch therapy. Nicotine nasal spray and nicotine inhalers are effective aids for smoking cessation, although their mechanisms of action are not entirely clear. All nicotine replacement therapies produce side effects, but these are rarely severe enough that patients must discontinue use. Nicotine nasal spray appears to have greater potential for inappropriate use than other nicotine replacement therapies. Nicotine replacement therapies, especially the gum and the patch, have been shown to delay but not prevent weight gain. All nicotine replacement therapies are thought to work in part by reducing withdrawal severity. The available evidence suggests that they do ameliorate some elements of withdrawal, but the relationship between withdrawal suppression and clinical outcome is inconsistent.

Bupropion is the first nonnicotine pharmacotherapy for smoking cessation to be studied in largescale clinical trials. Results suggest that bupropion is an effective aid to smoking cessation. In addition, bupropion has been demonstrated to be safe when used jointly with nicotine replacement therapy. In the only direct comparison with a nicotine replacement product, bupropion achieved quit rates about double those achieved with the nicotine patch. Bupropion appears to delay but not prevent postcessation weight gain. The available literature contains inconsistent evidence regarding bupropion-mediated withdrawal relief. Bupropion does not appear to work by reducing postcessation depressive symptomatology, but its mechanism of action in smoking cessation remains unknown. Further research is needed to characterize bupropion's central nervous system effects, particularly to assess whether the drug partially replaces smoking-related positive reinforcement.

Evidence suggested that clonidine is capable of improving smoking cessation rates. Clonidine is hypothesized to work by alleviating withdrawal symptoms. Although clonidine may reduce craving for cigarettes after cessation, it does not consistently ameliorate other withdrawal symptoms, and its effects on weight gain are unknown. Unpleasant side effects are common with clonidine use.

Antidepressants and anxiolytics are potentially useful agents for smoking cessation. At present, only nortriptyline appears to have consistent empirical evidence of smoking cessation efficacy. However, tricyclic antidepressants produce a number of side effects, including sedation and various anticholinergic effects.

Large-Scale Public Health Programs

The shift in recent years from a clinical to a public health perspective in smoking cessation research has led to an increased emphasis on developing and evaluating cost-effective strategies that can be widely disseminated (Lichtenstein and Glasgow 1992). This emphasis is reflected in the proliferation of research on self-help manuals (see "Self-Help Manuals," earlier in this chapter and "Community Programs," later in this chapter) and on media- and community-based interventions (Flay 1987; Gruman and Lynn 1993).

As is true for self-help strategies, media-, worksite-, and community-based programs have promise because they can potentially reach many smokers who may try to quit without formal, face-to-face assistance (Fiore et al. 1990). Moreover, some evidence suggests that less educated smokers profit from media campaigns at least as much as more highly educated smokers do (Macaskill et al. 1992). (Other large-scale interventions—educational [Chapter 3] and social [Chapter 7]—are discussed separately.)

Investigators have evaluated an array of such programs, but methodological variations across the individual trials have hampered comparisons among studies (Flay 1987; Schwartz 1992). Moreover, methodological challenges compromise how research on these programs may be interpreted. For instance, ongoing coverage of smoking and its health consequences in the general media may alter the effect of researchbased media information. Similarly, secular trends and events that could individually affect large populations of smokers (e.g., the introduction of a new nicotine replacement product) may alter the impact—and complicate the assessment—of media campaigns conducted around the time of such events. Such challenges may account for the inconsistencies seen in this area of research.

Media-Based Programs

Media used to transmit smoking cessation messages have included television (Brannon et al. 1989; Korhonen et al. 1992; Mudde and De Vries 1999), radio (Farquhar et al. 1990; COMMIT Research Group 1991), the telephone (Ossip-Klein et al. 1991; Pierce et

al. 1992), newspapers (Cummings et al. 1987), and the mail (Gritz et al. 1992; McFall et al. 1993).

The intensity of media-based programs has varied greatly, and these variations may be related to program success. For example, one study (Gritz et al. 1992) evaluated a minimal mail-based intervention. The investigators mailed self-help smoking materials to a sample of nonvolunteer women who smoked and who belonged to a health maintenance organization. The intervention had no impact; at no point during the 18month follow-up period were women who had received the materials more likely to quit smoking or report changes in their motivation to quit than women who had not. In contrast, a more intense media campaign evaluated in another study (Orleans et al. 1991) yielded encouraging findings, albeit among treatment volunteers. The investigators tested the impact of adding telephone calls from a smoking cessation counselor to an intervention that mailed self-help manuals to the volunteers. After 16 months, abstinence from smoking was reported by 23.0 percent of the volunteers who had received adjuvant telephone counseling and by 15.2 percent of those receiving the self-help materials alone.

Mass media campaigns of intermediate intensity, such as televised programs (Flay et al. 1989), generally produce modest increases in abstinence—increases that fall short of the moderate effect of telephone counseling found among volunteers (Orleans et al. 1991). The influence of intermediate-intensity interventions is difficult to determine precisely, because the results of individual trials may be affected by the peculiarities of the specific communities in which they are tested and (as previously discussed) by concurrent changes in secular attitudes toward smoking behavior. These problems are compounded by the designs of communitywide and mass media programs frequently failing to include matched control communities for comparison. Although more intensive interventions appear to increase cessation over time (Flay 1987), the absence of well-controlled experimental media trials limit any conclusions about a dose-response relationship for media-based programs.

The content of various media-based programs can be divided into three categories: (1) programs that present information about the negative health effects of smoking and exposure to secondhand smoke and attempt to motivate smokers to quit; (2) programs that promote the performance of simple cessation-related activities, such as calling a hot line, requesting self-help materials, or enrolling in a smoking cessation contest; and (3) programs that mimic intensive clinical interventions (Flay 1987). In general, informational

or motivational campaigns can be effective in changing smokers' attitudes, but the effect of such campaigns on behavior is not clear, in part because of the paucity of well-controlled trials that yield a consistent pattern of findings. Research suggests that other types of campaigns have greater potential than informational programs to influence smoking behavior, especially if the campaign has multiple components and intense exposure (Flay 1987; CDC 1996, 1999b; Pierce et al. 1998).

Worksite Programs

For many years, advocates for tobacco control have been enthusiastic about worksite-based programs, because worksites appear to furnish an ideal setting: a contained audience, an opportunity for smoker participation, an environment in which to convey coherent and consistent messages, and an opportunity to tie individual smoking cessation to overarching institutional policy. Much of the early work in this area provided some justification for the enthusiasm (USDHHS 1986; Glasgow 1987; Fielding and Piserchia 1989), but more recent data, described later in this section (Glasgow et al. 1995; Sorensen et al. 1996), give pause.

The main components of smoking cessation efforts in the workplace are nonsmoking policies and specific assistance for cessation attempts (Gruman and Lynn 1993). The evolution of worksite smoking policies, intimately tied to concerns about the health effects of environmental tobacco smoke (ETS) (Eriksen 1986; USDHHS 1986), is described in some detail in Chapter 5. Although early assessment suggested that restrictive policies had little effect on smoking outside of work (Glasgow 1987; Rigotti 1989; Tager 1989), most recent studies have demonstrated either reductions in daily consumption of cigarettes (Stillman et al. 1990; Borland et al. 1991; Jeffery et al. 1994) or increases in smoking cessation (Stave and Jackson 1991; Patten et al. 1995; Longo et al. 1996). As described in Chapter 5 (see "Clean Indoor Air Regulation"), there is persistent movement toward increasing restrictions in public workplaces.

The strategies for smoking cessation within workplaces are largely those discussed earlier in this chapter: self-help, physician's advice, and formal treatment (Gruman and Lynn 1993). As of 1989, about one-half of worksites that sponsored cessation activities offered self-help materials (Fielding and Piserchia 1989). Although initial dropout rates were high, 20–26 percent of participants had quit smoking by 6–12 months after the worksite programs had begun (Orleans and Shipley 1982; Glasgow 1987). Such proportions compare favorably with those observed in general populations. Physician's advice to quit

smoking was a component of only about 15 percent of the company programs, but in a number of studies, this modality seemed to exert an effect similar to that observed in general populations: 15–30 percent of participants had quit smoking at the one-year follow-up (Gruman and Lynn 1993). The programs offering formal treatment appeared to produce results at the worksite that were similar to those found for such programs outside the workplace.

A special feature of worksite cessation programs is the opportunity to provide incentives, such as competitions. Several studies have documented some efficacy in this approach. For example, in one study, 33 percent of participating workers and 25 percent of all workers remained abstinent at work (Glasgow 1987). In a second study, the use of a competition was associated with significantly greater success at quitting than was reported for persons not participating in the competition (Klesges et al. 1988). In a review of incentive programs, from 15 to 60 percent of participants quit smoking; the average was around 40 percent (Gruman and Lynn 1993). Some disadvantages of incentives are that (1) determining the award may be difficult, (2) employees may falsely claim cessation, and (3) nonsmokers may feel slighted (Fiore et al. 1996). On a population basis, incentives have not been found to be effective. In these settings, incentives may be most attractive to smokers who were going to attempt quitting in any case (Chapman et al. 1993).

In contrast, a trial of the Take Heart program, which involved 26 heterogeneous worksites, a low-cost intervention, random assignment, and use of worker and management steering committees, failed to produce short-term improvements in smoking cessation that exceeded the secular trend (Glasgow et al. 1995). These results were particularly disheartening in view of the methodological strengths of the study and the diversity of the workplace settings. The authors offer a number of potential reasons for the lack of impact: the cessation activities may have been inappropriate; the behaviors may have been more resistant to change than previously assumed; workers may have had insufficient "ownership" of the project; secular trends may have been so strong that they canceled out a modest effect; the variability among worksites may have been too great; and, in general, worksite programs may not work.

Similar negative findings were observed by Sorensen and colleagues (1996) in an even larger trial of 111 worksites randomized to sites receiving or not receiving the cessation program. The Working Well Trial involved more than 28,000 workers in 16 states and compared seven-day abstinence, six-month

abstinence, and changes in smoking prevalence for both types of worksites. Changes occurred in the direction hypothesized, but they were small and non-significant; for example, the six-month abstinence rate was only 1.5 percent higher in the program group. Similarly, the program sites showed a nonsignificant trend toward greater adoption of smoking bans. The authors observed that the overall cessation proportions at both types of sites compared favorably with those in other worksite programs. The lack of difference may have resulted from the higher than expected cessation at control sites, which is a phenomenon reflecting a general increase in antismoking awareness.

These studies postdate recent reviews of worksite cessation efforts. Several early reviews expressed optimism about the value of worksite programs but did not provide a quantitative assessment (Hallett 1986; Bibeau et al. 1988). In a detailed meta-analysis of 20 worksite programs involving 34 comparisons, Fisher and colleagues (1990) found that the mean weighted effect size was significantly positive and that an average of 13 percent of participants had quit smoking after treatment. Although modest, these effects provide some quantitative basis for the enthusiasm for worksite programs. The addition of the two recent large projects (Glasgow et al. 1995; Sorensen et al. 1996) may well alter the meta-analytic balance.

Although the worksite setting has aforementioned features favorable to large-scale programs (including the importance of adding to a generalized reduction in exposure to ETS), the strategy cannot be recommended without qualification. Nonetheless, the role of such activities, perhaps enlightened by further targeted research, may be important in multicomponent efforts at smoking cessation.

Community Programs

Results from a number of long-term trials of communitywide programs have recently appeared. (See Chapter 7 for a more detailed discussion of these projects in the context of approaches used in the 1990s.) These trials typically incorporate mass media strategies into larger health education programs. Some, such as the Stanford Five-City Project (Farquhar et al. 1990), the Minnesota Heart Health Program (Perry et al. 1992; Luepker et al. 1994), and the Pawtucket Heart Health Program (Elder et al. 1986; Carleton et al. 1995), have been aimed at modifying smoking, as well as other risk factors for cardiovascular disease. Final reports suggest that these trials have met with little success in promoting smoking cessation.

The Stanford Five-City Project (Farquhar et al. 1990; Fortmann et al. 1993) tested an intensive multimedia approach, including television, radio, newspaper, and mass-distributed printed materials. All materials contained information about modifiable risk factors for cardiovascular disease. The average resident of a community receiving the program was exposed to more than 500 educational episodes over the course of the five-year program. By the end of this period, smoking prevalence—the only risk factor on which an impact could be demonstrated—had declined 13 percent more in the program communities than in the control ones. The Minnesota Heart Health Program failed to demonstrate an appreciable impact (Lando et al. 1995). The Pawtucket Heart Health Program had little impact on smoking behavior; its first attempt at a smoking cessation program prompted only 11 smokers to quit (Elder et al. 1986, 1987). The final results confirmed the lack of impact (Carleton et al. 1995).

One ambitious community project—COMMIT (Community Intervention Trial for Smoking Cessation)—focused on smoking cessation and on policy strategies to reduce prevalence (COMMIT Research Group 1991; Gruman and Lynn 1993). In 1986, the NCI began COMMIT, the largest randomized smoking intervention trial in the world. The design of COMMIT included 11 pairs of matched communities—10 from across the United States and 1 in Canada. One community from each pair was randomly selected to be the site in which volunteers and local agencies carried out COMMIT's 58 mandated program activities. Designed to augment existing community-based efforts to reduce smoking, these activities occurred between 1988 and 1992.

The primary end point for COMMIT was smoking cessation among heavy smokers. Main goals included increasing the priority of smoking as a public health issue, increasing the community's ability to influence smoking behavior, strengthening the community's existing economic and policy factors designed to discourage smoking, and fortifying social norms and values that stressed nonsmoking (Gruman and Lynn 1993). Main strategies included training health care providers to routinely assess and manage nicotine dependence, working with community institutions and private organizations to create smoke-free environments, increasing the availability and visibility of smoking cessation services, and using the mass media and schools to educate communities about the dangers of tobacco use.

Results of COMMIT indicate that even intensive community-based programs may not have a demonstrable impact on smoking behavior (COMMIT Research Group 1995a,b). Declines in smoking prevalence were no greater in program communities than in control communities (COMMIT Research Group 1995b). Although the overall populations in the program communities became more aware of available resources for smoking cessation, the prevalence of smoking cessation among persons who smoked more than 25 cigarettes per day did not differ between program (18.0 percent) and control communities (18.7 percent). Persons who smoked fewer than 25 cigarettes per day were significantly more likely to quit in program communities than in control communities (30.6 vs. 27.5 percent), and that result was attributable to success among light smokers with less than a college education (COMMIT Research Group 1995a).

Statewide Programs

Recent statewide initiatives have integrated tobacco policy and smoking cessation programs. Although Minnesota was the first state to implement a statewide initiative to reduce tobacco use, California has provided what is perhaps the most ambitious example. Massachusetts has also conducted a similar statewide effort based on a tax increase and incorporating a mass media campaign, policy initiatives, and smoking cessation services. These initiatives and others are discussed in detail in Chapter 7.

The state findings are promising. If this success is replicated by other states that adopt a dedicated increase in cigarette excise taxes, or that are able to use resources from settlements with the tobacco industry,

statewide and nationwide initiatives may play an important role in achieving the public health goal of reducing smoking prevalence among U.S. adults to less than 12 percent by the year 2010 (USDHHS 2000).

Summary of Large-Scale Public Health Programs

Community- and media-based programs have the potential to reach large numbers of smokers who are reluctant to seek formal treatment. Such programs could greatly influence smoking prevalence in the United States. The results from major randomized trials and community-based efforts are thus especially disappointing. Though these projects have set new standards for such research and have produced numerous ancillary results of interest, the overall conclusions suggest that even large-scale, well-funded programs may have difficulty promoting changes in smoking behavior. Similarly, the results to date from numerous worksite cessation projects suggest either no impact or a small net effect. On the other hand, results of the California and Massachusetts initiatives (see Chapter 7) suggest that tobacco taxes may be an effective means of funding efforts to reduce tobacco use. The states that have devoted money obtained from Medicaid settlements with the tobacco industry have also had considerable success in implementing a comprehensive approach (Chapter 7). Their results suggest that the disappointing outcomes from research programs may be related to the reach and penetration of these programs and the isolated context in which they were conducted.

Contemporary Issues in Research on Tobacco Addiction

Epidemiologic Concerns and Clinical Issues

Because smoking cessation research has focused more on improving standard paradigms than on innovative approaches (Shiffman 1993b), much of the current energy is directed to pursuing well-trod paths. But current directions have an internal logic, because no new paradigms loom large. Established approaches are perhaps unfairly criticized for lacking innovation. As the foregoing discussion demonstrated, valid methods for treating nicotine addiction are available, but

they must be better understood and can be improved. Despite considerable research on smoking cessation during the past 40 years, the essential elements or combination of elements necessary for successful programs are difficult to extract. In a number of key areas, however, careful research can sharpen interpretation of existing results and provide direction for future investigation and perhaps even innovation.

Nicotine Dependence

Dependence, a central construct in research on drug abuse, has been defined as "self-administration of a psychoactive drug in a manner that demonstrates that the drug controls or strongly influences behavior" (USDHHS 1988, p. 248). Evidence strongly suggests that most smokers are dependent on nicotine (USDHHS 1988). However, most researchers agree that individual smokers differ in the degree to which they are dependent (Fagerström 1978; McMorrow and Foxx 1983; Pomerleau et al. 1983; Shiffman 1989; Killen et al. 1992; Niaura et al. 1994). Some occasional smokers may not meet the criteria for physical dependence (Shiffman et al. 1991). These differences in degree of nicotine dependence have important implications for treatment and research.

Flaws in the assessment of nicotine dependence have impeded progress toward understanding its role in smoking cessation. For example, nicotine dependence consists of both physical and behavioral components (USDHHS 1988). However, most smoking cessation researchers have used the term to refer to physical dependence exclusively. Although items in two widely used nicotine-dependence assessment instruments (the Fagerström Tolerance Questionnaire and its successor, the Fagerström Test for Nicotine Dependence) assess the extent to which nicotine controls behavior, the instruments are intended to measure physical dependence (Fagerström 1983; Fagerström and Schneider 1989; Heatherton et al. 1991). Other investigators have measured dependence by how much nicotine smokers typically self-administer (Hurt et al. 1994) or by the severity of withdrawal symptoms (Brigham et al. 1990–91); these two measures are typically not highly correlated with each other, and neither is highly correlated with the Fagerström questionnaires (Kenford et al. 1994). Furthermore, the scales themselves, especially the Fagerström Tolerance Questionnaire, suffer from psychometric limitations (Lichtenstein and Mermelstein 1986; Pomerleau et al. 1989; Tate and Schmitz 1993). In sum, tobacco research is hampered by an inadequate conceptualization of nicotine dependence and an inadequate assessment of the nicotine dependence construct.

Because widely used dependence instruments such as the Fagerström questionnaire are thought to measure physical dependence, it has been hypothesized that they can help identify patients who would benefit from nicotine replacement therapies (Fagerström and Schneider 1989) or from higher doses of these therapies. The evidence for this assertion is mixed, with support somewhat more consistent for the nicotine

gum than for the nicotine patch (Abelin et al. 1989; Fagerström and Schneider 1989; Transdermal Nicotine Study Group 1991; Killen et al. 1992; Kenford et al. 1994; Niaura et al. 1994; Tang et al. 1994). To the extent that current measures capture variation in dependence, they would be expected to predict outcome in trials not using nicotine replacement and in groups of subjects treated with placebo nicotine replacement. Although this hypothesized correlation between dependence measures and outcome has been found in several studies (Fagerström and Schneider 1989), the correlations have tended to be weak (Gritz et al. 1991; Kozlowski et al. 1994) and have usually been significant only at relatively short-term follow-up points (Hall and Killen 1985; Pinto et al. 1987; Gritz et al. 1991; Nørregaard et al. 1993). Specialized assessments of nicotine dependence are not recommended in current treatment guidelines, and pharmacotherapy is recommended for all tobacco users interested in quitting. The one exception is that highly dependent smokers may derive more benefit from 4-mg (as compared with 2-mg) nicotine gum (Fiore et al. 2000).

Other measures of nicotine dependence have been developed, but these have fared no better than the Fagerström questionnaire. For example, the Heaviness of Smoking Index, a derivative, offers no advantage in predicting cessation (Kozlowski et al. 1994). Older measures of smoking motives, such as the Horn-Waingrow Reasons for Smoking Scale (Horn and Waingrow 1966) and McKennell's occasion for smoking scales (McKennell 1970), have good psychometric properties but questionable construct validity (Shiffman 1993a).

Continued reconceptualization of nicotine dependence and improved consensus on mechanisms for measuring it are critical issues for future study. Stronger ties to generic issues of substance abuse—already begun but not discussed in detail here (see Orleans and Slade 1993)—can facilitate such research and improve recognition of behavioral mechanisms that are common to the use of all addictive substances.

Stages of Change

Smokers differ in their motivation to quit smoking, and these differences are thought to affect treatment prognosis. The transtheoretical model, advanced by Prochaska and DiClemente (1983), provides a theoretical structure for assessing these differences and has greatly influenced smoking cessation research in recent years. Briefly, the model proposes that smokers go through a series of stages (not necessarily linearly) on the way to achieving prolonged abstinence from smoking: not thinking seriously about quitting in the

next six months, thinking seriously about quitting in the next six months, planning to quit in the next month, actually trying to quit, and trying to remain abstinent. If relapse occurs, smokers return to an earlier stage in the model. It is hypothesized that smokers in the initial stages are less ready to quit and thus less likely to profit from traditional treatments (see Orleans 1993 for a more detailed discussion).

Some evidence supports the notion that smokers in earlier stages of change fare worse in smoking cessation than do smokers in later stages (DiClemente et al. 1991; Kristeller et al. 1992; Ockene et al. 1992; Rohren et al. 1994). The finding of interactions between treatment assignment and stage membership (Prochaska et al. 1993) has led to the recommendation that clinical protocols for smoking cessation be based on stage assessments (Abrams 1993; Orleans 1993; Velicer et al. 1993; Hughes 1994).

Evidence is not available, however, that linking motivational stage to a stage-appropriate strategy leads to better outcomes than do nontailored interventions of equal intensity (see Prochaska et al. 1993; Fiore et al. 2000), perhaps because motivation to change is more a continuum than a set of discrete states (Lichtenstein et al. 1994). Nonetheless, the stages-of-change model has considerable theoretical and empirical appeal as a typology that is easy to use in day-to-day decision making (Wiggins 1988). Further refinement and clarification of this model, coupled with continued assessment of its relationship to smokers' probability of quitting, is a potentially fruitful research area.

Negative Affect

A negative affective reaction to quitting tobacco use (Baker et al. 1987; Brandon 1994; Hall et al. 1994) may be an important predictor of relapse (Shiffman 1982; Brandon et al. 1990; Piasecki et al. 1997). As mentioned previously, depressed persons are less likely to quit smoking successfully than persons without a history of depression (Glassman et al. 1988; Anda et al. 1990), and depressed persons suffer an increase in symptoms after quitting (Covey et al. 1990; Hall et al. 1991). These related findings have special importance because the frequency of clinical depression among smokers may exceed that among nonsmokers (Frederick et al. 1988; Hall et al. 1991; Brandon 1994).

The role of adverse psychological states—even mild conditions—in prolonging smoking and impeding cessation is an important avenue for further investigation. For example, depressed or otherwise affectively disturbed persons may require special

interventions to succeed in smoking cessation; at least two studies have identified behavioral treatments that have boosted success rates among such persons (Zelman et al. 1992; Hall et al. 1994). As noted, antidepressants and anxiolytics have been proposed as smoking cessation aids and are undergoing clinical trials because of their ability to ameliorate negative affects.

Sex-Specific Differences

Some studies (Pomerleau et al. 1991; Kenford et al. 1993; Swan et al. 1993), but not all (Derby et al. 1994; Whitlock et al. 1997; Gritz et al. 1998), have suggested that women find it more difficult than men to quit smoking. The quit ratio (the proportion of persons who have quit smoking out of those who ever smoked) has increased at the same rate or at a faster rate among women than men in recent years (Fiore et al. 1989; Giovino et al. 1994; Husten et al. 1996). An extensive review of difference in nicotine effects between men and women (Perkins et al. 1999) cites complex differences in psychological and biologic aspects in the maintenance of nicotine self-administration. Women may differ from men in the response to withdrawal, possibly mediated by menstrual cycle phase (Perkins et al. 2000), as well as a variety of nonnicotine effects (Perkins et al. 1999). For example, although the same treatments benefit both women and men, some treatments (e.g., nicotine replacement therapies) may be less efficacious in women (Perkins 1996; Wetter et al. 1999; Fiore et al. 2000). Other reviews of this phenomenon (Fant et al. 1996; Christen and Christen 1998) confirm the need for further exploration of such differences.

A further difference between men and women may be related to genetic factors, particularly differences by sex in the metabolism of nicotine (Messina et al. 1997; Tyndale et al. 1999). These studies have focused on differences in the roles of enzymes involved in the metabolism of nicotine to cotinine (enzymes CYP2A6 and CYP2D6). The considerable variability in nicotine metabolism appears to be due to variable expression of CYP2A6 (Messina et al. 1997) and may play a role, as yet undefined, in gender response to therapeutic modalities. Other researchers, using studies of twins, have postulated that genetic factors may play a role in predicting which cigarette smokers progress to long-term addiction, an effect that may be stronger for men than for women (Heath et al. 1998).

Withdrawal Symptoms

The vast majority of smokers become physically dependent on nicotine, and these persons commonly

display several withdrawal symptoms when deprived of the substance (Shiffman and Jarvik 1976; USDHHS 1988; Hughes et al. 1991b). Conventional wisdom holds that two persons who have different degrees of nicotine dependence will have different degrees of withdrawal severity when they quit smoking (Fagerström 1978; Gritz et al. 1991; Hughes 1993). Withdrawal symptoms are presumed to give a conflicting (and often canceling) motivation to people who have otherwise been motivated to quit (West 1984; Hughes et al. 1991b). The severity of the withdrawal is thus expected to be a strong predictor of eventual relapse (Gritz et al. 1991; West 1992; Hughes 1993). Some research suggests that the various discomforts of abstinence are valid indicators of eventual relapse (Baker et al. 1987; Anda et al. 1990; Hughes 1992; Zelman et al. 1992). Despite the intuitive appeal of this proposed association, other studies have found an inconsistent relationship between withdrawal severity and relapse (Hughes et al. 1984; Hughes and Hatsukami 1986; Stitzer and Gross 1988; West et al. 1989; Transdermal Nicotine Study Group 1991; Prochazka et al. 1992; West 1992; Hughes 1993). Interpretation of this literature remains complicated because researchers use different instruments to assess withdrawal, sometimes reporting total withdrawal discomfort and other times reporting results on a symptom-by-symptom basis, and because they assess symptomatology at different time points. Improved assessment of withdrawal and consensual definitions, coupled with epidemiologic assessment, may better clarify the critical connection between the withdrawal syndrome and the likelihood of relapse. Recent studies demonstrate that there is considerable between-subject variability in the time course of smoking withdrawal and suggest that more consistent links between withdrawal and relapse may be found if this variability is systematically assessed (Piasecki et al. 1998).

Weight Gain

As noted earlier in the discussion of specific modalities, weight gain is a common concomitant of smoking cessation (Klesges et al. 1989). The average smoker gains 5–10 pounds after cessation, and a small percentage of smokers gain more than 25 pounds (Klesges et al. 1989; Williamson et al. 1991). The concern that smokers express about gaining weight may be great enough to prevent them from attempting to quit (Klesges et al. 1988; Gritz et al. 1989; French et al. 1992). Similarly, persons who quit smoking and who do subsequently gain weight may be more likely to relapse (Wack and Rodin 1982; Hall et al. 1986). Two

prospective studies, however, found that concern about weight did not predict cessation success (French et al. 1995; Jeffery et al. 1997). Innovative strategies have failed to reduce weight gain or to improve abstinence rates among persons concerned about gaining weight (Hall et al. 1992; Pirie et al. 1992). Because weight change is a complex metabolic phenomenon (about which there is a considerable epidemiologic and biologic literature, not reviewed here) that is subject to the interplay of behavioral and pharmacologic influences, further research on the behavior and physiological mechanisms that produce postcessation weight gain may suggest new strategies for dealing with this problem and may provide insights into mechanisms of addiction.

Early Relapse

Three recent reports from four trials of the nicotine patch have found that any smoking during the first two weeks of using either the nicotine or the placebo patch is a strong predictor of relapse at long-term follow-up (Hurt et al. 1994; Kenford et al. 1994; Stapleton et al. 1995). For example, Kenford and colleagues (1994) analyzed data from two patch trials. In both trials, large proportions (97.1 and 83.3 percent) of patients treated with the nicotine patch who smoked during the second week of treatment had relapsed by the six-month follow-up. Early relapse may predict longer-term failure—regardless of the cessation strategy, if any—because physiological and behavioral forces may present their most significant challenges to smokers during the first two weeks they try to quit. Strategies that could shepherd smokers through the first two weeks without a single cigarette might be expected to improve treatment outcome. According to another view, most lapses during the first two weeks of treatment merely identify those smokers who will find it difficult to quit no matter what the intervention. Even if given adjunctive interventions to help them pass this two-week period without smoking, these smokers would be expected to relapse soon after these adjuncts were withdrawn. Research on treatments for persons who are strongly addicted and likely to relapse early (should they attempt cessation at all) is a great challenge for cessation research.

Dose-Response

More intense interventions yield better outcomes (Kottke et al. 1988; Lichtenstein and Glasgow 1992; Fiore et al. 1994c, 2000). Although this general relationship has not been precisely explained, outcomes

may be influenced by a host of structural factors, including session length, session frequency, total number of sessions, and number and types of treatment modalities (e.g., telephone contacts and individual vs. group formats).

More specific issues must be clarified, such as determining what level of adjuvant behavioral support is most cost-effective when used with pharmacotherapy. However, a central question surrounding the use of intensive interventions is whether a greater proportion of smokers can be motivated to enroll in such treatment. Debate over whether program refinements can improve outcomes may be moot, from a public health perspective, if most smokers continue to shy away from—or cannot afford to spend the time or money needed for-intensive interventions (Fiore et al. 1990; Lichtenstein and Hollis 1992). A final area for dose-response research concerns the optimal dose for nicotine replacement. Two recent studies (Jorenby et al. 1995b; Hughes et al. 1999) have found that doubling the normal patch dose does not improve cessation outcomes. There may be some benefit, however, to combining different smoking cessation pharmacotherapies (Blöndal et al. 1999; Jorenby et al. 1999), including two different nicotine pharmacotherapies (Fiore et al. 2000).

Treatment Components

Defining the individual impact of treatment components will require controlled trials that systematically manipulate individual treatment components against a background of constant treatment intensity. As Lichtenstein and Glasgow (1992) have noted, smoking cessation researchers have largely abandoned this line of research because most comparison studies (though not all; see Stevens and Hollis 1989) failed to find significant treatment effects. Nonetheless, until the combined effects of treatment components can be determined, empirical design of multicomponent treatments will be difficult.

Individualized Treatment

Investigators have become increasingly interested in seeking interactions between treatment content and smokers' characteristics. Identifying such interactions would allow individual smokers to be given specific interventions to maximize their chances of attaining long-term abstinence. Although subject-by-treatment interactions have been obtained (Zelman

et al. 1992; Niaura et al. 1994), these relationships remain too elusive to suggest an overall strategic theory. Research that incorporates unconfounded comparisons of specific ingredients may suggest algorithms for matching patient and treatment. In view of the increasing presence of the computer in many people's lives, computer-assisted tailored treatments warrant further exploration. Some tailoring and individualization may be appropriate for older smokers whose other medical problems and pharmacologic treatment must be given special consideration (Rimer and Orleans 1993). Currently, however, there is insufficient evidence to recommend individually tailored interventions (Fiore et al. 2000).

An alternative to treatment matching is the strategy of offering smokers increasingly more intensive treatments as they continue to have trouble quitting (Abrams 1993; Orleans 1993), despite the risk that this strategy will reinforce failure. There is insufficient evidence, however, to recommend such a stepped-care approach (Fiore et al. 2000). Research must first reveal hierarchies of treatment as well as determine when patients should be given more intensive interventions.

Dissemination and the Role of the Clinician

Because self-help and minimal clinical interventions are likely to continue to be the preferred method of cessation for most smokers, innovative strategies must be developed to improve efficacy and delivery (Cohen et al. 1989b; Orleans et al. 1991; Fiore et al. 1995). Some of the most effective of the minimal clinical interventions include the institutionalization of system changes as core components of health care (Glynn and Manley 1993; Fiore et al. 2000). For example, having a screening system in place to identify smokers triples clinician intervention (Fiore et al. 2000).

Dissemination is intimately tied to the willingness of clinicians to advise their patients about smoking. An important area for ongoing research is the investigation of strategies that foster this behavioral role not only among physicians but also among a broad range of health care providers, including dentists, nurses, pharmacists, chiropractors, psychologists, physician assistants, and pulmonary technicians. But it is unlikely that behavioral modification for clinicians would be sufficient to produce the required dissemination. Reimbursement policies, financial incentives, and underlying institutional support are all critical for the effective management of tobacco addiction through clinical interventions (Kaplan et al. 1995; Rothenberg et al. 1998).

Cost-Effectiveness

Ultimately, the test of clinical modalities for treatment of nicotine addiction will be their survival in the current environment of cost containment and managed care. Private insurers are unlikely to embrace such treatment unless "they are convinced that there is a market for such a product and that it is viable financially" (Schauffler and Parkinson 1993, p. 189). For public insurers, demonstration of cost-effectiveness has become the de facto standard for adoption of new technology (G. Wilensky, cited in Schauffler and Parkinson 1993, reference 17), though some may insist on cost-savings, a strict standard of proof, for preventive practices.

Smoking cessation has been called the "gold standard" of cost-effective interventions (Eddy 1992). A number of studies (and several reviews [Elixhauser 1990; CDC 1992; Tsevat 1992]) have addressed issues of cost-effectiveness in behavioral counseling. Cummings and colleagues (1989c) calculated that the cost-effectiveness of brief office counseling during a routine visit ranges from \$705 to \$988 per year of life saved for men and from \$1,204 to \$2,058 for women. The use of nicotine gum increases the cost-effectiveness fourfold. Oster and colleagues (1986) performed a similar study incorporating nicotine gum with brief office counseling. The costs per year of life saved ranged from \$4,113 to \$6,465 for men and from \$6,880 to \$9,473 for women. Both studies noted that these costs compare favorably with those derived for other widely accepted preventive practices. Altman and colleagues (1987) found that self-help materials cost \$22–144 per person who quit, a cessation contest costs \$129-239, and a cessation class costs \$235–399. In the setting of acute myocardial infarction, Krumholtz and colleagues (1993) concluded that a nurse-managed smoking cessation program after myocardial infarction was cost-effective, particularly when compared with other modalities. (These studies are not necessarily reported in standardized dollars and are then only roughly comparable.)

An analysis of the cost-effectiveness of implementing the 1996 Agency for Health Care Policy and Research-sponsored Clinical Practice Guideline *Smoking Cessation* reported that cost per quality-adjusted-life-year saved ranged from \$1,108 to \$4,542. This compares very favorably with \$61,744 for annual mammography for women aged 40–49 years and \$23,335 for hypertension screening in 40-year-old men (Cromwell et al. 1997).

Because smoking during pregnancy is associated with lower birth weight, which in turn has been linked to various adverse outcomes of pregnancy, cessation of

smoking in pregnancy has been the subject of a number of economic analyses. Several of these have been performed in a managed care setting. Using patients in a study performed by the Maxicare Research and Educational Foundation, Ershoff and colleagues (1990) weighed the intervention's programmatic costs against the smoking-related increased costs of medical care incurred by mothers who continue smoking and by their infants. The program consisted of an initial interview, smoking counseling by a health educator, and a series of self-help books mailed to participants. The nonsmoking message was reinforced at prenatal care visits. The investigators concluded that in a health maintenance organization of 100,000 members, the cost savings from the cessation program was \$13,432, the net benefit was \$9,202, and the benefit-to-cost ratio was 3.17:1.

Windsor and colleagues (1988) compared three cessation protocols for women in public health maternity clinics: standard care, standard care combined with use of a cessation manual developed by the American Lung Association, and standard care combined with the use of that manual and a pregnancy-specific manual. At the end of pregnancy, smoking cessation had been achieved by 2 percent, 6 percent, and 14 percent, respectively, of women in the three groups. The investigators calculated cost-effectiveness as the cost per patient divided by the percentage who quit. The respective values were \$104.00, \$118.83, and \$50.93. In a second study (Windsor et al. 1993), the treatment group in a multicomponent intervention involving counseling and support had a cessation rate of 14.3 percent, and the control group had a rate of 8.5 percent. Under varying assumptions, the economic analysis found that benefit-to-cost ratios ranged from 6.72:1 to 17.18:1 and that estimated savings from statewide use of the program ranged from \$247,296 to \$699,240.

Marks and colleagues (1990) estimated the benefits that would accrue from shifting low-birth-weight infants into the normal-birth-weight category, from averting deaths attributable to prematurity, and from avoiding the long-term costs associated with the care of premature infants. They concluded that the ratio of savings to costs would be as high as 6:1. If long-term costs were omitted, the ratio would still be \$3.31 for each \$1 spent. Finally, in a somewhat different approach to the problem, Shipp and colleagues (1992) tried to identify the break-even point for the cost of a smoking cessation program. Under general circumstances, the break-even cost was \$32 per pregnant woman, but this cost varied from \$10 to \$237, depending on the probability of adverse outcomes in various populations.

As Schauffler and Parkinson (1993) point out, economic analyses of smoking cessation are often based on hypothetical populations, start with different assumptions about prevalence and intervention effectiveness, and differ in their estimation of outcomes. Although initial results are encouraging, considerable work is needed to codify the results and make them appealing to insurers and employers. In a recent survey, only 8.6 percent of large corporations in California had even considered using smoking status in their risk ratings, and only 2.2 percent had implemented such a rating. About 20 percent of companies offered plans that covered smoking cessation services (Schauffler and Parkinson 1993). Perhaps observations comparing long-term hospitalized care of smokers and nonsmokers will alter this policy. A recent study estimated that helping one smoker to quit reduces anticipated medical costs associated with acute myocardial infarction and stroke by \$893 over seven years (Lightwood and Glantz 1997). Wagner and colleagues (1995) point out that smokers have consistently increasing rates of hospitalization over five to six years of follow-up. In contrast, smokers who quit have increased hospitalization during the year in which they quit (probably associated with the medical reason—e.g., emphysema—for quitting in many cases); this rate declines thereafter. The authors note that the cost savings that accrue from reduced utilization would more than pay for effective cessation interventions within three to four years.

The alteration of terminology—from "smoking cessation" to "treatment of nicotine dependence"—acknowledges the need to make cessation activity consonant both with modern medical practice and with the current climate for health care delivery. The current body of evidence suggests that efficacious and cost-effective therapeutic modalities are available and that such consonance can be achieved. Further investigation not only of theoretical cost-effectiveness but also of actual use-effectiveness will have considerable impact on institutionalizing the treatment of nicotine addiction.

Conclusions

- 1. Tobacco dependence is best viewed as a chronic disease with remission and relapse. Even though both minimal and intensive interventions increase smoking cessation, most people who quit smoking with the aid of such interventions will eventually relapse and may require repeated attempts before achieving long-term abstinence. Moreover, there is little understanding of how such treatments produce their therapeutic effects.
- 2. There is mixed evidence that self-help manuals are an efficacious aid to smoking cessation. Because these materials can be widely distributed, such strategies may have a significant public health impact and warrant further investigation.

- 3. Programs using advice and counseling—whether minimal or more intensive—have helped a substantial proportion of people quit smoking.
- The success of counseling and advice increases with the intensity of the program and may be improved by increasing the frequency and duration of contact.
- 5. The evidence is strong and consistent that pharmacologic treatments for smoking cessation (nicotine replacement therapies and bupropion, in particular) can help people quit smoking. Clonidine and nortriptylene may have some utility as second-line treatments for smoking cessation, although they have not been approved by the FDA for this indication.

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Introduction

Efforts to regulate the use of tobacco date back to its introduction to European colonists of North America (see Chapter 2). As noted, these early movements to restrict tobacco use were motivated less by health concerns than by complex political, economic, and social factors. With the appearance in the 1950s of substantial scientific evidence on specific health risks of smoking, and with subsequent dissemination of that information in the 1960s, general support for a government regulatory response emerged.

As noted in Chapter 1, such regulatory activities do not necessarily fit the traditional concept of "intervention," but their effect is to change the way people use tobacco. Because advertising and promotion are perhaps the chief social force for continued tobacco use, their regulation—or the failure to regulate them can have substantial effects on smoking prevalence. The manner in which the product is manufactured, packaged, and distributed can similarly influence people's decision to smoke. Regulation of smoking in public places provides an opportunity to reduce the quantity of tobacco used, the prevalence of smoking, and the exposure of nonsmokers to environmental tobacco smoke. The regulation of minors' access to cigarettes has considerable potential for postponing or preventing the uptake of smoking, thereby making a long-term impact on the smoking epidemic. Finally, personal litigation and the tort system can influence the policies and practices of the tobacco industry and can have an impact on social perceptions of smoking.

Thus, if a broad definition of intervention can be entertained, each of these regulatory processes can be assessed for the nature of its influence on the use of tobacco. Unlike assessments of more traditional interventions (see Chapters 3 and 4), evaluation of regulatory processes must invoke a different set of measurement tools that are less quantitative but not necessarily less compelling (see Chapter 1).

Several key developments in the mid-to-late 1990s have propelled tobacco regulation in new directions and into new forums. Three key events have catalyzed these changes. They are discussed briefly in the next sections and in greater detail later in this chapter in "Further Regulatory Steps" and "Litigation Approaches."

Food and Drug Administration (FDA) Regulations

First, on August 28, 1996, after receiving public comment on a proposed rule, the FDA issued final regulations restricting the sale, distribution, advertising, and promotion of cigarettes and smokeless tobacco (Federal Register 1996). Several tobacco companies, retailers, and advertisers sued the FDA to block the implementation of the regulations, arguing that the agency lacked the jurisdiction or authority to regulate these products and that the proposed advertising restrictions violated the First Amendment of the United States Constitution (Coyne Beahm, Inc. v. Food and Drug Administration, No. 2:95CV00591 [N.C. Aug. 10, 1995], cited in 10.5 Tobacco Products Litigation Reporter [TPLR] 3.379 [1995]).

On April 25, 1997, the federal district court in Greensboro, North Carolina, ruled that the FDA had the authority to regulate cigarettes and smokeless tobacco products, as drug delivery devices, under the Federal Food, Drug, and Cosmetic Act (Coyne Beahm, Inc. v. U.S. Food & Drug Administration, 966 F. Supp. 1374 [M.D.N.C. 1997]). The court upheld all of the FDA's 1996 restrictions involving youth access to tobacco products and regulating product labeling. However, the court "stayed," or temporarily blocked, implementation of most of these provisions. The only FDA regulations that escaped this stay were the prohibition on sales of cigarettes and smokeless tobacco to minors and the requirement that retailers check photo identification of customers who appear to be under 27 years of age. These provisions went into effect on February 28, 1997. The age and identification provisions remained in force until the Supreme Court's March 21, 2000, decision.

Most notably, the court invalidated the FDA's restrictions on the advertising and promotion of cigarettes and smokeless tobacco. Both sides in the FDA case appealed the decision to the Fourth Circuit of the United States Court of Appeals in Richmond, Virginia. A three-member panel of the court overturned the lower court's decision and ruled that the FDA lacked the authority to regulate tobacco products. The full Fourth Circuit Court of Appeals declined to review

this reversal. The government petitioned the United States Supreme Court for review, and the Supreme Court accepted the case in April 1999. Oral argument was held December 1999, and the Court, in a 5 to 4 decision, upheld the Fourth Circuit's decision on March 21, 2000. The FDA continued to enforce the age and photo identification provisions while the case was appealed to the United States Supreme Court. On March 21, 2000, the Supreme Court ruled that although premature deaths from tobacco use present "one of the most troubling health problems facing our nation today" (Food and Drug Administration v. Brown & Williamson, 529 U.S. _ [2000], 120 S. Ct. 1291), the FDA lacks the authority to issue and enforce its tobacco regulations.

These developments, central to most of the regulatory efforts covered in this chapter, are discussed in detail in the major section "Product Regulation," later in this chapter.

Initial Attempts at Multistate Settlement and Federal Legislation

Second, on June 20, 1997, a group of 41 state attorneys general presented a tobacco settlement proposal to the American public (Tobacco Products Litigation Reporter 1997a; see "Legislative Developments" and "Master Settlement Agreement," later in this chapter). In essence, the proposal was intended to settle all pending lawsuits against the tobacco industry brought by states and other governmental entities as well as all pending class action lawsuits. Although the settlement did not include 9 of the 50 states, its scope was inherently national: to enact its stipulated regulations of the tobacco industry, the settlement presumed the passage of congressional legislation that would necessarily affect the legal rights of all Americans. The settlement included provisions for FDA authority, new warning labels, advertising restrictions, youth access prohibitions, rules to reduce public exposure to environmental tobacco smoke, and a provision designed to provide financial incentives for tobacco manufacturers to reduce sales to underaged consumers.

Despite its intuitive appeal—that the slow, and largely unsuccessful, course of change possible through individual lawsuits would be retired for a sweeping, national, unified policy that dealt with the tobacco problem—the settlement raised concerns from the start. Public health advocates recognized that given the settlement's national scope, it was taking on the role of being the chief public health policy tool for reducing tobacco use. These critics feared that the

settlement (and moreover the legislation it presumed) would fail in this role. In particular, by limiting future lawsuits against the tobacco industry, the settlement might in the end benefit the industry more than the public.

A number of bills filed in Congress in 1997 and 1998 intended to codify the terms of the proposed national settlement. One of the bills, S. 1415 (National Tobacco Policy and Youth Smoking Reduction Act, 105th Cong., 2nd Sess., S. 1415, Congressional Record, 144:S5034–S5084), which ultimately departed from the settlement proposal in a number of areas, was debated on the Senate floor for several weeks. It was vehemently opposed by the tobacco industry and rejected by the Senate almost one year to the day after the attorneys general announced the proposed national settlement. The regulatory implications of the national settlement proposal are discussed together with the FDA rules, primarily in the "Product Regulation" section of this chapter.

Ultimately, this activity served as prologue to a Master Settlement Agreement that was negotiated in November 1998. On November 23, 1998, the agreement was reached between state attorneys general and major U.S. tobacco companies to settle pending and prospective lawsuits by states to recover Medicaid expenditures incurred as a result of tobacco use. Fortysix states signed the agreement, pending the required ratification in state courts (four states settled separate, individual lawsuits with the industry). The agreement requires tobacco companies to pay \$246 billion to states over 25 years and to adhere to specified restrictions on tobacco advertising and promotion. Some provisions are also made for improved disclosure of tobacco industry documents released in litigation. A separate, parallel agreement with the United States Tobacco Company was negotiated for smokeless tobacco products.

Public and Private Litigation

Third, throughout 1997 and 1998, while federal legislation was being filed and debated, the states of Mississippi, Florida, Texas, and Minnesota settled their lawsuits against the tobacco industry. Besides producing sizable settlement funds for the individual states, these settlements (in all but Mississippi) feature provisions akin to public health regulations. For example, the Florida settlement (*Florida v. American Tobacco Co.*, Civil Action No. 95-1466 AH, secs. II.A.1 and II.A.2 [Fla., Palm Beach Cty. Aug. 25, 1997]) was the first to incorporate a ban on outdoor advertising and to call for statewide restrictions on vending machines. The

Minnesota settlement (*Minnesota v. Philip Morris Inc.*, No. C1-94-8565 [Minn., Ramsey Cty. May 8, 1998], *cited in* 13.2 TPLR 3.39 [1998]), which followed a trial and the release of thousands of incriminating internal documents from the tobacco industry, contains an even wider array of public health restrictions, including a ban on promotional items and a national prohibition on commercial placement of tobacco products in movies.

Settlements of other private suits against the industry in the late 1990s have also resulted in important regulatory measures. For example, in a class action lawsuit alleging that flight attendants were injured by exposure to environmental tobacco smoke (*Broin v. Philip Morris Inc.*, No. 91-49738 CA [22] [Fla., Dade Cty. Oct. 9, 1997], *cited in* 12.6 TPLR 3.397 [1997]), the tobacco industry agreed to support legislation banning smoking on all airlines departing from or landing in the United States. In a California case, R.J. Reynolds

Tobacco Company agreed to accept advertising restrictions and to fund counteradvertising programs for teens. The latter provision was based on a claim that the company was violating the California consumer protection law by using their Joe Camel advertising campaign to target minors (*Mangini v. R.J. Reynolds Tobacco Co.*, No. 939359 [Calif. Sept. 8, 1997], cited in 12.5 TPLR 3.349 [1997]).

As of September 1998, these nonnational litigations against the tobacco industry had had a greater and more immediate impact on tobacco regulation than the delayed FDA rules, proposed national settlement, and defeated federal legislation. Regulation through litigation is a new tool for reducing tobacco use. Specific regulatory measures contained in these smaller-scope settlements are discussed in relevant sections of this chapter.

Advertising and Promotion

Introduction

Industries use various marketing tools and strategies to influence consumer preference, thereby increasing market share and attracting new consumers. The tobacco industry is among the most intense in its efforts; among U.S. manufacturers, only the automobile industry markets its products more heavily (Centers for Disease Control [CDC] 1990a). It may be assumed that cigarette manufacturers, like other industrial entities, direct their money and marketing efforts in ways that will reach consumers they believe are most likely to purchase their products. The ensuing discussion focuses on direct product marketing and excludes other promotional and public relations efforts that are not product specific.

The potential influence of cigarette advertising and promotion on smoking prevalence has been a subject of concern and debate for many years (U.S. Department of Health and Human Services [USDHHS] 1994). Much of the concern has focused on whether consumers know about the adverse health effects of smoking and can make informed choices; whether children and adolescents are exposed to and are affected by tobacco advertising and promotion; and whether tobacco companies inappropriately target

advertising and promotion to specific consumer groups. A contentious debate has persisted about whether marketing induces demand and what the appropriate role of government is in protecting the consumer. Although some of these issues are not fully settled, they provide the background for considering the reduction of smoking through regulating cigarette advertising, promotion, product availability, and product presentation.

In May 1981, a Federal Trade Commission (FTC) staff report (see "A Midcourse Assessment," later in this chapter) concluded that consumer knowledge about the health effects of cigarette smoking was generally inadequate (Myers et al. 1981). Since then, adult smoking prevalence has declined substantially (from 33.5 percent in 1980 [Giovino et al. 1994] to 24.7 percent in 1995 [CDC 1997a]), and the general population's knowledge about the adverse health effects of tobacco use has improved (in recent years, 80–90 percent of

¹In the following discussion, *advertising* refers to company-funded advertisements that appear in paid media (e.g., broadcasts, magazines, newspapers, outdoor advertising, and transit advertising), whereas *promotion* includes all company-sponsored nonmedia activity (e.g., direct-mail promotion, allowances, coupons, premiums, point-of-purchase displays, and entertainment sponsorships).

the general population has known that smoking is a health hazard [USDHHS 1989, 1998b]). During the same period, revenue devoted to advertising and promotion by the tobacco companies has increased from \$1.24 billion in 1980 to a high of \$6.03 billion in 1993 (FTC 1999) and \$5.10 billion in 1996 (FTC 1999). Tobacco companies spent \$5.66 billion on advertising and promotion in 1997 (FTC 1999). The relationship among these three events is not straightforward, and considerable ancillary information is needed for proper interpretation. In particular, the effects that both knowledge and advertising and promotion have on smoking prevalence are complex. For example, the increase in smoking uptake among women beginning in 1967 was associated with the marketing of specific cigarette brands for women (Pierce et al. 1994a). Similarly, an increase in smoking initiation among adolescents during 1985-1989 has been ecologically associated with considerable increases in promotion expenditures, as exemplified by the Joe Camel campaign (see "A Critical Example: Joe Camel," later in this chapter) (CDC 1995b). Regardless of how these associations are interpreted, the actions of the tobacco industry bespeak the industry's belief in corporate benefit from a major investment in advertising and promotion—an investment that may be interpreted as even exceeding an economically optimal level (see Chapter 6).

The tobacco industry has argued that its main purpose in advertising is to maintain brand loyalty and to capture a greater market share of current smokers (USDHHS 1994). Intensive review of the available data, however, suggests a positive correlation between level of advertising and overall tobacco consumption that is, as advertising funds increase, the amount of tobacco products purchased by consumers also increases (USDHHS 1989, 1994; Smee 1992; Pierce and Gilpin 1995; also see Chapter 6). Furthermore, several judicial opinions (reviewed in "Constitutionality of Regulating Tobacco Advertising," later in this chapter) have questioned whether the enormous investment in advertising serves only brand loyalty. It has also been argued that a significant part of the expanding budget for tobacco marketing is for promotion to specific market segments (Hollie 1985). Other observers have suggested that marketing campaigns heavily target cultural and ethnic minorities through product development, packaging, pricing, and brand promotion (Warner et al. 1986; Ernster 1993).

Underlying these observations is awareness of a basic commercial principle: to continue to be successful, a product must not only retain consumers but also, over time, gain new consumers. Gaining new consumers is necessarily of particular concern to the tobacco industry. Advocates for reducing tobacco use have pointed out that if the tobacco industry is to maintain current consumption or even slow the ongoing decline in smoking, the industry must aggressively seek replacement smokers for the estimated 3,500 Americans who quit smoking each day and for the additional 1,200 tobacco customers and former customers who die each day of smoking-related illnesses (CDC 1993b, 1997b).

The facts about uptake of tobacco use strongly suggest where the industry's replacement smokers will come from. Epidemiologic studies show that nearly all first use of tobacco occurs before high school graduation (USDHHS 1994). Whether tobacco companies deliberately market their products to preadults is difficult to ascertain. Nonetheless, indirect evidence of the importance of advertising and promotion to the tobacco industry is provided by surveys that suggest that most adolescents can recall certain tobacco advertisements, logos, or brand insignia; these surveys correlate such recall with smoking intent, initiation, or level of consumption (Alexander et al. 1983; Goldstein et al. 1987; Pierce et al. 1991; Evans et al. 1995).

The American Medical Association (Utah Delegation 1989), together with a broad range of public health organizations, has called for stricter regulation of cigarette advertisements and even for a complete banresolutions that were reiterated in 1995 (American Medical Association House of Delegates 1995). Many public health and smoking prevention groups specifically seek government regulation to address what they consider discriminatory practices of tobacco manufacturers in targeting members of minority groups (Warner et al. 1986). These groups claim that advertisements overwhelm smoking prevention messages and increase the number of people who smoke each year beyond the number that would smoke if advertising and promotion affected only market share. Industry officials deny targeting and argue that because most of the population is now aware of the risks associated with tobacco products, citizens can make informed decisions for themselves. More important, the tobacco industry claims its First Amendment constitutional right to promote its products (Cotton 1990; Tollison and Wagner 1992; see the discussion in "Constitutionality of Regulating Tobacco Advertising," later in this chapter).

Such arguments and counterarguments have been at the heart of a 30-year endeavor to regulate advertising and promotion in the tobacco industry. A review of this effort, with some specific examples from the United States and other countries, provides insight into the strengths and weaknesses of both sides of the argument and suggests several areas for policy development.

Attempts to Regulate Tobacco Advertising and Packaging

Regulatory efforts to restrict the advertising and promotion of cigarettes were among the earliest responses to the 1964 landmark report of the Surgeon General's Advisory Committee, which set forth overwhelming scientific evidence on the health hazards of cigarette smoking. A week after the January 11, 1964, release of the report, the FTC filed a Notice of Rule-Making Proceeding (January 17, 1964) that appeared in the January 22, 1964, Federal Register. The notice set forth the agency's tentative views of how the requirements of the Federal Trade Commission Act (Public Law 96-252) would apply to the advertising and labeling of cigarettes in light of the Advisory Committee's report (Federal Register 1964). In a pertinent part, section 5 of the Federal Trade Commission Act states that "unfair or deceptive acts or practices [are] declared unlawful" and that the commission has the power to proceed against them as an administrative agency.

In its notice of rulemaking, the FTC stated its concern with "two ways in which cigarette advertising may be unlawfully misrepresenting or concealing the health hazards of smoking. First, the Commission has reason to believe that many current advertisements falsely state, or give the false impression, that cigarette smoking promotes health or physical well-being or is not a health hazard, or that smoking the advertised brand is less of a health hazard than smoking other brands of cigarettes" (Federal Register 1964, p. 530). The FTC also stated that much cigarette advertising then current portrayed cigarette smoking as pleasurable, desirable, compatible with physical fitness, or indispensable to full personal development and social success—all without informing the consumer of the health hazards of cigarette smoking.

The FTC posited that the dangers to health from cigarette smoking are so serious that knowledge and appreciation of them would be a material factor in influencing a person's decision to smoke cigarettes or to smoke a particular brand. (This point is considered in detail in "Tobacco Packaging and Informed Choice," later in this chapter.) Affirmative disclosures of these health hazards might thus be necessary in cigarette advertising that could cloud or obscure public consciousness of these health hazards. After receiving

written comments and materials from interested parties and after conducting hearings in March 1964 on the proposed rule (see the text box "Response From the Tobacco Industry—1964"), the FTC issued on June 22, 1964, the "Statement of Basis and Purpose" regarding its proposed Trade Regulation Rule. (A Trade Regulation Rule is, in effect, an administrative statute with the force of law.) In this document, the commission announced that it would require warnings on cigarette packages and in advertisements for cigarettes that cigarette smoking is dangerous to human health.

Cigarette Warning Labels

After participating in hearings before the U.S. House of Representatives Committee on Interstate and Foreign Commerce on cigarette labeling and FTC rules, the commission postponed until 1965 the implementation of any Trade Regulation Rule. In that year, the Federal Cigarette Labeling and Advertising Act of 1965 (Public Law 89-92) required that the warning "Caution: Cigarette Smoking May Be Hazardous to Your Health" (Federal Cigarette Labeling and Advertising Act, sec. 4) be placed in small print on one of the side panels of each cigarette package. The act permitted no additional labeling requirement under any federal, state, or local law, thus effectively preempting any other health messages on cigarette packages. The act also suspended for three years the FTC's authority to require health warnings on cigarette advertising.

This preemption was strongly opposed in the minority view of Representative John E. Moss (D-CA), who presented the argument as follows:

I most strongly object to sections 6 and 7 of this bill. Section 6 would prevent the Federal Trade Commission, the Food and Drug Administration, and the U.S. Public Health Service in administering their respective laws from imposing any additional requirement with regard to the labeling of cigarettes involving a health warning. The bill would also preclude State and local health authorities from imposing such requirements.

Section 7, the preemption provision of the bill, provides that no cautionary statement with respect to smoking and health other than specified in this legislation shall be required on any package; and that no such statement with respect to smoking and health shall be required in advertising for cigarettes packaged in conformity with the labeling provisions of this legislation.

The Secretary of Health, Education, and Welfare has said that preventing any regulatory agency from imposing a label warning requirement other than that prescribed in the bill is "a position which we consider too inflexible."

The National Interagency Council on Smoking and Health submitted a petition to the committee asking us "not to approve any legislation which will prevent the Federal Trade Commission from carrying out its reaffirmed intention of requiring health warnings in cigarette advertising" (Moss 1965, pp. 2365–6).

Representative Moss concluded his minority report with a strong condemnation:

In summary, I am strongly opposed to those features of this legislation which would preclude the imposition of more stringent labeling requirements or the imposition of health warnings in advertisements which Federal, State, or local health authorities may deem necessary in the future in the proper exercise of their respective powers. We must face the facts as presented to us by the Surgeon General, American Cancer Society, American Medical Association, American Heart Association, and the

National Tuberculosis Association. We must first concern ourselves with public health and welfare, not legislate to the whims of a special interest (Moss 1965, p. 2367).

In commenting on the 1965 labeling law, the Secretary of the Department of Health, Education, and Welfare outlined an alternative view of effective health warnings on cigarette packages (Celebrezze 1965). Secretary Anthony J. Celebrezze recommended that the warning appear in large type on the main faces of the package. He commented:

The statute should require the warning to be prominent and conspicuous but should leave the precise location and size of the warning on the label, and related matters, to regulation in the light of the expertise and experience of the regulatory agency. . . . [Ten]-point type, which is 2 points smaller than the type size used in typing this letter, is hardly calculated to invite the consumer's attention. . . .

If the required warning is in effect negated or disclaimed on the label or in accompanying literature by words, statements, designs, or other graphic material, the warning requirement shall be deemed

Response From the Tobacco Industry—1964

n April 1964, in rapid response to the Surgeon **▲**General's report, the tobacco industry published a voluntary code for advertising and marketing practices (Gray 1964). The stated purpose of the code was "to establish uniform standards for cigarette advertising and to provide means whereby compliance with this code can be ascertained promptly and fairly and on a consistent basis" (p. 141). The code was designed to restrict cigarette advertisements aimed at young people, to limit implied or direct health claims to those that could be medically and scientifically proved, and to curb the so-called virility theme in cigarette advertisements. The code specifically prohibited advertising that suggested that cigarette smoking was essential to "sexual attraction," "success," sophistication, athletic abilities, physical stamina, and "social prominence" (p. 143) images that the industry recognized as influencing smoking by young people.

At hearings before the House Interstate and Foreign Commerce Committee on June 25, 1964, Bowman Gray, Chairman of the Board of R.J. Reynolds Tobacco Company, speaking on behalf of the industry, told Congress, "This advertising code represents a sincere effort by the industry to respond to criticism of the industry's advertising which has been voiced in some quarters. It is an earnest effort at industry self-regulation. I hope the industry will be given reasonable opportunity to implement this code" (Gray 1964, p. 141).

The code was to be enforced by an independent administrator. All advertisements were to be precleared, and violations of the code were subject to a fine of \$100,000. Enforcement provisions of the code were dropped shortly after passage of the Federal Cigarette Labeling and Advertising Act in 1965.

not to have been met. . . . [Congress should consider giving the department] specific authority to prohibit or regulate the use of statements that while not clearly negating the warning and while literally true or at least not demonstrably false, may give the consumer the misleading impression that a given cigarette is safer than others (Celebrezze 1965, p. 2359).

These recommendations predate by three decades similar implementation of warnings in other countries (described in "Examples of Product Labeling in Other Countries," later in this chapter); such an approach, however, has not been taken in this country.

The 1965 law also required that the FTC annually transmit to Congress a report on the effectiveness of cigarette labeling, on current cigarette advertising and promotion practices, and on recommendations for legislation. In June 1967, in its first report to Congress, the FTC recommended that the package label be changed to "Warning: Cigarette Smoking Is Dangerous to Health and May Cause Death from Cancer and Other Diseases" (FTC 1967, p. 30).

Broadcast Advertising Ban

In 1969 Congress passed the Public Health Cigarette Smoking Act (Public Law 91-222), which prohibited cigarette advertising on all media subject to Federal Communications Commission (FCC) regulation, especially radio and television broadcasting, and required that each cigarette package contain the label "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health" (Public Health Cigarette Smoking Act, sec. 4). This new law also preempted any other health warning requirements for cigarette packages. The prohibition on broadcast media advertising became effective on January 2, 1971. The FTC issued complaints against the cigarette companies that eventually led to a consent decree requiring the companies to add the statutory label warning to their advertising in magazines, newspapers, and outdoor displays (Trade Regulation Reporter 1973).

The prohibition on television and radio advertising was challenged—not by the cigarette companies, but by a group of broadcasters—in *Capital Broadcasting Co. v. Mitchell* (333 F. Supp. 582 [D.D.C. 1971]). That case upheld the constitutionality of the congressional prohibition by a 2 to 1 vote. Despite this victory, a sobering note was struck in the dissenting opinion of Judge J. Skelly Wright. Far from casting his vote against smoking prevention, Judge Wright was concerned that

upholding the act, and thus upholding the prohibition on broadcast advertising, would actually aid the tobacco industry. His reasoning—which proved correct—was that the ban would put an end not only to tobacco advertising but also to the cost-free counteradvertising that had been running in the electronic media since 1969, when the FCC's Fairness Doctrine was first held applicable to cigarette advertising.

The Fairness Doctrine, which was put forth in 1949 (and ceased applying to tobacco in 1971 after cigarette advertising on radio and television ended), required that whenever material covering "'a controversial issue of public importance'" (Banzhaf v. FCC, 405 F.2d 1082, 1086 [D.C. Cir. 1968], cert. denied, 396 U.S. 842, 90 S. Ct. 50 [1969]) was aired, the broadcaster had an obligation to present, to some degree, both sides of the issue. Although the Fairness Doctrine had not previously been interpreted to apply to advertising, in Banzhaf the Federal Circuit Court of Appeals ruled that the FCC had the authority, through the Fairness Doctrine, to require that radio and television stations carrying cigarette advertising devote (i.e., without charging advertising fees) a significant amount of broadcast time to presenting the case against smoking. (For more on the plaintiff, John F. Banzhaf, see "The Attack on Advertising" in Chapter 2.) In the court's ruling, Chief Judge David Bazelon observed that "if we are to adopt [the tobacco industry's] analysis [of Congress' intention in enacting the Federal Cigarette Labeling and Advertising Act], we must conclude that Congress legislated to curtail the potential flow of information lest the public learn too much about the hazards of smoking for the good of the tobacco industry and the economy. We are loathe to impute such a purpose to Congress absent a clear expression" (Banzhaf, p. 1089).

However, three years later, in Capital Broadcasting Co. v. Acting Attorney General (405 U.S. 1000 [1972], aff'd sub nom. Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582 [D.D.C. 1971]), it was Judge Wright's view that the television and radio counteradvertising that had arisen from the Fairness Doctrine was so effective that the tobacco companies actually favored the challenged ban. There is some support for this view. Per capita cigarette consumption in the United States, which had declined (with some fluctuation) generally since the 1964 report to the Surgeon General on the health effects of smoking, had leveled off and then increased after cigarette advertising was removed in 1971 from radio and television. Some analysts have asserted that these changes indicate that the cost-free counteradvertisements opposing cigarette use, which along with the commercials promoting cigarettes,

largely disappeared from the airwaves except for a relatively few public service announcements, were more effective in discouraging consumption than cigarette commercials were in encouraging consumption (Warner 1979). Moreover, the prohibition of cigarette advertising on broadcast stations has allowed the tobacco companies to avoid the significant expense of advertising on national television and to devote their promotional dollars to other media.

A Midcourse Assessment

A decade after the broadcast ban, the FTC issued a staff report in May 1981 on cigarette advertising (Myers et al. 1981). This report asserted that "the dominant themes of cigarette advertising are that smoking is associated with youthful vigor, good health, good looks and personal, social and professional acceptance and success, and that it is compatible with a wide range of athletic and healthful activities" (p. 2-13). Although such advertising included the required general warning about the health hazards of cigarette smoking and listed the cigarette's tar and nicotine contents (as determined by FTC testing methods), the advertisements otherwise made no mention of the adverse health consequences of smoking cigarettes. The overriding message of cigarette advertising was thus that smoking is a positive, desirable experience.

Details from a nonpublic version of the FTC report revealed, for example, that a primary theme for the marketing of Salem cigarettes was the association of the cigarette with the lifestyle of young adult males who were (in the words of the company's campaign notes) "masculine, contemporary, confident, selfassured, daring/adventurous, mature" (Banzhaf 1982, p. 260). The report quoted from a Doral cigarette campaign that sought to project the image of "an independent, self-reliant, self-confident, take-charge kind of person" (p. 260) and a campaign that depicted a "Winston man" as "a man's man who is strong, vigorous, confident, experienced, mature" (p. 260). Taking another tack, the Eve cigarette campaign sought to portray the smoker as a "sophisticated, up-to-date, youthful and active woman who seems to have distinct ideas about what she wants" (p. 261). The campaign for the Lark brand was designed to position it as a "youthful, contemporary brand that satisfies the lifestyles of the modern smoking public" (p. 260) and emphasizes "moments of post-tension and relaxation" (pp. 260-1).

The nonpublic version of the FTC report also detailed and quoted from the conclusion of a marketing and research firm that had conducted focus group

interviews to help Ted Bates and Company, Inc., develop a marketable image for Viceroy cigarettes. The report, summarizing the results of the research, asserted that many smokers perceived the smoking habit as a dirty and dangerous one engaged in only by "very stupid people" (Banzhaf 1982, p. 262). The report concluded: "Thus, the smokers have to face the fact that they are illogical, irrational and stupid. People find it hard to go throughout life with such negative presentation and evaluation of self. The saviors are the rationalization and repression that end up and result in a defense mechanism that, as many of the defense mechanisms we use, has its own logic, its own rationale" (p. 262).

This marketing analysis went on to state that because there "are not any real, absolute, positive qualities or attributes in a cigarette" (Banzhaf 1982, p. 262), the most effective advertising is designed to "reduce objections" (p. 262) to the product by presenting a picture or situation ambiguous enough to provide smokers with a rationale for their behavior and a means of repressing their health concerns about smoking. The advertisement must thus project the image that cigarettes have clearly beneficial functions, such as improving the smoker's self-image and self-acceptance or serving as a stimulant or tranquilizer that offers an acceptable means of self-reward. Accordingly, the analysis recommended that advertisers should start from "the basic assumption that cigarette smoking is dangerous to your health" (p. 263) and then try to circumvent the problem rather than fight what would be a losing battle.

A particularly notable element of the report was how to persuade young people to smoke:

For the young smoker, the cigarette is not yet an integral part of life, of day-to-day life, in spite of the fact that [young smokers] try to project the image of a regular, run-of-the-mill smoker. For them, a cigarette, and the whole smoking process, is part of the illicit pleasure category. . . . In the young smoker's mind a cigarette falls into the same category with wine, beer, shaving, wearing a bra (or *purposely* not wearing one), declaration of independence and striving for self-identity. For the young starter, a cigarette is associated with introduction to sex life, with courtship, with smoking "pot" and keeping late studying hours (Banzhaf 1982, p. 263).

The survey then recommended a strategy for attracting young people to start cigarette smoking: present the cigarette as one of a few initiations into the adult world and show the cigarette as part of the illicit pleasure category of products and activities. To the

degree possible under legal constraints, the strategy advised relating the pleasure of smoking cigarettes to the pleasures of adult or illicit activities, such as drinking alcohol, smoking marijuana, or having sex (Myers et al. 1981). Brown & Williamson Tobacco Corporation stated that these proposals were never implemented and did not represent their policy.

In sum, the marketing and research firm recommended that successful cigarette advertising must either consciously or unconsciously deal with smoking and health issues by repressing the health concerns of the consumers of the product and providing a rationalization for consumption. The 1981 FTC report also concluded that the federally mandated health warning had little impact on the public's level of knowledge and attitudes about smoking. The report further observed that the warning was outworn, abstract, difficult to remember, and not perceived as personally relevant (Myers et al. 1981). These concerns contributed to Congress' enactment of the Comprehensive Smoking Education Act of 1984 (Public Law 98-474), which required four specific, rotating health warnings on all cigarette packages and advertisements (Comprehensive Smoking Education Act, sec. 4):

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

The Comprehensive Smoking Education Act of 1984 thus amended the Federal Cigarette Labeling and Advertising Act and required warnings to be placed on advertisements as well as on cigarette packages. The act preempts state and federal attempts to place additional warnings on packages, but it preempts only state action with regard to advertising. The FTC retains such jurisdiction under section 5.

From the first, the exact appearance of warning labels (wording, layout, and positioning on packages and advertisements) has represented compromises between the recommendations of the FTC and smoking prevention advocates and those of the tobacco

industry. In 1969, for example, the FTC recommended a warning on cigarette packages that specifically mentioned death, cancer, heart disease, chronic bronchitis, and emphysema. The resulting legislation required the legend to provide the general warning only that smoking is "dangerous" to one's health (Public Health Cigarette Smoking Act of 1969, sec. 4). Similarly, in its 1981 report on cigarette advertising, the FTC recommended that new warning labels use a "circle-andarrow" format that would be more effective than the traditional rectangular format, but Congress did not take this approach in the Comprehensive Smoking Education Act of 1984. Also, the new labels did not incorporate the FTC's recommendations to contain specific references to addiction, miscarriage, and death and to disclose the brand's yields of tar, nicotine, and carbon monoxide.

Smokeless Tobacco Warning Labels

Requirements for warning labels on smokeless tobacco products lagged behind those on cigarettes by more than 20 years. By the mid-1980s, the strong evidence that smokeless tobacco causes oral cancer, nicotine addiction, and other health problems and that its use was increasing among boys led Massachusetts to adopt legislation requiring warning labels on packages of snuff and caused 25 other states to consider similar legislation (USDHHS 1989).

The Massachusetts law was preempted, before it could take effect, by the federal Comprehensive Smokeless Tobacco Health Education Act of 1986 (Public Law 99-252). This law not only required three rotating warning labels on smokeless tobacco packaging and in all advertising (except billboards) but also stipulated that the labels have the circle-and-arrow format that the FTC had recommended earlier for cigarette warnings. The three rotating labels read as follows (Comprehensive Smokeless Tobacco Health Education Act of 1986, sec. 3):

WARNING: This product may cause mouth cancer.

WARNING: This product may cause gum disease and tooth loss.

WARNING: This product is not a safe alternative to cigarettes.

Initially, the FTC excluded utilitarian items—such as hats, T-shirts, lighters, and jackets—bearing the name or logo of smokeless tobacco products. A consortium

of Public Citizen and several prominent health organizations sued the FTC, arguing that this exclusion was contrary to the provisions of the act, which sought a comprehensive rather than a narrow use of health warnings (Public Citizen v. Federal Trade Commission, 869 F.2d 1541 [D.C. Cir. 1989]). The Court of Appeals for the District of Columbia ruled for the plaintiff, stating that the act was intended to cover utilitarian items, since those were among the smokeless tobacco industry's most effective means of promoting its products to adolescents. The court elaborated its point, saying that adolescents were less likely than adults to read magazines and newspapers and thereby less likely to encounter the mandated warnings there. Adolescents were also likely to have passed the critical moment of decision by the time they obtained the product itself and encountered its warning label. Accordingly, in 1991, the FTC issued a final rule requiring health warnings to be displayed on utilitarian items and providing for the manner in which the warnings were displayed.

All advertising of smokeless tobacco products is also banned on any medium of electronic communication subject to the jurisdiction of the FTC. Under this act, federal agencies and state and local governments are preempted from imposing additional health warnings on smokeless tobacco products and advertisements (except for billboards, which were excluded from this act). Furthermore, instead of stipulating where the labels must be positioned, the act required only "conspicuous and prominent" placement (Comprehensive Smokeless Tobacco Health Education Act of 1986, sec. 3). Implementation was left to the FTC, which enacted enabling regulations on November 4, 1994.

Regulation of Tobacco Packaging

Package size of tobacco products has been another area of public health concern and action. Evidence that levels of tobacco consumption reflect the affordability of tobacco products (see Chapter 6) has raised concern about selling cigarettes in packs containing fewer than the usual 20 cigarettes. In many countries, cigarettes are sold in packages of 15, 10, or 5 cigarettes. These smaller package formats have been dubbed "kiddie" packs in Canada by smoking prevention activists (Chrétien 1994). Research has shown that young people account for many sales of smaller cigarette packages (Wilson et al. 1987; Nova Scotia Council on Smoking and Health 1991; IMPACT Research 1993), probably because of their low price and ease of concealment.

These findings have led some jurisdictions to prohibit the marketing of packages containing fewer than 20 cigarettes. An Australian state legislature has also passed such a ban (the Western Australia Tobacco Control Act of 1990). In Canada, several provinces have banned small package sizes, and the revised federal Tobacco Sales to Young Persons Act of 1993 nationally banned packages of fewer than 20 cigarettes.

Another issue of concern regarding tobacco packaging is the use of potentially misleading descriptive words in the labeling of some tobacco products (Davis et al. 1990). A recent Gallup poll found that words such as "slim," "low tar," and "light" conveyed messages viewed as healthful (Gallup Organization, Inc. 1993, pp. 23, 25). Cohen (1992) reported that tobacco companies have long known that their customers equate the marketing term "low tar" (p. 85) with health benefits. Chapman and colleagues (1986) reported that smokers tend to systematically underestimate the actual tar deliveries of their particular brands, and Gori (1990) found that one-half of smokers interviewed in the United States and Europe assume that the lower the tar rating, the lower the brand's propensity to cause disease. The Coalition on Smoking OR Health (1988) has further analyzed how promoting cigarette brands as having low tar and low nicotine content communicates a message to consumers that these brands have health benefits.

The use of such descriptive words in cigarette brand names has been called into question because variations in the way cigarettes are actually smoked may mean that the actual yield of toxic constituents from cigarettes differs from the levels determined by currently accepted testing procedures (Henningfield et al. 1994; see "Compensatory Smoking," later in this chapter). For example, smokers of reduced-tar cigarettes may (deliberately or not) inhale harder to draw more smoke through the denser filter and deep into the lungs and may smoke the cigarette down closer to the filter, thereby inhaling greater concentrations of toxins. This concern led to the appointment of an ad hoc committee of the President's Cancer Panel of the National Cancer Institute (NCI) to evaluate the current FTC protocol for testing tar, nicotine, and carbon monoxide. One of the conclusions of this panel was that "brand names and brand classifications such as 'light' and 'ultra light' represent health claims and should be regulated and accompanied, in fair balance, with an appropriate disclaimer" (NCI 1996, p. vii). This recommendation has not yet been carried out.

A further aspect of tobacco packaging that is currently receiving significant attention, although primarily outside the United States, is the possibility of

legislated plain (or "generic") packaging for tobacco products. This initiative is partly motivated by the belief that removing much of the brand image of tobacco products would not only make the product less attractive but also weaken the connection with—and thus lessen the effect of—visual and verbal imagelinked efforts to promote particular brands (Mahood 1995). There is evidence that young people find plain packaging less attractive (Beede and Lawson 1992; Centre for Health Promotion 1993) and that plain packaging makes health messages more noticeable (Centre for Behavioural Research in Cancer 1992). In Canada, the federal government has considered using plain packaging for tobacco products (Standing Committee on Health 1994; Health Canada 1995b), and the province of Ontario, in enacting the Tobacco Products Control Act in 1994, authorized the requirement for plain packaging on all cigarettes sold in Ontario. Such packaging reforms have not yet been enacted in any jurisdiction.

Examples of Product Labeling in Other Countries

In recent years, many countries have taken significant action on specifying packaging and warning labels for tobacco products. All countries of the European Union must comply with a May 15, 1992, directive (Council Directive 92/41/EEC 1992 O.J. [L 158]) that requires stipulated health warnings on each of the main package panels. In Thailand, pursuant to its Tobacco Products Control Act, which was based on principles developed in Canadian regulations (discussed later in this section), prominent black-and-white health messages are required on the front of the package. South Africa and New Zealand require detailed health messages on the main package panels; the messages are based largely on Australian packaging.

The messages appearing on Australian cigarette packages are based on the work of the Centre for Behavioural Research in Cancer (1992). These messages were required as of January 1, 1995, and were incorporated into a broad effort "to inform smokers of the long-term health effects of tobacco use" (Lawrence 1994, p. 1). The Australian system uses six rotating messages covering 25 percent of the front of the cigarette packets. One side of the packet is entirely given to the labeling of dangerous constituents, and all the labels must be in black and white. Thirty-three percent of the rear main packet panel must be covered by the same health message given on the front of the pack and followed by an elaboration of that message (Chapman 1995).

Of special interest are the package regulations currently in place in Canada. The Canadian health messages were established by regulatory power granted under the 1988 federal Tobacco Products Control Act, which came into effect on January 1, 1989. This legislation gives broad regulatory powers over tobacco product packaging. It also gives regulatory authority to require package inserts, although this power has not yet been acted on. By eventually delegating formulation of the precise warnings to administrative regulation, this legislation took the approach that had been recommended 25 years earlier by the U.S. Department of Health, Education, and Welfare (Celebrezze 1965; see also "Cigarette Warning Labels," earlier in this chapter). This law also makes clear that the various provinces of Canada can require additional messages and that the provision of federal messages does not preempt other messages. The first set of regulations following this law required that four specific rotating health messages be placed on the two main panels of cigarette packages and be printed in a large typeface; this set of regulations stipulated that the messages must be "prominently displayed in contrasting colours" (Department of National Health and Welfare 1989, p. 64) and cover at least 20 percent of the panel face.

When the mandated Canadian health messages started appearing on tobacco products in 1989, it was clear to many public health workers that the language of the regulations had left the tobacco companies too much room for interpretation and had resulted in less prominence and contrast than the regulations had intended. Minister of National Health and Welfare Henry Perrin Beatty commented, "It's very clear that, when you look at [the health warning on cigarette packs], it's not designed to stand out. If our experts [at the Department of National Defence] knew as much about camouflage as the tobacco company did, nobody'd ever find our fellows" (Spectator 1989). This situation gained more attention when it was revealed that a prominent tobacco lobbyist had apparently influenced development of the regulations (Fraser 1989). Health advocates subsequently campaigned to attain more prominent messages through revising the regulations (Mahood 1995).

New legislation was enacted on August 11, 1993 (Department of National Health and Welfare 1993), and all packaging for tobacco products destined for sale in Canada had to comply by September 11, 1994. Among these precedent-setting regulations (Mahood 1995) were the following requirements:

• The message must cover at least 25 percent of the top of each main panel.

- The message must be framed by a stipulated border (on many packs, this border yields a total message area that uses over 40 percent of the surface).
- Each of eight rotating messages must be presented one-half of the time in black on a white background with a black border. The other one-half of the time, the messages must be white on a black background surrounded by a white border.
- One entire side panel must be used to present information on the toxic constituents.
- Every side panel of tobacco cartons must display a black-on-white message covering 25 percent of the panel area and stating "Cigarettes are addictive and cause lung cancer, emphysema, and heart disease" (Department of National Health and Welfare 1993, p. 3278).
- The message must bear no attributions.

One ironic result of these requirements was that cigarettes manufactured in the United States for the Canadian market were produced, albeit only for export, with health messages that conform with the recommendations provided in 1965 by the U.S. Department of Health, Education, and Welfare.

The Canadian regulations were reversed in 1995, when the Supreme Court of Canada held that the country's complete ban on overt tobacco advertisements (another key component of the 1993 regulations) and its requirement of unattributed health warnings on packages were in violation of the tobacco industry's freedom of expression and the Canadian Charter of Rights and Freedoms (RJR-MacDonald Inc. v. Attorney General of Canada, File Nos. 23460, 23490 [Can. Nov. 29-30, 1994, Sept. 21, 1995], cited in 10.6 TPLR 2.167 [1995]). These central elements of Canada's Tobacco Products Control Act fell because the Canadian government did not meet its constitutional obligation of proving that the approach taken was the least drastic means of achieving a public health objective. These narrow evidentiary grounds on which the decision was made left room for the Canadian government to counter. The government offered a new proposal, called Tobacco Control: A Blueprint to Protect the Health of Canadians, that reinstated the advertising ban, imposed restrictions on brand-name promotion and sponsorship, instituted controls over packaging and labeling, and increased product regulation and reporting requirements.

In creating a new legal framework, the Canadian government would make tobacco a de facto illegal product whose sale could be permitted but would be

subject to specific conditions. This reversal of the burden of proof gives constitutional allowance to the advertising restrictions in Canada. Following the unveiling of the *Blueprint*, the tobacco industry brought forward a voluntary proposal to restrict advertising. Subsequent resumption of advertising has been controversial, and the industry has been accused of breaching its own code (LeGresley 1996).

Tobacco Advertising, Commercial Speech, and the First Amendment

Regulation of tobacco advertising in the United States is legally problematic. Although protections afforded by the First Amendment to the U.S. Constitution may be modified for commercial speech, including advertising, such modification is an area of intensive legal debate. The two decades of lawsuits described in this section make it clear that a concerted and persistent government interest is essential if such restriction of free speech is to be upheld in courts. To satisfy legal scrutiny, the government's efforts must clearly show that any restrictions directly and materially advance its asserted interest—protecting the health of the American people.

The United States Supreme Court has defined commercial speech as "expression related solely to the economic interests of the speaker and its audience" (Central Hudson Gas & Electric v. Public Service Commission of New York, 447 U.S. 557 [1980]). Commercial speech thus includes advertisements by cigarette manufacturers that invite consumers to buy their product. As the Supreme Court has observed, "For most of this Nation's history, purely commercial advertising was not considered to implicate the constitutional protection of the First Amendment" (United States v. Edge Broadcasting Co., 113 S. Ct. 2696, 2703 [1993]). Restrictions on commercial speech were viewed as being similar to economic regulation and were routinely upheld. A midcentury example key to later efforts to restrict tobacco advertising occurred when the Supreme Court, in Valentine v. Chrestensen (316 U.S. 52 [2d Cir. 1942], rev'd), held that the state could prohibit the street distribution of handbills containing commercial advertising matter (see also Village of Schaumburg v. Citizens for a Better Environment, 444 U.S. 620 [1980]). Such precedents enabled the courts to uphold the 1972 congressional ban on tobacco advertising on radio and television (Capital Broadcasting Co., 405 U.S. 1000). Subsequent legal scrutiny, however, has acted to reverse this trend.

Constitutionality of Regulating Advertising

In 1975, the United States Supreme Court held for the first time that commercial advertising in general was entitled to protection under the First Amendment. In *Bigelow v. Virginia* (421 U.S. 809 [1975]), the Court struck down a state statute banning commercial advertisements for abortion referral services. The Court found that "the relationship of speech to the marketplace of products or services does not make [commercial advertising] valueless in the marketplace of ideas" (p. 826). However, the Court emphasized that it was defending not merely commercial speech, but speech that contained "material of clear 'public interest'" (p. 822).

The Court also defended commercial speech in a case involving advertising of the price of pharmaceuticals. In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc. (425 U.S. 748 [1976]), the Court found that the constitutional protection afforded to advertisements of the price of pharmaceuticals was shared by advertisers and recipients of the information. The Court noted the importance of information to consumers: "As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate" (p. 763). The Court pointed out that advertising is disseminating information to the consumer about who is producing the product, for what reason, and at what price, even if it does not "editorialize on any subject, cultural, philosophical, or political" (p. 761).

In that same ruling, however, the Supreme Court emphasized that commercial speech would not be afforded the same level of protection as other forms of speech and therefore that the state can regulate advertising if such regulation is in conformity to a valid public interest. These interests include avoiding deceptive and misleading claims; preventing unlawful activities, such as the sale of alcoholic beverages to minors; and protecting public health. "The First Amendment . . . does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely" (*Virginia State Board of Pharmacy*, pp. 771–2).

Most cases involving regulated advertising are assessed through a four-pronged test to determine whether the regulations violate the First Amendment. This test was set forth in *Central Hudson* (447 U.S. 557). First, the speech being suppressed must have forfeited its First Amendment protection by being unlawful or deceptive or fraudulent: "The First Amendment's

concern for commercial speech is based on the informational function of advertising. . . . Consequently, there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it" (p. 563). Second, the government must assert a substantial interest in regulating the speech. Third, regulating commercial speech must directly and materially benefit this government interest. Fourth, the government must show that the means chosen to benefit its interest are no more extensive than necessary. (This four-pronged test is discussed more fully in "Constitutionality of Regulating Tobacco Advertising," later in this chapter.)

The level of deference the Supreme Court gives to legislatures in meeting these four requirements seems to vary. In some cases, the Court defers to the legislative judgment that the speech restriction will be effective (*Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*, 478 U.S. 328 [1986]; *Edge Broadcasting*), while in other cases the Court demands more empirical support for the legislature's assumptions and conclusions (*Rubin v. Coors Brewing Co.*, 514 U.S. 476, 115 S. Ct. 1585 [1995]; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 116 S. Ct. 1495 [1996]).

In Posadas de Puerto Rico, the Supreme Court upheld a statute that prohibited advertising legal gambling casinos to residents. The Court found that even though nonfraudulent advertising that concerned a legal activity deserved First Amendment protection, the commonwealth's legislature could take steps to regulate it. The government has a substantial interest in protecting the health, safety, and welfare of its citizens, and this interest includes reducing the demand for gambling among residents through the regulation of advertising. The Court accepted the argument by the commonwealth that resident gambling would disrupt moral and cultural patterns, cause an increase in crime, foster prostitution, and develop corruption. In Board of Trustees of the State University of New York v. Fox (492 U.S. 469 [1989]) (also known as Fox III), the Court deferred to the legislature and refused to set aside a State University of New York statute that prohibited private commercial enterprises from operating on campus. In Edge Broadcasting (113 S. Ct. 2696), the Court upheld a federal statute that prohibited the broadcast of lottery advertisements generally but permitted advertisements of state-run lotteries on stations licensed to a state that conducts lotteries. The Court held that "the State [has] 'a strong interest in adopting and enforcing rules of conduct designed to protect the public' " (p. 2706). Citing Fox III with approval, the Court said, "Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments" (p. 2707).

In contrast, in 44 Liquormart, the Supreme Court looked closely at the logic of the Rhode Island government in the ban it imposed on liquor price advertising. The Court considered that the Rhode Island restriction was a total prohibition and that there was too weak a connection between banning speech regarding prices and the state's assertion that this restriction would reduce liquor consumption. Furthermore, the Court was aware of the concern that the legislature had been captured by one group of economic competitors (small liquor stores that could not otherwise compete in price wars) and that the law was then drafted at the expense of the disfavored economic competitor (larger liquor chains). In the 44 Liquormart decision citing the dissent in Rhode Island Liquor Stores Association v. Evening Call Pub. Co. (497 A.2d 331 [R.I. 1985]), it was "suggested that the advertising ban was motivated, at least in part, by an interest in protecting small retailers from price competition" (p. 491, FN4).

In *Coors Brewing Co.*, the Supreme Court struck down a regulation restricting the printing of alcohol strength on beer labels. The Court found that the restriction did little to advance the government interest in preventing "strength wars" between competing beer manufacturers, particularly when other types of alcohol were required to list the alcohol potency on their labels. Finding that the speech restriction lacked a logical foundation, the Court viewed the regulation skeptically.

The pattern that emerges from these legal judgments is that where a law restricting commercial speech has a solid grounding in logic and empirical data, the Court will uphold it. If the regulatory system has a faulty connection between its goal and its method, the law will fail the third prong of the Central Hudson test and be struck down. In 44 Liquormart, Justice John Paul Stevens' plurality opinion required that the social science evidence supporting the legislative rationale directly and materially tie the government's goal (reducing liquor consumption) to its methodology (restricting liquor price advertising); the government failed to meet this legal requirement. Furthermore, the Court views harshly laws that impose a total ban on speech and thus paternalistically deprive consumers of information because the government perceives that the ban is "for their own good."

Constitutionality of Regulating Tobacco Advertising

Government regulations of tobacco product advertising can withstand legal scrutiny if they are carefully crafted and are not overbroad (*Edge Broadcasting*, p. 2705 [citing *Fox III*, p. 480]). Courts have found state and local regulations of tobacco advertising to be preempted by the Federal Cigarette Labeling and Advertising Act when they conclude that the regulation is based on "smoking and health." If the regulation is not preempted, then it must pass the four-pronged test advanced in *Central Hudson*. Reasonable regulations on tobacco advertising are likely to be upheld.

Preemption and the Federal Cigarette Labeling and Advertising Act

The Federal Cigarette Labeling and Advertising Act preempts a "requirement or prohibition based on smoking and health . . . imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter" (15 U.S.C. [United States Code 1334[b]). In Cipollone v. Liggett Group Inc. (505 U.S. 504, 112 S. Ct. 2608 [1992]), the Supreme Court interpreted that language narrowly, allowing Cipollone to sue the tobacco industry if the claim were not based on a failure to warn about smoking and health issues in product advertising or promotion. The claim would not be preempted if it were based on more generalized state interests, such as preventing intentional fraud or enforcing manufacturer warranties. In Mangini v. R.J. Reynolds Tobacco Co. (22 Cal. App. 4th 628 [1993]), the California Court of Appeals restated the Cipollone holding by declaring that regulations are preempted only if they demand a "requirement or prohibition based on smoking and health. . . . imposed under State law with respect to.... advertising or promotion." If one of these elements is missing, the state law is not preempted.

State and local governments can still regulate to-bacco advertising if they justify the law with a valid rationale not related to health. For example, Baltimore asserted that its ordinance restricting tobacco advertising on billboards was a reasonable and necessary measure for reducing illegal consumption of cigarettes by minors (*Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 862 F. Supp. 1402 [Md. 1994]). The city claimed that the focus of the ordinance was not on protecting the health of young people; the language of the ordinance was instead exclusively related to preventing youth from engaging in illegal transactions. (This assertion was made even though Baltimore does not criminalize youth purchase or

possession of tobacco products; Baltimore criminalizes the sale of tobacco to minors.) The district court accepted this stated intent of the ordinance. Even when legislators who supported the ordinance made certain health-related comments, the court discounted these as not necessarily being representative of the motives of the city council as a whole.

On appeal by the advertising company that was the plaintiff in the case, the Fourth Circuit Court of Appeals further held that the Baltimore ordinance was not preempted by the Federal Cigarette Labeling and Advertising Act because it did not relate to the content of advertising, but rather to billboard location (Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore, 63 F.3d 1318 [4th Cir. 1995]). The court interpreted the ordinance as a limited physical restriction in a limited media, for Baltimore allows such billboards in parts of the city zoned for commercial and industrial use. The court also observed that the Baltimore ordinance did not restrict tobacco industry advertising in other media, such as newspapers and magazines. State or local governments that cannot separate such ordinances from health-related issues, however, will have difficulty passing the preemption test. In Minnesota, for example, the court struck down a municipal statute that restricted tobacco advertising explicitly to protect health (Chiglo v. City of Preston, 909 F. Supp. 675 [D. Minn. 1995]).

The Four-Pronged Test

Is the Advertising Unlawful or Misleading?

A central justification for affording constitutional protection to advertising is the consumer's interest in the free flow of information (*Central Hudson*). Public health and smoking prevention groups often question whether attractive images that portray smoking as a socially acceptable, sexual, and athletic activity have any informational use to the consumer (Lowenstein 1988). Despite the emotive, noninformative character of cigarette advertising, the tobacco industry might argue that restricting such advertising should fail the first prong of the *Central Hudson* test because the product being advertised is lawful for adults and its promotion is not directly deceptive or fraudulent.

Certainly, advertisements that use images to connect health, vitality, and the good life with cigarette smoking distort the truth (Law 1992). Yet the United States Supreme Court's definition of "inherently misleading" refers to advertisements that promote fraud, represent overreaching, or create consumer confusion (*Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 462 [1978]). Proscriptions against misleading advertising have not

traditionally extended to "puffery" or imagery alone (Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 [1985]). For example, courts have held that advertisements for alcoholic beverages that project images of drinkers as successful and funloving and do not warn of the dangers of alcohol abuse are not legally "misleading" (Oklahoma Telecasters Association v. Crisp, 699 F.2d 490, 500 [10th Cir. 1983], rev'd on other grounds sub nom.; Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691 [1984]). By analogy, courts may not find that promotions are directly misleading simply because they project images of smokers as glamorous people and do not mention the associated dangers of smoking.

A cigarette advertisement would be found to be misleading, however, if it included unsubstantiated health claims. Advertisements could not assert that cigarette smoking poses little or no risk to health or does not affect breathing. For example, the FTC challenged as false and misleading a newspaper advertisement (or advertorial), paid for by R.J. Reynolds Tobacco Company, that claimed smoking is not as hazardous to health as the public has been led to believe. Although the tobacco company initially stated that the statement was not commercial speech because it did not invite the public to purchase a particular product, the parties entered into a consent decree under which R.J. Reynolds agreed to stop the advertisement and to avoid future misrepresentation of scientific studies (Bureau of National Affairs, Inc. 1990).

Some proponents of restricting tobacco advertising argue that courts in the future could find the visual images projected in cigarette advertisements to be inherently deceptive or misleading. A legal opinion for the American Medical Association concluded, "Given what the cigarette advertising does portray, what it fails to say, and the vast public ignorance of the dangers and addictive quality of smoking, particularly among young persons, it is plain to us that this kind of advertising can be proscribed as deceptive or misleading" (Blasi and Monaghan 1986, p. 506). Analogously, the Supreme Court has construed the preemptive provisions of the cigarette labeling act to permit tort actions against cigarette manufacturers in the instance of fraudulent misrepresentation or conspiracy to misrepresent or conceal material facts (*Cipollone*).

Furthermore, to the extent that recent documents from the tobacco industry show that the industry purposefully marketed to minors, the courts may find this to be a deceptive advertising practice that leads to an illegal act. There is no constitutional speech protection for proposing illegal transactions, such as sales of cigarettes to minors. The tobacco company Liggett

Group Inc. has admitted that the entire tobacco industry conspired to market cigarettes to children (Settlement Agreement Between Settling States and Brooke Group LTD, Liggett & Myers, Inc. and Liggett Group, Inc., cited in 13.1 TPLR 3.11 [1998]), and documents obtained in litigation from the other tobacco companies and recently made public confirm that tobacco companies have purposefully marketed to children as young as 14 years old (Coughlin et al. 1999). Regulation of some tobacco advertising may thus pass the first prong of the Central Hudson test (see the discussion of the Mangini case in "A Critical Example: Joe Camel," later in this chapter).

Is the Government's Interest Substantial?

Appellate courts have consistently found that states have a substantial interest in limiting tobacco advertisements (see, for example, Penn Advertising; Oklahoma Telecasters; and Dunagin v. City of Oxford, 718 F.2d 738 [5th Cir. 1983], cert. denied, 467 U.S. 1259 [1984]). Because of the strong epidemiologic evidence associating smoking with lung cancer, heart disease, and other causes of morbidity and mortality (USDHHS 1989), no court would deny that the federal government has a compelling interest in reducing smoking. As evidence mounts concerning the health hazards of environmental exposure to cigarette smoke (Environmental Protection Agency [EPA] 1992; Leary 1993; Reynolds 1993; Bero et al. 1994; California EPA 1997), the federal government may also exercise its police powers to protect nonsmokers.

The Federal Cigarette Labeling and Advertising Act preempts state and local governments from regulating cigarette advertising based on "smoking and health." Instead, as noted, many governments (such as those of Baltimore and New York City) are asserting an interest in preventing minors from being involved in illegal transactions. Additional nonhealth rationales include avoiding deceptive advertising and providing economic (as opposed to health-based) consumer protection.

Does the Regulation Directly Benefit the Public Interest?

The third prong of the *Central Hudson* test requires that governmental regulation of commercial speech must advance the government interest. The Supreme Court has not yet given clear direction as to what level of evidence is required to show that such regulation directly advances the government interest, but the Court is beginning to demand some scientific or statistical evidence of efficacy. In *Florida Bar v. Went For It, Inc.* (515 U.S. 618, 632 [1995]), the Court was satisfied with a general assertion by the state that common sense

dictated that restricting attorneys from advertising by direct mail would reduce ethical violations by attorneys and have a positive effect on the public's opinion of attorneys. Limited social science evidence was presented, yet the restriction was upheld. On the other hand, in 44 Liquormart, Justice Stevens' plurality opinion stated that one reason the Rhode Island statute was struck down was that the state had not produced evidence that its speech restriction would directly and materially produce the results desired to advance the government interest.

Even if the courts require empirical support of efficacy, tobacco advertising restrictions can still satisfy the third prong of the Central Hudson test. There is extensive social science research regarding the effect of tobacco advertising on the purchasing habits of teen smokers and on the positive imagery with which children regard and recognize tobacco advertising images. After R.J. Reynolds Tobacco Company introduced the Joe Camel advertising campaign in the late 1980s, the market share of Camel cigarettes among teenagers increased at least 20-fold; from the same point in time, the previous decline in overall teenage smoking prevalence was reversed (CDC 1994b). An association between a rise in young girls' smoking habits and the tobacco industry's decision to target marketing to adolescent girls has also been documented (Pierce et al. 1994a).

Some relevant legal judgments suggest that although the courts tend to require more than a commonsense assertion of the government's interest in restricting commercial speech, something less than empirical evidence may suffice. For example, although Justice Stevens in 44 Liquormart demanded empirical evidence, he also recognized there is "some room for the exercise of legislative judgment" (p. 508). The Supreme Court in Edenfield v. Fane (113 S. Ct. 1792 [1993]) suggested the need for a scientific validation of a connection between regulation and the achievement of a substantial state interest: the Court stated that the government "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree" (p. 1800).

In cases involving advertising restrictions for alcoholic beverages, the courts have consistently accepted—even in the absence of objective scientific studies—the reasonable legislative belief that such restrictions would lower consumption. The Tenth Circuit Court of Appeals found it not "constitutionally unreasonable for the State of Oklahoma to believe that advertising will not only increase sales of particular brands of alcoholic beverages but also of alcoholic beverages generally" (*Oklahoma Telecasters*, p. 501).

Similarly, the Ohio Supreme Court found that the advertising of drink prices would encourage and stimulate consumption of alcoholic beverages (*Queensgate Investment Co. v. Liquor Control Commission*, 433 N.E.2d 138, 142, 69 Ohio St. 2d 361 [Ohio 1982]). The advertising prohibition was thought to be closely connected to the state's interest in preventing consumption.

Courts have found a direct relationship between advertising and consumption or abuse in other dangerous products and activities (see, for example, Williams v. Spencer, 622 F.2d 1200 [4th Cir. 1980]; Capital Broadcasting). In Central Hudson, the Supreme Court found an immediate connection between advertising and the demand for electricity. The Court in Metromedia, Inc. v. City of San Diego (453 U.S. 490 [1981]) similarly found a link between billboard advertisements and traffic safety. The Court stated that this link is established by the "accumulated, common-sense judgments of local lawmakers" (p. 509).

Claims made on behalf of the tobacco and advertising industries that tobacco advertising is designed not to increase consumption but only to develop brand loyalty and gain an increased market share (Boddewyn 1989) may be unpersuasive to the courts (Chetwynd et al. 1989; Joossens 1989). Although some of the studies showing that advertising increases tobacco consumption have methodologies that are controversial—such as econometric (Lewit et al. 1981; Schneider et al. 1981; Seldon and Doroodian 1989), cross-cultural (Hamilton 1976; Reuijl 1982), and advertising recognition (Goldstein et al. 1987; DiFranza et al. 1991; Fischer et al. 1991a)—the courts would likely accept the legislature's reasonable belief that what the studies show is true. For example, the Ninth Circuit, in a 1997 opinion after 44 Liquormart, maintained that "common sense suggests that advertising increases participation" (Valley Broadcasting Co. v. United States, 107 F.3d 1328, 1344 [9th Cir. 1997]). This portion of Posadas de Puerto Rico has survived 44 Liquormart.

In an analogous situation, alcohol industry arguments against the relationship between advertising and consumption were rejected by the Fifth Circuit Court of Appeals, which held that Mississippi's ban on intrastate liquor advertising directly promoted the state's interests in the health and safety of its citizens. The court said that it did not "... believe that the liquor industry spends a billion dollars a year on advertising solely to acquire an added market share at the expense of competitors.... we hold that sufficient reason exists to believe that advertising and consumption are linked to justify the ban, whether or not 'concrete scientific evidence' exists to that effect" (*Dunagin*, p. 750). Because the tobacco industry spends six times as much as the

liquor industry on advertising and promotion (FTC 1995), because smoking remains the leading cause of avoidable death in America (McGinnis and Foege 1993), and because about 50 million Americans still smoke, even small reductions in smoking behavior—whether consumption or uptake—resulting from reduced advertising could achieve significant health benefits.

Cases trying to restrict alcohol advertising have also, however, set precedents that may stand in the way of comparable cases involving tobacco advertising. Most notably, in 44 Liquormart, Inc. v. Racine (829 F. Supp. 543 [R.I. 1993]), the Rhode Island District Court judge found that the state's specific statute banning liquor price advertising had had "no significant impact on levels of alcohol consumption" (p. 549). Justice Stevens, in his plurality opinion, found that the statute could not survive without social science evidence because "speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends" (44 Liquormart, Inc. v. Rhode Island, p. 507).

Yet the Fourth Circuit Court of Appeals, the highest court to rule on tobacco advertising restrictions, has twice upheld Baltimore's limitation on tobacco advertising. The Fourth Circuit noted several differences between the liquor price advertising prohibition in 44 Liquormart, Inc. v. Rhode Island and the limited restrictions in the Baltimore ordinance. 44 Liquormart dealt with a total ban on speech directed to adults, whereas the Baltimore ordinance was a partial restriction of speech that targeted children as consumers of an adult product. The Fourth Circuit Court also held there was a close connection between the government's goal of preventing teen participation in illegal transactions and the limited speech restriction intended to support that goal (Penn Advertising, 63 F.3d 1318; Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore, 101 F.3d 332 [4th Cir. 1996]). By contrast, a notable reason for the Supreme Court's rejection of advertising restrictions in 44 Liquormart was that the government had not proved a clear tie between its interest and the restrictions supposedly supporting that interest.

The Fourth Circuit reaffirmed its decision in *Penn Advertising* after the Supreme Court had asked it to review the decision in light of 44 *Liquormart*. The Fourth Circuit specifically stated, "We have read the opinion in 44 *Liquormart* and have considered its impact on the judgment in this case . . . we conclude that 44 *Liquormart* does not require us to change our decision" in this case (*Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore,* 101 F.3d 332 [4th Cir. 1996], *cert. denied,* 117 S. Ct. 1569 [1997]).

Because a restriction like that upheld in *Penn Advertising* cannot constitutionally be a complete ban on all advertising of the product, some minors will be exposed to some level of adult tobacco advertising. This limit in scope does not constitute serious grounds for an appeal. A recent decision involving liquor regulation notes that the "Supreme Court has made it clear in the commercial speech context that underinclusiveness of regulation will not necessarily defeat a claim that a state interest has been materially advanced" (*Bad Frog Brewery, Inc. v. New York State Liquor Authority*, 134 F.3d 87, 99 [2d Cir. 1998]). In sum, the regulation need not cure all ills but it does need to advance the state interest in a demonstrably significant, rather than a small or otherwise circumstantial, way.

Is the Regulation of Advertising a Reasonable Fit?

The Supreme Court has made it clear that this standard is not to be confused with the "least restrictive means" test. In *Edge Broadcasting* (p. 2705), the Court said that the "requirement of narrow tailoring was met if 'the . . . regulation promotes a substantial government interest that would be achieved less effectively absent the regulation,' provided that it did not burden substantially more speech than necessary to further the government's legitimate interests." The existence of less restrictive methods of achieving the government's goals does not automatically defeat the legislation as it would in political speech cases. Instead the Court looks to see if the restriction does not sweep more broadly than necessary. In *Florida Bar* the Court stated,

In *Fox*, we made clear that the "least restrictive means" test has no role in the commercial speech context . . . "What our decisions require," instead, "is a 'fit' between the legislature's ends and the means chosen to accomplish those ends, a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served,' that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective" (citations omitted) (p. 632).

In practical terms, the decision implies that restrictions on tobacco advertising that target areas where children gather, such as schools and playgrounds, do not create a total ban, because the tobacco industry will still have many alternative channels to communicate with its adult customers. Adults can still receive information on price, quality, comparative product features, and any other information to help

them make an informed decision on tobacco products. Even if the tobacco industry were limited to communicating in tombstone format (black letters on a white background), the government would not have prohibited the flow of information.

For a similar reason, 44 Liquormart, Inc. v. Rhode Island does not change this analysis. The rationale the Supreme Court used there in overturning Rhode Island's alcohol advertising restriction—that the statute was a paternalistic ban on the free flow of truthful information—does not apply in tobacco advertising regulations like those upheld in Penn Advertising, because the tobacco industry would still have many avenues of communication open to it and could communicate all aspects of information.

Justice Stevens in 44 Liquormart also generally rejected a vice exception to commercial speech restrictions. In *Posadas de Puerto Rico*, the Court was willing to allow the legislature broad deference to curb speech that promoted "vice" activities such as gambling. Justice Stevens rejected this approach that allowed legislatures to ban speech rather than the vice itself. He stated, however, that "a 'vice' label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity" (44 Liquormart, Inc. v. Rhode Island, p. 514). In the case of restricting tobacco advertising aimed at children, the restriction matches the prohibition. It is illegal to sell tobacco products to minors, and therefore the legislature has a principled reason to prevent commercial speech in the limited area where it has already prohibited the commercial activity. This is in accord with Justice Clarence Thomas' view that a jurisdiction "may not restrict advertising regarding commercial transactions except to the extent that it outlaws or otherwise directly restricts the same transactions within its own borders" (p. 525).

In 44 Liquormart, Justice Sandra Day O'Connor's concurrence set out the guideposts she would use to judge commercial speech restrictions. "The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny. If alternative channels permit communication of the restricted speech, the regulation is more likely to be considered reasonable" (44 Liquormart, Inc. v. Rhode Island, pp. 529–30 [internal citations omitted]). The ruling presupposes that other less restrictive alternatives, such as price increases and access restrictions, have been tried (if enacted) and have not completely solved the problem. It is reasonable for a legislature

to conclude that limited restrictions on commercial speech aimed at youth must be a component of an overall plan to limit youth involvement with tobacco products. At the same time, the tobacco industry will have alternative channels to communicate to adults all the information in which adults are interested, including price, tar and nicotine levels, and taste. In the context of alcohol advertisements, courts have asserted that "the state's concern is not that the public is unaware of the dangers of alcohol. . . . The concern instead is that advertising will unduly promote alcohol consumption despite known dangers" (*Dunagin*, cert. denied, 467 U.S. 1259).

The preceding review of relevant cases suggests that carefully designed, reasonable government restriction of cigarette advertising would likely meet the Supreme Court's four criteria for restricting commercial speech and would therefore be found constitutional.

A Critical Example: Joe Camel

Perhaps the most discussed tobacco promotion of the 1990s—and one that brings together many of the issues discussed in the preceding section—is the advertising campaign for Camel cigarettes that features a cartoon camel character called Old Joe (often referred to as Joe Camel). Assertions have been made that this campaign improperly targeted minors, seeking to attract them to cigarette smoking. These concerns were heightened in the wake of the 1994 Surgeon General's report on smoking and health, which focused on adolescents (USDHHS 1994). That report's major conclusions included the following: those who smoke usually begin by age 18; most adolescent smokers become addicted to nicotine; tobacco addiction is associated with the later development of other drug addiction; tobacco use is related to psychosocial risk factors; and some cigarette advertising appears to be particularly effective on adolescents.

Critics argue that the cartoon character of Joe Camel, which has been used by R.J. Reynolds Tobacco Company in its advertising campaign for Camel cigarettes since 1988, has had substantial impact on smoking among underaged youth (DiFranza et al. 1991; Fischer et al. 1991a; Breo 1993; CDC 1994b). The character appears in print advertising and on promotional products disseminated by the company, such as mugs, matchbooks, store exit signs, and soft drink can holders. After a staff investigation, in 1994 the FTC declined, by a 3 to 2 vote, to issue a complaint charging that advertising using the Joe Camel character violated

section 5 of the Federal Trade Commission Act by inducing minors to smoke. Subsequently, the FTC did bring a complaint against R.J. Reynolds on May 28, 1997, alleging that "the purpose of the Joe Camel campaign was to reposition the Camel brand to make it attractive to younger smokers. . . . The Joe Camel campaign induced many of these children and adolescents under the age of 18 to smoke Camel cigarettes or increased the risk that they would do so. . . . R.J. Reynolds' actions . . . have caused or were likely to cause substantial and ongoing injury to the health and safety of children and adolescents under the age of 18 that is not offset by any countervailing benefits and is not reasonably avoidable by these consumers" (In re R.J. Reynolds Tobacco Co., Docket No. 9285 [FTC, May 28, 1997], cited in 12.3 TPLR 8.1, 8.2 [1997]). As late as the spring of 1998, Joe Camel memorabilia were still being offered for sale in R.J. Reynolds catalogs. The FTC ultimately dismissed its complaint as no longer necessary after the November 23, 1998, Master Settlement Agreement banned the use of all cartoon characters, including Joe Camel, in the advertising, promotion, packaging, and labeling of any tobacco product.

The Federal Trade Commission Act grants no private right of enforcement (Holloway v. Bristol-Myers Corp., 485 F.2d 986 [D.C. Cir. 1973]). However, the California Unfair Competition Law authorizes actions for injunctive relief (a measure sought to prevent a given course of action) not only by specified state and local officers but also by persons acting for the interest of themselves or the general public. A private action was brought in California state court by Janet Mangini, who asserted that R.J. Reynolds' advertising practices in the Joe Camel campaign violated the Federal Trade Commission Act and the California statutory law of unfair competition (Mangini v. R.J. Reynolds Tobacco Co., 7 Cal. 4th 1057, 875 P.2d 73 [Cal. 1994], cert. denied, 1994 U.S. LEXIS 8361 [Nov. 28, 1994]). Unfair competition is defined to include "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising" (California Business & Professions Code, sec. 17200). R.J. Reynolds, in contesting Mangini's action, asserted that federal law preempted any action in the state courts. The Federal Cigarette Labeling and Advertising Act, as amended by the Public Health Cigarette Smoking Act of 1969, provides that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provision of this Act" (Public Health Cigarette Smoking Act of 1969, sec. 5[b]).

The Supreme Court of California rejected the preemption argument and held that the cause of action against the advertising—that it improperly targeted minors—would stand. According to the court, the advertising had apparently been effective in targeting adolescents: Camel cigarettes were chosen by an estimated 0.5 percent of teenage smokers in 1988 (the last full year of sales before the Joe Camel campaign) and by an estimated 25-33 percent in 1992 (as quoted in the decision; other sources cite a substantial, although smaller, increase [CDC 1994b]). In 1992, teenage smokers accounted for about \$476 million of Camel sales, a vastly greater amount than the \$6 million in sales for 1988 (Mangini, p. 1060). The portion of the *Mangini* lawsuit regarding the Joe Camel advertising campaign was settled September 8, 1997, when R.J. Reynolds agreed to cease placing Joe Camel on California billboards, placing Joe Camel materials in magazines and newspapers, and distributing promotional materials through retail mechanisms (Mangini v. R.J. Reynolds Tobacco Co., cited in 12.5 TPLR 3.349 [1997]). It also agreed to pay the cities and counties that had joined the action as co-plaintiffs \$9 million for a counteradvertising campaign, presumably to dispel the lingering effects of the Joe Camel marketing.

In another state, Washington, a private action using that state's law failed to prohibit advertising using Joe Camel (Sparks v. R.J. Reynolds Tobacco Co., No. C94-783C [W.D. Wa. Dec. 9, 1994], cited in 9.6 TPLR 2.171 [1994]). Nonetheless, the decision of the Supreme Court of California indicates that at least in some instances in some jurisdictions, private parties acting as representatives of the general public can bring an action normally brought only under specific federal or state law against cigarette advertising.

Thus, as with a number of other legal issues (see "Litigation Approaches," later in this chapter), the judicial response to aggressive pursuit of legal policy options is still unfolding. Although the process of legally regulating tobacco advertising and promotion has been under way for decades, the extent of such regulation and its ultimate limits are not yet known.

The most significant developments in this area revolved around the release of-and subsequent reaction to—the FDA's August 10, 1995, preliminary determination. The determination accompanied a proposed rule that sought to restrict the availability and marketing of tobacco products to children and adolescents. The FDA's final determination that it had authority to regulate cigarettes and smokeless tobacco products (released on August 28, 1996) is discussed later in this chapter, where the analysis of product regulation focuses on "Further Regulatory Steps."

Arguably the second most important development in this area was the June 20, 1997, proposed agreement that would have settled lawsuits between 41 state attorneys general and the tobacco industry. Because the advertising and promotion provisions of that agreement directly presupposed legislation that would have upheld the FDA's asserted jurisdiction to regulate tobacco products, this key multistate agreement is, like the FDA announcement, discussed later in this chapter, where the analysis of product regulation focuses on "Legislative Developments" and "Master Settlement Agreement."

Product Regulation

Introduction

Cigarette smoke contains approximately 4,000 chemicals, including a number of carcinogens and other toxic chemicals, such as hydrogen cyanide and oxides of nitrogen (USDHHS 1989). Regulating tobacco products requires appropriate assessment of these primary and secondary products of combustion and other substances that may be inhaled. Current tobacco product regulation requires that cigarette advertising disclose levels of "tar" (an all-purpose term for particulatephase constituents of tobacco smoke, many of which are carcinogenic or otherwise toxic) and nicotine (the psychoactive drug in tobacco products that causes addiction [USDHHS 1988]) in the smoke of manufactured cigarettes and that warning labels appear on packages and on some (but not all) advertising for manufactured cigarettes and smokeless tobacco;2 the current federal

²In California, a state suit against tobacco manufacturers for failure to comply with the state's Safe Drinking Water and Toxic Substances Enforcement Act of 1986 led to an agreement requiring that a warning about the possibility of reproductive harm and cancer appear on packages not covered by federal requirements (USDHHS 1989).

laws preempt, in part, states and localities from imposing other labeling regulations on cigarettes and smokeless tobacco (see the previous major section, "Advertising and Promotion").

Since the mid-1980s, federal law has required makers of manufactured cigarettes and of smokeless tobacco products to submit lists of additives to the tobaccos (but not to filters or papers) in their products to the Secretary of Health and Human Services (Comprehensive Smoking Education Act, Public Law 98-474, sec. 5; Comprehensive Smokeless Tobacco Health Education Act of 1986, Public Law 99-252, sec. 4). Information about the quantity of additives used and their placement in specific brands is not required, and the Secretary is bound by law to safeguard the lists from public disclosure. In 1994, attorneys for six manufacturers released to the public the list of ingredients added to tobacco in 1993.

Tobacco products are explicitly protected from regulation in various federal consumer safety laws (USDHHS 1989). Although regulation requires public reporting of some constituents in cigarette smoke, cigarette manufacturers are not required to report to a governmental body (or to include on product labels for consumers) brand-specific information about the nicotine content or any other property (e.g., nitrosamine levels, ammonia level, pesticide residues, heavy metals [lead, cadmium, mercury, or chromium], pH, or sugar content) of the material that forms the tobacco rod of their products. At the very least, knowledge of the upper bound of nicotine in the tobacco rod of cigarettes is important because actual smoking may produce constituent levels that vary considerably from that in smoke delivery yields reported to the FTC (USDHHS 1988; see also "Compensatory Smoking," later in this chapter). Those measurements were conducted by the Tobacco Institute Testing Laboratory.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 requires smokeless tobacco manufacturers to report the total nicotine content of their products to the Secretary of Health and Human Services (Public Law 99-252, sec. 4), but the Secretary may not release the data to the public. A uniform protocol implementing this provision was published in the March 23, 1999, Federal Register. No federal public health laws or regulations apply to cigars, pipe tobaccos, or fine-cut cigarette tobaccos (for "roll-your-own" cigarettes) in any manner other than prohibiting the advertising of small cigars through electronic media (USDHHS 1989).

The Constituents of Smoke From Manufactured Cigarettes

Since 1967, the FTC has regularly published tables of tar and nicotine delivery of smoke from manufactured cigarettes. Since 1980, the tables have also included a measurement for carbon monoxide delivery. The data are based on results of a standardized, machine-driven test procedure (Pillsbury et al. 1969) that provides a basis of comparison among various brands of cigarettes. Manufacturers are not required to print these values on the product package, but "ultra low" cigarette brands often include tar and nicotine deliveries on the package, presumably to differentiate these brands (Davis et al. 1990). No brand having a tar yield above 11 mg prints this information on the package. Carbon monoxide deliveries are not listed either on packages or in advertising (USDHHS 1989).

Regulation by Tar Levels

The FTC's tables of tar levels have provided some jurisdictions with criteria for regulating tar content by levying taxes on higher-tar cigarettes or, in the case of countries in the European Union, by altogether banning high-tar cigarettes. The apparent assumption behind such actions—that discouraging or banning consumption of higher-tar cigarettes will result in reduced morbidity and mortality from smoking-related diseases—has been questioned, as is discussed in the section "Compensatory Smoking," later in this chapter.

Tar content has in several instances served as the basis for cigarette taxation, on the presumption that the taxing structure would provide a competitive advantage to low-tar brands—an advantage of interest, for supposed public health reasons, to the jurisdiction levying the tax. For several years beginning in 1971, New York City taxed cigarettes that had either tar yields over 17 mg or nicotine yields over 1.1 mg an additional 3 cents per pack and cigarettes that exceeded both thresholds, 4 cents (Long Island Tobacco Co., Inc. v. Lindsay, 74 Misc. 2d 445, 343 N.Y.S.2d 759 [N.Y. 1973]). Although the levy was upheld by the courts, the law seems to have been repealed because of allegations that unequal taxation across political boundaries was fostering smuggling (Ranzal 1973). There are no reports on the effects this tax may have had on consumption patterns.

In 1978, the British government imposed a supplementary tax on cigarettes having a measured tar yield greater than 20 mg (Gray and Daube 1980)

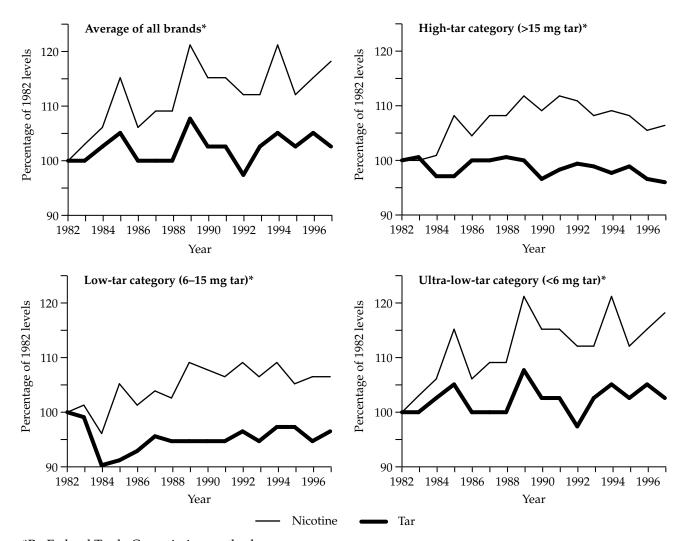


Figure 5.1. Sales-weighted nicotine and tar levels in smoke as percentage of 1982 levels

*By Federal Trade Commission method.

Source: Kessler 1994b; Federal Trade Commission, unpublished data, 1998.

[note misprint in this publication: on page 93, line 3, "more" should have been "less"; correction furnished by Michael Daube, February 13, 1996]). Within three months of the imposition of the tax, the market share of such brands fell from 15 to 3 percent (Michael M. Daube, letter to John Slade, February 24, 1995). A similar tax was used in Sweden, but it was repealed to achieve uniformity with tax policies of the European Union (Paul Nordgren, letter to David T. Sweanor, December 23, 1994).

Among countries in the European Union, a fixed ceiling on tar content has been used as a regulatory method. The European Union has imposed a

graduated decline in the upper limit of tar deliveries permitted for cigarettes sold in member countries. Beginning January 1, 1993, the ceiling was 15 mg tar delivery per cigarette; after December 31, 1997, the ceiling was 12 mg (Council Directive 90/239/EEC 1990 O.J. [L 137]).

Implications of Nicotine Levels

The FTC's tables on nicotine levels have revealed a recent change in the ratio of tar to nicotine in cigarettes. Kessler (1994b) has reported that for 1982–1991, the ratio of average sales-weighted nicotine yield to

tar yield³ in cigarette smoke has risen steadily for each of three major tar-yield categories and for the overall market (Figure 5.1). Given the addictive properties of nicotine and its contribution to cardiovascular disease (USDHHS 1988), this change may have important public health implications. Moreover, "low-yield" and "ultra low-yield" cigarettes in the same period had higher nicotine yield to tar ratios than did brands in the high tar-yield categories. Consumers who pay more heed to the "numbers" for tar levels than to the much smaller (but no less important) numbers for nicotine levels may be under the illusion that they are reducing their health risks and increasing their chances of quitting by smoking "low-tar" cigarettes. (This illusion is further discussed in "The Low-Tar 'Alternative,' " later in this chapter.)

A manufactured cigarette generally contains 8-10 mg of nicotine (USDHHS 1988), regardless of the machine-measured nicotine delivery in the smoke. Under usual smoking conditions, consumers absorb about 10–30 percent of the nicotine contained in the tobacco rod of the cigarette (USDHHS 1988; Benowitz and Henningfield 1994). Some thought has recently been given to systematically lowering the nicotine content of tobacco products to levels that would not pose a threat of addiction (Benowitz and Henningfield 1994; Douglas 1994). Benowitz and Henningfield (1994) have suggested that addiction is unlikely to be sustained below a nicotine dose of about 5 mg per day. This dose is about one-fourth the daily dose commonly ingested by tobacco users. To achieve such a ceiling for cigarettes, the nicotine content of the tobacco rod would have to be 0.5 mg or less, assuming that the smoker consumes about 30 cigarettes per day and receives 30 percent of the nicotine available. However, cigarettes with such low levels of nicotine may not be popular (Campbell 1994). The experience of Philip Morris Companies Inc. in trying to sell a low-nicotine-content cigarette, "Next," illustrates this point; the company judged the test-marketing of this cigarette a failure. Such failure provides indirect support for the importance of nicotine addiction to the tobacco industry.

Mandating the reduction of nicotine for the purpose of weaning smokers from tobacco products was contemplated as a strategy available to the FDA in legislation proposed to enable the multistate settlement agreement with the tobacco companies (see

"Legislative Developments" and "Master Settlement Agreement," later in this chapter). A similar strategy is used in some voluntary stop-smoking programs (e.g., Gahagan 1987). But this strategy cannot work unless accurate measures are available of the actual nicotine uptake that smokers and other tobacco users receive.

In 1994, the NCI convened an ad hoc expert committee to determine the adequacy of the standard, smoking-machine-based, FTC protocol for determining the tar and nicotine content of cigarettes. The committee concluded that "the FTC test protocol was based on cursory observations of human smoking behavior. Actual human smoking behavior is characterized by wide variations in smoking patterns, which result in wide variations in tar and nicotine exposure. Smokers who switch to lower tar and nicotine cigarettes frequently change their smoking behavior, which may negate potential health benefits" (NCI 1996, p. vi).

In 1996, Massachusetts enacted a law designed to obtain reports of brand-specific nicotine levels that more closely approximate the uptake by actual smokers of these brands. The statute instructs the state Department of Public Health to establish standards for nicotine yield ratings that "accurately predict nicotine intake for average consumers" (Mass. Gen. Laws ch. 94, sec. 307B). Each cigarette and smokeless tobacco manufacturer must then report, in a manner consistent with these standards, the nicotine yield rating of each brand of tobacco products it produces. These reports become public records.

Other Constituents in Cigarette Smoke

Tar and nicotine measurements have traditionally been used as surrogate measures for other toxic constituents in cigarette smoke, because changes in tar and nicotine levels presumably are predictive of changes in the levels of most other particulates. Studies suggest otherwise. For example, tar level as measured by smoking machines is not a good predictor of benzo[a]pyrene level (Kaiserman and Rickert 1992). In general, declared tar values are not predictive of tobacco-specific nitrosamine levels (Fischer et al. 1990, 1991b). Similarly, tar delivery is a poor predictor of the delivery of gas-phase constituents, such as carbon monoxide, hydrogen cyanide, and acrolein (Young et al. 1981).

In Canada, the Department of National Health and Welfare (Health Canada) has undertaken a program to develop methods for collecting and analyzing toxic constituents, other than tar, nicotine, and carbon monoxide, in tobacco smoke. Methods have been developed to measure the levels of benzo[a]pyrene, the

³ Average sales-weighted nicotine-to-tar yield means that the average amount reported here was calculated by taking the yield from all brands of cigarettes and weighting each yield by its sales figures. Thus, the yield for a popular cigarette would "count" more in the average of all brands than the yield for a less popular brand

tobacco-specific nitrosamines, hydrogen cyanide, benzene, formaldehyde, 4-amino-biphenyl, and heavy metals such as lead and cadmium (Health Canada 1995a). The Department of National Health and Welfare intends to require manufacturers to use these test methods to provide quantitative reports on these chemicals in tobacco smoke or, in the case of heavy metals, in the tobacco itself (Health Canada 1995a).

Rickert (1994) has described the presence of the potent bladder carcinogen 4-amino-biphenyl in the sidestream smoke from all 10 brands of cigarettes tested in a study for Health Canada. Under occupational safety regulations, the permissible level of exposure to 4-amino-biphenyl is zero. Applying these standards to cigarette smoke would require either that this material be absent from cigarette smoke entirely or that cigarette smoke not be permitted in spaces subject to regulation.

An important development indicating a possible design flaw in the manufacture of cigarettes has been the report that cellulose acetate fibers are shed from cigarette filters. Such fibers, coated with tar, have been observed in the lungs of smokers; this observation suggests that these fibers may be long-lived in human tissue and may be associated with disease (Pauly et al. 1995).

Additives to Tobacco Products

Hundreds of ingredients besides tobacco are used in the manufacture of tobacco products. Additives make cigarettes more acceptable to the consumer; they can make smoke seem milder (and easier to inhale), prolong shelf life, prolong burning, and improve taste. These additives may be a single chemical used as a humectant or a complex mix of chemicals used as a flavorant.

Cigarette Additives

The six major cigarette manufacturers reported a pooled list of 599 ingredients that were added to the tobacco of manufactured cigarettes as of 1994 (R.J. Reynolds Tobacco Company 1994). The list is annotated with references to which materials are approved for use as food additives by the FDA (under the category "Generally Recognized as Safe") and are thought to be safe by the Flavor and Extract Manufacturers Association of the United States. However, that a material is regarded as safe when ingested in foods provides no assurance of its safety in a tobacco product, where it will be combined with other substances, heated to high temperatures, and may be inhaled into the lungs.

The American Health Foundation (1990) has pointed out the toxic potential of numerous cigarette tobacco additives under expected conditions of use. Heating and burning may lead to the formation of carcinogens from some of the additives used. For instance, amino acids used as additives are known to form compounds of various elements, including genotoxic agents (known to damage DNA) and experimental carcinogens, during heating. Licorice root extract contains glycyrrhizin, and both are used as additives in cigarettes; glycyrrhizin produces carcinogenic by-products when burned. The leukemiaproducing agent benzene is a component of cigarette smoke that may be formed from the combustion of many cigarette additives. Because the Federal Food, Drug, and Cosmetic Act requires that a food additive "be safe under the conditions of its intended use" (sec. 321), tobacco additives in manufactured cigarettes may not fulfill the specifications of the law were the law applied to tobacco.

The use of additives may reinforce cigarette smoking by strengthening the addictive effects of nicotine. At least one major domestic cigarette maker uses some additives to boost the absorption of nicotine in cigarette smoke (Kessler 1994c). Ammonia compounds alter the pH of nicotine in tobacco, converting it from the protonated, bound form (various nicotine salts) to the unprotonated, freebase form. Freebase nicotine more readily enters the smoke stream and has been predicted to cross lung and oral cavity membranes more quickly than nicotine salts do (Henningfield et al. 1995). The broader issue of enhancing the delivery of nicotine is discussed in the introductory section of "Further Regulatory Steps," later in this chapter.

Several European countries regulate cigarette additives, but only to a modest extent. In France, the total percentage of the cigarette that consists of additives is listed on the side of the package. Among representative brands manufactured in the United States but sold in France (e.g., Camel, Kent, Marlboro, and Winston), the cigarette labels indicate that between 6.2 and 10.0 percent of each cigarette is composed of additives. The British government maintains a list of "permitted" or "approved" additives for smoking tobacco and cigarette paper (Lewis and Davis 1994, p. 206). The list, which had 474 ingredients in 1988, specifies the maximum level permitted for each specific additive (Lewis and Davis 1994). In Canada, the Tobacco Products Control Act (sec. 10; Department of National Health and Welfare 1989) requires manufacturers to report a quarterly list of ingredients used in their products. Canadian producers use far fewer additives—about 50 in all—than do American manufacturers.

Massachusetts, Minnesota, and Texas have enacted laws to require the disclosure of nontobacco ingredients in tobacco products (Mass. Gen. Laws ch. 94, sec. 307B; Minn. Laws ch. 227 [1997]; Vernon's Texas Statutes and Codes Annotated ch. 161, sec. 161.252 [1997]). Health officials in the Canadian province of British Columbia have announced their intention of taking similar steps there.

The Massachusetts law, applicable to cigarettes and smokeless tobacco, requires the manufacturer to report, in descending order by weight, measure, or numerical count, the identity of each brand's added constituents other than tobacco, reconstituted tobacco sheet, or water. Ingredients that are recognized as safe when burned and inhaled are exempted. The Department of Public Health is then instructed to disclose the reported information to the public to the extent that "there is a reasonable scientific basis for concluding that the availability of such information could reduce risks to public health" (Mass. Gen. Laws ch. 94, sec. 307B).

The tobacco industry challenged the statute in court on both preemption and trade secret grounds. The Federal District Court ruled that nothing in federal law preempted Massachusetts from taking this action, and the court of appeals affirmed (Philip Morris Inc. v. Harshbarger, 122 F.3d 58 [1st Cir. 1997]). However, the same Federal District Court thereafter issued a preliminary injunction that prevented the state from enforcing the ingredient disclosure provision of the statute; the court ruled that doing so would expose the trade secrets of the manufacturers (Philip Morris Inc. v. Harshbarger, Civil Action No. 96-11599-GAO, Civil Action No. 96-11619-GAO, 1997 U.S. Dist. LEXIS 21012 [D. Mass. Dec. 10, 1997]). That ruling is currently under appeal. Texas has adopted a similar statute requiring the tobacco industry to submit a list of ingredients and nicotine yield ratings to the Texas Department of Health by December 1998 (Vernon's Texas Statutes and Codes Annotated ch. 161, secs. 161.252, 161.254, 161.255).

The Minnesota statute requires manufacturers of tobacco products to publicly disclose, for each brand, whether the product contains detectable levels—in either its unburned or its burned states—of ammonia or ammonia compounds, arsenic, cadmium, formaldehyde, or lead. The industry filed suit in Federal District Court to enjoin the enforcement of the statute but agreed to drop the suit as part of its May 1998 settlement of the state's Medicaid reimbursement lawsuit (discussed in "Recovery Claims by Third-Party Health Care Payers," later in this chapter) (*Minnesota v. Philip Morris Inc.*, cited in 13.2 TPLR 3.39, 3.45 [1998]).

Most recently, British Columbia health officials announced plans to require cigarette manufacturers to disclose to the government all ingredients, including additives used to treat the papers and filters. Manufacturers would also have to test and report on 44 poisons that the health officials claim are contained in cigarette smoke (Reuters 1998).

Smokeless Tobacco Additives

In 1994, ten manufacturers of smokeless tobacco products released a list of additives used in their products (Patton, Boggs & Blow 1994). As with the additive list for cigarette tobacco, the smokeless tobacco list notes which of the 562 materials listed have been approved for use in foods by the FDA and also notes which are regarded as safe by the Federal Emergency Management Agency. As with cigarette tobacco, applying these safety standards to nonfood substances is problematic; however, smokeless tobacco used in an unaltered (unburned) state lessens some of the concern over the possible hazards of additives.

The list of additives to smokeless tobacco includes sodium carbonate and ammonium carbonate, which are alkalinizing agents that increase the level of "free" (chemically uncombined) nicotine in moist snuff by raising the pH level (Slade 1995). A division of the Swedish Tobacco Company has stated that sodium carbonate is added to its moist snuff brands to alkalinize the tobacco and thus enhance nicotine absorption (Kronquist 1994). The pH of moist snuff products—which is not reported to consumers varies from acidic to alkaline, providing a wide range of free-nicotine levels in various products (Djordjevic et al. 1995; Henningfield et al. 1995). Products for persons entering the market (such as those that have easyto-use unit dosages) are acidic (thus reducing absorption) and have very low levels of free nicotine, whereas products for more experienced users (such as the Copenhagen brand) are alkaline and have high levels of free nicotine. The epidemiology of moist snuff use among teenagers and young adults indicates that most novices start with brands having low levels of free nicotine and then graduate to brands with higher levels (Tomar and Henningfield 1992; Tomar et al. 1995). These patterns are consistent with the industry's marketing strategies as reflected in their advertising and marketing activities and their internal documents (Connolly 1995).

Sweeteners and flavorings, such as cherry juice concentrate, apple juice, chocolate liqueur, and honey, are used in various smokeless tobacco products, and dominant flavors are often mentioned in the product

name (e.g., the Skoal Cherry Long Cut brand). As with manufactured cigarettes, these additives increase palatability and may intensify use of smokeless tobacco, at least among novices (Freedman 1994).

The Low-Tar "Alternative"

As the health hazards of smoking have been increasingly documented, the production of lower-tar cigarettes has increased. The FTC's tables on average sales-weighted tar levels for cigarettes on the U.S. market from 1968 through 1987 reflect this shift toward lower-tar cigarette brands (USDHHS 1981, 1989). The public health implications of this shift merit closer inspection.

Compensatory Smoking

Considerations of product regulation must take into account the variability in toxic exposure attributable to specific smoking practices. The overall evidence suggests that many smokers compensate when smoking low-delivery cigarettes by inhaling more tar and nicotine than are measured by smoking machines under standard conditions. Any potential health benefit implied by machine measurements of lower tar and nicotine yields may thus be mitigated by such compensatory smoking.

Studies have shown that as consumers switched to lower-yield cigarettes in Great Britain, they tended to smoke more cigarettes each day (Ferris 1984), apparently to compensate for the lower nicotine yield per cigarette. Similar compensatory measures may have occurred in the United States. For example, smokers in Cancer Prevention Study I, conducted during the 1960s when lower-yield brands were rare, smoked fewer cigarettes per day than smokers in Cancer Prevention Study II, which was conducted during the 1980s, by which time most smokers used lower-yield brands (Thun et al. 1997). Strong evidence suggests that smokers increase the number of cigarettes consumed as nicotine availability is reduced, and vice versa (USDHHS 1988; Kaufman et al. 1989; Palmer et al. 1989; Stellman and Garfinkel 1989; Negri et al. 1993; Thun et al. 1997). In addition, lower nicotine delivery in the FTC test is associated with smoking a greater number of cigarettes (USDHHS 1988). This compensatory effect has been confirmed in other studies (Benowitz et al. 1983; Bridges et al. 1990; Höfer et al. 1991; Woodward and Tunstall-Pedoe 1992; Coultas et al. 1993); only one published study found no such effect (Rosa et al. 1992). In an abstract, Byrd and colleagues (1994) reported no compensatory effect, but their small study population may not have been representative of all smokers; for instance, the nicotine intake seen among the group that smoked the ultra low-delivery cigarettes was smaller than that observed by others.

Health Risks From Low-Tar Cigarettes

Even when compensatory smoking is not accounted for and calculations are derived from machine-rated tar levels, the risk of lung cancer is only slightly lower from using low-tar cigarettes than from using high-tar cigarettes, and reduced tar level has little if any impact on the occurrence of other cigarette-caused lung disease or of heart disease (USDHHS 1981, 1989; Parish et al. 1995; Wannamethee et al. 1995).

Giovino and colleagues (1996) have examined results from several national surveys of tobacco use for attitudes and behaviors related to the use of lowtar cigarettes. In these surveys, current smokers of lowtar brands were found to be more likely than smokers of high-tar brands to acknowledge the health risks of smoking, to express concerns about these risks, to report that they had been advised by a physician to stop, and to report that they had experienced negative health consequences from smoking. These smokers were also more likely, however, to believe that smoking a lowtar brand reduced those risks. For example, in the 1987 National Health Interview Survey, 44 percent of smokers reported that they had switched to a low-tar cigarette to reduce their health risk, and 48 percent of low-tar brand users thought their brand was less hazardous than most other brands (Giovino et al. 1996). These attitudes were confirmed by a 1993 Gallup poll in which 49 percent of respondents stated that they believed that the advertising message in terms such as "low tar," "low nicotine," or "lower yield" was that the "brand [was] safer"; only 4 percent believed that the advertisements were "false/misleading" (Gallup Organization, Inc. 1993, p. 23).

The analysis by Giovino and colleagues (1996) also suggested that many smokers of low-tar cigarettes may have used these brands instead of quitting. Low-tar users were more likely than high-tar users to have tried unsuccessfully to stop smoking. Similarly, a greater proportion of people who had successfully quit smoking had been high-tar cigarette users. This latter

⁴Some reports have included data from 1957 to 1967 (e.g., USDHHS 1989, p. 88). However, those data are unpublished and first appeared in a chart attributed to a personal communication from Dr. Helmut Wakeham, then a research scientist with Philip Morris Companies Inc. (Wynder and Hecht 1976, p. 151).

observation has been confirmed in another survey: those who had stopped smoking tended to have been higher-tar cigarette smokers (Cohen 1996). As was previously suggested (Kessler 1994b), the higher ratios of nicotine yield to tar yield in lower-tar cigarettes than in higher-tar cigarettes could impede efforts to quit among persons who smoke lower-tar cigarettes.

Assessment of consumer attitudes, as well as epidemiologic consideration of health risks from lower-yield cigarettes, has raised concerns about the reporting of FTC test results (Henningfield et al. 1994). An ad hoc committee of the President's Cancer Panel, convened in December 1994 (Jenks 1995), concluded that consumers misunderstand the FTC test results and should be given a range of values for smoke deliveries (reflecting the way cigarettes are actually smoked) and that these values should be included on each package and in all advertisements (NCI 1996). The committee also concluded that terms such as "light" and "ultra light" are in fact health claims that mislead consumers.

Nicotine Replacement Products

The "safe cigarette," long sought, has not been found (Gori and Bock 1980; USDHHS 1981, 1989; Slade 1989, 1993), and the axiom that no tobacco product is safe when used as intended remains true (USDHHS 1989). As long as tobacco products are sold, some people will be unable to stop using nicotine (Kozlowski 1987). Novel nicotine delivery devices have been tried in test markets (R.J. Reynolds Tobacco Company 1988; Slade 1993; Hilts 1994), and several tobacco companies have patents for various designs (David A. Kessler, letter to Scott D. Ballin, February 25, 1994; Slade 1994; Hwang 1995b). All designs share the ability to deliver nicotine for inhalation with a minimum of, or no, tar thereby avoiding the smoking-associated increased risk of cancer (although not the nicotine-associated increased risk of cardiovascular disease) (USDHHS 1988).

Nicotine replacement products have been developed and marketed by pharmaceutical companies as adjuncts to help people stop smoking (Jarvik and Henningfield 1993). As was discussed in Chapter 4 (see "Pharmacologic Interventions"), concerns over possible intentional or unintentional misuse of these products have been weighed against the health benefits resulting from their effectiveness as a cessation aid. Nicotine gum and nicotine patches, previously approved by the FDA as prescription drugs for brief use (months), were approved in 1996 for over-the-counter use, concluding an intense examination of the

issues of nicotine availability. Both a nicotine nasal spray and a nicotine inhaler were approved for prescription use. The Drug Abuse Advisory Committee (1994) of the FDA has expressed concern about the potential abuse liability of the spray and the inhaler, because the pharmacokinetics of their delivered dose of nicotine comes closer than the gum or patch to what occurs through using tobacco products. Benowitz and Pinney (1998) concluded that the benefits from overthe-counter availability of the gum and patch would outweigh the risks. In December 1996, the FDA's Drug Abuse Advisory Committee recommended approval of the nicotine inhaler for prescription use (FDA Drug Abuse Advisory Committee, draft minutes of December 13, 1996, meeting).

Nicotine maintenance is not an approved therapeutic approach, but some observers have called for a coordinated clinical and public health program to explore this option (Slade et al. 1992). A useful program not only must substantially reduce health risks and satisfy addicted individuals who cannot otherwise stop using tobacco products but also must include realistic safeguards to prevent the new onset of nicotine dependence among the young, to prevent relapse among those who have already stopped, and to further reduce overall smoking prevalence.

The elements of such a program would include research to (1) fully characterize the population that would benefit from nicotine maintenance, (2) identify potential delivery devices for nicotine or an appropriate analogue, (3) explore fully the safety of these devices as well as the safety of nicotine or the chosen analogue (including assessments of potential cardiovascular, fetal, cognitive, and performance problems consequent to use of the drug, as well as other potential health effects), and (4) design a drug distribution system that would be acceptable to intended users but that would substantially limit access by novices to tobacco use and by those who have already been successful at achieving abstinence from nicotine (Slade et al. 1992).

Product Regulations for Consumer Education

The previous discussion of product regulation centered on the contents of the tobacco product itself. Another critical focus for product regulation is packaging, a promising field for public information and education on smoking and health. Government actions in this area have included product packaging to convey health messages (see "Attempts to Regulate

Tobacco Advertising and Packaging," earlier in this chapter). The goal of this packaging strategy, as discussed in the following section, is to help ensure that the purchase of tobacco products occurs only as a transaction involving informed consumer choice. Also discussed is a related, more complex goal for this strategy: to help ensure a situation of informed consumer consent rather than simply choice.

Tobacco Packaging and Informed Choice

The current required warning labels on U.S. to-bacco packages are but a single, narrow means by which package-based messages can promote informed choice among consumers. The vast amount of information available on the adverse health effects of to-bacco use constitutes a wide range of messages that can be presented this way (USDHHS 1989). This information can appear on packages in many ways, given the numerous variables such as size, wording, placement, colors, graphics, typefaces, and package inserts.

The potential public education value of package-based health messages is inherent in their exceptionally large rate of exposure to consumer view. In the United States, about 478 billion cigarettes were consumed in 1997 (Tobacco Institute 1998). Each of these cigarettes will be removed from a package that could be viewed by many cigarette users at exactly the time they are preparing to engage in the activity such messages are intended to prevent. These messages can be seen not only immediately before use but also at the point of sale or at any time the package is in the possession of the user. The messages do not have to be directed only at tobacco users; any exposed package can be viewed by, and can provide information equally germane to, users and nonusers alike.

An example of the potential inherent in package messages is provided from Canada. In legislation supplementing the Tobacco Products Control Act (sec. 9), the federal government of Canada not only increased the number of rotating messages from four to eight but also made new stipulations regarding the messages' size, location, and color (Department of National Health and Welfare 1993; for details on these changes, see "Examples of Product Labeling in Other Countries," earlier in this chapter). These changes followed studies undertaken to determine the existing messages' legibility, readability, believability, and ease of understanding. These studies had indicated that health warnings were read about 1.4 times per day (women, 1.8 times; men, 1.2 times) and that cigarette packs were a primary source of tobacco-related health information for 55 percent of smokers, second only to television (59 percent) and well ahead of newspapers (17 percent) (Tandemar Research Inc. 1992; Kaiserman 1993).

Tobacco Use and Informed Consent

Although many discussions of tobacco use invoke "free choice," the more rigorous legal concept is "informed consent." As applied to tobacco use, informed consent would obtain only when potential purchasers of tobacco products could make fully informed purchase decisions after carefully weighing the health risks of using those products. Thus, like patients considering whether to undergo potentially harmful medical procedures, consumers considering whether to use tobacco would have to know which health problems are caused by the product's use, what increases in personal risk of these various problems occur through this use, what the prognosis is should any of these problems arise, and what effect ending or adjusting the use could have on these problems. Courts of law in this country and elsewhere have articulated the duty of product manufacturers to warn consumers about product hazards. A particularly clear statement of the principles involved in informed consent is found in an Ontario Court of Appeal decision concerning oral contraceptives:

Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard, and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. The nature and extent of any given warning will depend on what is reasonable having regard to all the facts and circumstances relevant to the product in question (*Buchan v. Ortho Pharmaceutical [Canada] Ltd.*, [1986] 54 O.R.2d 101 [Ct. App.] [Can.]).

Similarly, a U.S. court has described an adequate product warning in the following way:

In order for a warning to be adequate, it must provide "a complete disclosure of the existence and extent of the risk involved" (*Pavlides v. Galveston Yacht Basin, Inc.,* 727 F.2d 330 [5th Cir. 1984]) citing *Alman Brothers Farms & Feed Mill, Inc. v. Diamond Laboratories, Inc.,* 437 F.2d 1295, p. 1303 [5th Cir. 1971]). . . . A warning must (1) be designed so it

can reasonably be expected to catch the attention of the consumer; (2) be comprehensible and give a fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk (*Pavlides*, p. 338).

At issue, then, is whether consumers have received adequate warning for informed consent to apply to tobacco use. Although public knowledge about the health effects of tobacco use has improved over the past 15 years (FTC 1984; USDHHS 1989), evidence persists of gaps in understanding. An American Cancer Society (ACS) study showed respondents a list of selected causes of death and asked which was responsible for the greatest number of deaths (Marttila & Kiley, Inc. 1993). The study found that only one in five Americans could correctly identify cigarette smoking as the listed cause associated with the most deaths. Similar studies in other countries (Hill and Gray 1984; Gallup Canada, Inc. 1988; Environics Research Group Limited 1991; Health and Welfare Canada 1992 [unpublished data]) have found a similar lack of knowledge.

These studies indicate that the public continues to underestimate the magnitude of the risks arising from tobacco use. The resulting inability of consumers to make fully informed decisions about tobacco use could be interpreted as a failure on the part of the manufacturer to achieve informed consent from users of the product. To date, this issue has not been legally addressed, and the previously discussed notion of informed choice, which carries clearer legal implications, is generally invoked.

Further Regulatory Steps

Although some of the aforementioned product regulations address the chemical constituents of tobacco use, none directly broaches the issue of whether tobacco, as a nicotine delivery system, should be subject to federal regulation as an addictive product. In March 1994, the Coalition on Smoking OR Health ([CSH] composed of the American Heart Association, the American Lung Association, and the American Cancer Society) filed a petition with the FDA to declare all cigarette products to be drugs under section 201 of the Federal Food, Drug, and Cosmetic Act (CSH 1994a). This petition followed an earlier one by the same coalition requesting the classification of low-tar and low-nicotine cigarettes as drugs and similarly classifying the proposed new R.J. Reynolds Tobacco Company "smokeless cigarette" as a drug (CSH 1988).

A few weeks earlier, the FDA had made public that it was investigating whether it might assert jurisdiction over tobacco products (Kessler 1994a). The legal basis for such a move requires demonstrating that the manufacturers of tobacco products intend to affect the structure or function of their customers' bodies (21 U.S.C. section 321 [g] [1]). The Commissioner of the Food and Drug Administration, David A. Kessler, M.D., had indicated in testimony before Congress that there was evidence that pointed to this conclusion (Kessler 1994b,c).

The FDA has concluded that words used by to-bacco companies to describe some effects of smoking (e.g., "satisfaction," "strength," and "impact") are euphemisms that actually describe pharmacologic effects of nicotine (Kessler 1994b, p. 150). Dr. Kessler has noted that cigarettes are sophisticated, carefully designed devices. Industry patents disclose a detailed knowledge of nicotine pharmacology and describe as desirable those product refinements that increase the efficiency of nicotine delivery. One company has patented a series of nicotine analogues having desired pharmacologic effects, much as a conventional pharmaceutical company might develop a new drug that produces effects similar to those of an existing drug.

The FDA has disclosed several specific examples of product manipulation to adjust the delivered dose of nicotine in cigarettes (Kessler 1994c). The Brown & Williamson Tobacco Corporation has used in cigarettes sold in the United States a strain of tobacco (Y-1) that had been genetically engineered to have a high nicotine content. According to a major American tobacco company's handbook on leaf blending and product development, ammonia compounds can be used as additives to boost the delivery of nicotine in smoke to enhance the "impact" and "satisfaction" from smoke (Kessler 1994c, p. 365). In an official prosecution memorandum to the U.S. Attorney General, Representative Martin T. Meehan (D-MA) has asserted that product manipulation of Eclipse brand cigarettes has taken place. Meehan cites the addition of high-nicotine-content tobacco near the filter and the addition of potassium carbonate to change the pH of the tobacco (or to enhance absorption through the mucous membranes) (Meehan 1994; see "Criminal Proceedings," later in this chapter). Moreover, information obtained from internal industry documents suggests that at least some tobacco companies have long had an accurate and detailed knowledge of nicotine pharmacology. Dr. Kessler told Congress that "such research would be of interest to the industry only if the industry were concerned with the physiological and pharmacological effects of nicotine. Certainly, this is

not consistent with the industry's representation that nicotine is of interest to it only because of flavour and taste" (Kessler 1994c, p. 367).

Following his testimony before Congress, in a speech at Columbia University School of Law, Dr. Kessler emphasized the importance of preventing nicotine dependence among children and teenagers. Calling it "a pediatric disease" (David A. Kessler. Remarks. Presented at the Samuel Rubin Program, Columbia University School of Law, New York City, March 8, 1995, unpublished), he outlined a number of specific priorities for public health action:

A comprehensive and meaningful approach to preventing future generations of young people from becoming addicted to nicotine in tobacco is needed. Any such approach should: First, reduce the many avenues of easy access to tobacco products available to children and teenagers; second, get the message to our young people that nicotine is addictive, and that tobacco products pose serious health hazards—and not just for someone else; and third, reduce the powerful imagery in tobacco advertising and promotion that encourages young people to begin using tobacco products (p. 19).

On August 10, 1995, the FDA announced the result of its investigation. The agency stated that evidence appears to indicate that "nicotine in cigarettes and smokeless tobacco products is a drug and [that] these products are nicotine delivery devices under the Federal Food, Drug, and Cosmetic Act" (Federal Register 1995a). In August 1995, the FDA issued in the Federal Register (1) a proposed rule of regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents and (2) an analysis of the FDA's jurisdiction over cigarettes and smokeless tobacco. The FDA requested comments on its proposed regulations and analysis of its jurisdiction, and indicated that it would give serious consideration to comments filed with the agency concerning the evidence amassed during its investigation. The Clinton administration also suggested that Congress could eliminate the need for this rulemaking by passing new legislation to affirm the FDA's authority over tobacco products and address the issue of tobacco use among minors.

In its legal analysis of its proposed jurisdiction over tobacco products, the FDA argued that cigarettes and tobacco products "affect the structure or any function of the body" (key language for invoking the agency's authorizing legislation) and that it is the intent of tobacco manufacturers that their products have

addictive effects (Federal Register 1995a). The argument was presented as a logical chain of inference: the addictive properties of tobacco are "widely known and foreseeable" by tobacco manufacturers; consumers use the product to satisfy their addiction; and tobacco manufacturers know of the addiction, know of consumers' use, and have facilitated that use (Federal Register 1995a). An extensive analysis, including internal documents from tobacco companies, was used to elucidate these assertions (Federal Register 1995a). The FDA presented a further legal discussion of whether the cigarette is a device and postulates that the cigarette is "a consciously engineered instrument . . . to effectuate the delivery of a carefully controlled amount of the nicotine to a site in the human body where it can be absorbed" (Federal Register 1995a).

The proposed regulations centered on restricting the availability and appeal of tobacco products to children and adolescents and consisted of the following provisions:

- The tobacco industry would be required to spend at least \$150 million per year to support smoking prevention education for children.
- Tobacco sales would be prohibited to those under 18 years of age, and vendors would be required to see photo identification as proof of age.
- Vending machines, self-service displays, and mailorder sales would be prohibited, as would the sale of individual cigarettes or packs of fewer than 20 cigarettes.
- The sale or gift of promotional items bearing brand names, logos, or other brand identity would be prohibited.
- Free samples would be banned.
- Only black-and-white text advertising for cigarette products would be permitted in publications for which more than 15 percent of the readership is under age 18 and in publications with more than 2 million young readers.
- Outdoor tobacco advertising would be prohibited within 1,000 feet of schools and playgrounds. All other outdoor tobacco advertising would have to be in black-and-white text.
- Sponsorship of sporting or entertainment events using specific brand names or product identification would be prohibited, although the use of company names would not.

The proposed regulations stirred immediate action from the tobacco industry. Four lawsuits were filed immediately after the Federal Register announcement. A lawsuit filed by tobacco companies in federal court in Greensboro, North Carolina, asserted that the FDA had no jurisdiction over cigarettes. The plaintiffs were Brown & Williamson Tobacco Corporation, Liggett Group Inc., Lorillard Tobacco Company, Philip Morris, and R.J. Reynolds Tobacco Company (Wall Street Journal 1995). Parts of the advertising industry, which has a large stake in the outcome of the proposed regulations, also filed suit on the grounds of infringement of First Amendment rights (American Advertising Federation v. Kessler, Civil Action No. 2:95CV00593 [M.D.N.C. Aug. 10, 1995], cited in 10.5 TPLR 3.401 [1995]). In addition, a smokeless tobacco company (United States Tobacco Co. v. Food and Drug Administration, Civil Action No. 6:95CV00665 [M.D.N.C. Sept. 19, 1995]) and a trade group representing convenience stores (National Association of Convenience Stores v. Kessler, Civil Action No. 2:95CV00706 [M.D.N.C. Oct. 4, 1995]) filed suit.

By the January 2, 1996, close of the public comment period on the proposed rules, the FDA had received more than 95,000 individual comments, the largest outpouring of public response in the agency's history. From March 18 to April 19, 1996, the FDA reopened the comment period for the limited purpose of seeking comments on the statements of three former Philip Morris employees about that company's alleged manipulation of nicotine in the design and production of cigarettes and to seek comments on further explanations of certain provisions in the proposed rule.

The review process culminated in a Rose Garden ceremony at the White House on August 23, 1996, in which President Clinton announced the publication of the final FDA rules. To emphasize that the FDA's central intent was to reduce tobacco use among young people, these final rules essentially regrouped the regulations from the original announcement into two categories: reducing minors' access to tobacco products and reducing the appeal of tobacco products to minors. The only notable changes to the former rules were that the ban on mail-order sales was eliminated and the ban on vending machines and self-service displays was relaxed to allow exceptions for certain nightclub and other "adults-only" facilities totally inaccessible to persons under the age of 18. Similarly, the limitation to black-and-white text for in-store advertising excepted adults-only facilities if the advertising was not visible from the outside.

In place of its original regulation requiring the tobacco industry to spend at least \$150 million each

year to support tobacco prevention education for children, the final rules were less explicit. The FDA proposed to require the six tobacco companies with a significant share of sales to minors to educate that population about the health risks of using tobacco products. This action would be pursued under processes dictated by section 518(a) of the Federal Food, Drug, and Cosmetic Act (FDCA). Under the act, the FDA may require manufacturers to inform the consumer about unreasonable health risks of their products.

The various provisions were to be phased in between six months and two years from August 28, 1996, the date of publication in the *Federal Register*. Two principal hurdles to quick and full implementation of the FDA regulations soon emerged. First, as noted above, several tobacco companies, retailers, and advertisers had sued the FDA to block implementation of the regulations. Second, various legislative proposals, which began circulating in Congress both before and after publication of the FDA's final rule, threatened to alter or bar the FDA's regulation of tobacco products.

Judicial Developments and the Status of FDA Regulations

Three briefs filed on October 15, 1996, on behalf of the plaintiffs in these suits moved for summary judgment, arguing that the proposed regulations exceed the agency's jurisdiction and are contrary to congressional intent, that tobacco products are not "drugs" or "devices" within the agency's statutory grant of authority, and that the advertising restrictions are a violation of the First Amendment (*Mealey's Litigation Reports: Tobacco* 1996b).

On April 25, 1997, the federal district court in Greensboro, North Carolina, ruled that the FDA possessed the authority to regulate cigarettes and smokeless tobacco products as drug delivery devices under the FDCA (Coyne Beahm, Inc. v. U.S. Food & Drug Administration, 966 F. Supp. 1374 [M.D.N.C. 1997]). The ruling, however, marked a considerably qualified victory for the FDA. Although the court upheld all of the agency's restrictions involving youth access and labeling, the court temporarily blocked implementation of most of these provisions. Only the FDA's prohibition on sales of cigarettes and smokeless tobacco to minors and the requirement that retailers check photo identification of customers who are under 27 years of age escaped the court's stay. These provisions went into effect on February 28, 1997, and remained in force until March 21, 2000, the date of the Supreme Court decision.

Notably, the court invalidated the FDA's restrictions on advertising and promotion of cigarettes and smokeless tobacco on the basis that they exceeded the agency's statutory jurisdiction. The pertinent federal statute, 21 U.S.C. section 360j(e), provides, in part, that the government may "require that a device be restricted to sale, distribution or use . . . upon such other conditions as the Secretary may prescribe." The FDA had argued that it was authorized to restrict the "sale, distribution or use" of tobacco products pursuant to section 360j(e) and that its advertising and promotion restrictions were valid because advertising and promotion constitutes an "offer of sale" (Coyne Beahm, p. 1398). Judge William L. Osteen Sr. disagreed. The court reasoned that the word "sale" as employed in the statute did not encompass the advertising or promotion of a product. The court also ruled that the "section's grant of authority to FDA to impose 'other conditions' on the sale, distribution, or use of restricted devices [does] not authorize FDA to restrict advertising and promotion" (p. 1398). Furthermore, because the court ruled that the FDA was not authorized to restrict advertising and promotion, the court did not reach or discuss arguments that these provisions violated the First Amendment to the United States Constitution.

Most important, however, Judge Osteen agreed with the FDA's contention that tobacco products fall within the "drug" and "device" definitions of the FDCA. To position its authority within these definitions, the FDA had to have demonstrated that tobacco products are "intended to affect the structure or any function of the body" (21 U.S.C. section 321 [g][1][C]). Judge Osteen ruled that the effects of tobacco products are "intended" within the meaning of the FDCA and that tobacco products affect the structure or function of the body within the meaning of that act. The court also ruled that pursuant to its "device authorities," the FDA could regulate tobacco products as medical devices.

Both sides in the case appealed the decision to the Fourth Circuit of the United States Court of Appeals in Richmond, Virginia. The government and the tobacco companies presented oral arguments to a three-member panel of this court on August 11, 1997. The case became inactive following the death of one of the panel judges on February 22, 1998. A new judge was appointed, and on June 9, 1998, the threemember panel conducted a second hearing on the appeal.

The Court of Appeals Ruling on FDA Authority

On August 14, 1998, the Fourth Circuit Court of Appeals overturned the lower court decision and ruled in a 2 to 1 decision that the FDA lacks the authority to regulate tobacco products (Brown & Williamson Tobacco Corp. v. Food & Drug Administration, No. 97-1604 [4th Cir. 1998]). The majority opinion (Judge H. Emory Widener Jr.) found that the FDA had based its determination of authority solely on literal interpretations of "drug" and "device" in the FDCA but did not consider statutory language as a whole, the legislative history, and the history of evolving congressional regulation in the area, including consideration of other relevant statutes. Judge Widener held that there is an internal inconsistency in the FDA's claim of authority to regulate tobacco under the FDCA, since a declaration that cigarettes are unsafe (the basis of the FDA's claim) necessitates a ban on cigarette sales—an action that would be opposed by powerful economic and political forces. Widener reasoned that although the FDA would have the authority to grant exemptions to the ban because potential public health benefits might outweigh harms, such exemptions would undermine the agency's essential view that cigarettes are unsafe. The only exemption open to the FDA would thus be based on social and economic rather than healthrelated considerations. A well-known catch would then come into play: social and economic considerations are within the purview of Congress, not the FDA. Judge Widener pointed out that Congress had been aware for decades that the FDA lacked the authority to regulate tobacco on social and economic grounds, had rejected attempts to give the FDA such authority, and had enacted numerous pieces of legislation that did not grant such authority.

The dissenting opinion (Judge Kenneth K. Hall) took the position that the intrinsic contradiction in the FDA's authority under the FDCA is irrelevant: "... whether the regulations contravene the statute is a question wholly apart from whether any regulations could be issued. . . . It is no argument to say that the FDA can do nothing because it could have done more" (Brown & Williamson, p. 48). The opinion proposed that the FDA's current position is a response to "the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the addictive effect of tobacco products" (p. 50). Judge Hall stated that precedents in administrative law clearly indicate latitude for an agency to change its approach in the light of new information. He further asserted that earlier congressional action did not have the benefit of the level of evidence gathered by the FDA in forming its current position. Finally, he pointed out that the term "sale, distribution and use" (p. 58) is not fully defined in the FDCA and is therefore subject to agency interpretation. This term "can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home" (p. 58). Thus, the judge reasoned, the authority to regulate tobacco promotion should be upheld. The full Fourth Circuit Court of Appeals declined to review this reversal. The government petitioned the United States Supreme Court for review, and the United States Supreme Court accepted the case in April 1999. Oral argument was held December 1999, and the Court, in a 5 to 4 decision, upheld the Fourth Circuit's decision on March 21, 2000.

The U.S. Supreme Court Ruling on FDA Authority

On March 21, 2000, by a 5 to 4 vote, the United States Supreme Court affirmed the Fourth Circuit decision and overturned the FDA's assertion of jurisdiction over cigarettes and smokeless tobacco products (Food and Drug Administration v. Brown & Williamson Tobacco Corp., 529 U.S. _____ [2000], 120 S. Ct. 1291). As a result, the FDA no longer has regulatory authority to enforce the final rule it issued in 1996.

Justice Sandra Day O'Connor wrote the majority opinion for the Court. In ruling against the FDA, she noted that "The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States" (p. 1315). Nevertheless, the majority ruled that Congress had precluded the FDA from asserting jurisdiction over tobacco products as customarily marketed because "Such authority is inconsistent with the intent that Congress has expressed" (p. 1297) in the Federal Food, Drug, and Cosmetic Act and other tobacco-specific statutes.

Justice O'Connor noted the unusual nature of both the case the Court was deciding and the role of tobacco in the United States. She wrote:

Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area (p. 1315).

Justice Stephen Breyer wrote the dissenting opinion. He disagreed with the majority view that Congress never intended the FDA to have the authority to assert jurisdiction over tobacco products. In summarizing why the four justices in the dissent believed the FDA had acted lawfully, Justice Breyer wrote:

The upshot is that the Court today holds that a regulatory statute aimed at unsafe drugs and devices does not authorize regulation of a drug (nicotine) and a device (a cigarette) that the Court itself finds unsafe. Far more than most, this particular drug and device risks the life-threatening harms that administrative regulation seeks to rectify (p. 1331).

Legislative Developments

In an effort to clarify the public health perspective on potential legislation, on September 17, 1997, President Clinton outlined the principles he believed must be at the heart of any national tobacco legislation (Hohler 1997):

- A comprehensive plan to reduce youth smoking, including tough penalties if targets are not met.
- Full authority for the FDA to regulate tobacco products.
- An end to the tobacco industry's practice of marketing and promoting tobacco to children.
- Broad document disclosure (especially of those documents relating to marketing tobacco to children).
- Progress toward other public health goals, such as reducing environmental tobacco smoke (ETS), expanding smoking cessation programs, strengthening international efforts to control tobacco, and providing funds for health research.
- Protection for tobacco farmers and their communities.

A number of bills intended to enable the enactment of the June 20, 1997, multistate settlement agreement were introduced into the U.S. Senate in late 1997 and early 1998. In March 1998, the Senate Commerce Committee bill introduced by Senator John McCain (R-AZ) became the focus of all settlement-related legislative activity in the Senate. The Commerce Committee endorsed a preliminary version of a substitute bill, S. 1415, on March 30, 1998, by a vote of 19 to 1. On May 1, 1998, the Commerce Committee's version of the bill—S. 1415.RS (the "McCain Committee

Bill")—was reported by Senator McCain to the full Senate. Among other things, the McCain Committee Bill would have done the following:

- Required the tobacco industry to pay \$516 billion (\$147.5 billion more than was specified in the June 20th multistate settlement agreement) over 25 years to help states and the federal government bear the medical costs of smoking-related illness.
- Raised cigarette taxes by \$1.10 per pack over five years.
- Preserved the FDA's ability to regulate the tobacco industry in ways that the June 20th agreement did not.
- Drastically reduced cigarette marketing, advertising, and promotion (Kelder 1998).

In addition, the Floor Manager's Amendment to the bill would have established a detailed regulatory scheme to be administered by the FDA (S. 1415.RS [Floor Manager's Amendment of May 18, 1998, 105th Cong., 2nd Sess.]). First, the FDA could designate demonstrably safer products as "reduced risk tobacco products" (sec. 913[a][2][A]). Second, the FDA would have the authority to promulgate performance standards, including "the reduction or elimination of nicotine yields" (sec. 907[a][2][A][I]) and "the reduction or elimination of other constituents or harmful components of the product" (sec. 907[a][2][A][ii]). The agency would follow normal administrative procedures, unless it sought to eliminate "all cigarettes, all smokeless tobacco products, or any similar class of tobacco products" (sec. 907[b][3][A]) or to require "the reduction of nicotine yields of a tobacco product to zero" (sec. 907[b][3][B]). In that event, the amendment stipulated, "the standard may not take effect before a date that is 2 years after the President notifies the Congress that a final regulation imposing the restriction has been issued" (sec. 907[b][3][B]). Third, the Floor Manager's Amendment would have required that the FDA be given the additive information specified in the settlement agreement within six months of enactment (sec. 904[a][3]).

The amendment would also have required that manufacturers share with the FDA "all documents . . . relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) to the health, behavioral, or physiologic effects of tobacco products, their constituents, ingredients, and components, and tobacco additives" (sec. 904[a][4]) or "to marketing research

involving the use of tobacco products" (sec. 904[a][5]). Tobacco product advertising would be required to include a "brief statement of the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications" (sec. 903[a][8][B][i]). Furthermore, the FDA would be given explicit power to impose "restrictions on the access to, and the advertising and promotion of, the tobacco product" (sec. 906[d][1]).

Senate bill 1415 was vehemently opposed by the tobacco industry. On April 8, 1998—nine days after the Commerce Committee endorsed the preliminary version of the McCain Committee Bill—Steven F. Goldstone, RJR Nabisco's chief executive officer, announced that his company was pulling out of the congressional process for developing comprehensive tobacco legislation. Blaming Congress for failing to stick to the terms of the June 20th agreement, Mr. Goldstone, speaking to the National Press Club in Washington, DC, declared his company's intention not to sign the consent decrees to voluntarily limit advertising that were part of the McCain Committee Bill. Philip Morris, Brown & Williamson, United States Tobacco, and Lorillard made similar announcements shortly after Mr. Goldstone's speech.

In retrospect, one can conclude that this tobacco company brinkmanship—when paired with a widely disseminated, industry-sponsored advertising campaign that portrayed the McCain Committee Bill as a vast "tax-and-spend" proposal—was a major force in scuttling the proposed legislation. Emboldened by the effect that the industry-sponsored advertising campaign had on public opinion, the tobacco industry's Senate allies greatly altered the McCain Committee Bill, culminating in the Floor Manager's Amendment on May 18, 1998. Some of these amendments would have increased the bill's potential harmful impact on public health. For example, in this final form, the bill had been shorn of almost all of its funds for initiatives to fund tobacco use reduction, and the tobacco industry had been given a potential means of immunity in the form of caps on plaintiffs' attorneys' fees (Kelder 1998).

On June 17, 1998, the McCain Committee Bill died after four weeks of intense debate and political maneuvering. In the absence of congressional action to enact the proposed settlement, individual state lawsuits proceeded. Four states—Mississippi, Florida, Texas, and Minnesota—have settled their suits with the tobacco industry. Because these settlements involve the recovery of Medicaid payments made by the states, they are discussed with other such litigation approaches, later in this chapter (see "Recovery Claims by Third-Party Health Care Payers").

Master Settlement Agreement

On November 23, 1998, 11 tobacco companies executed a legal settlement with 46 states, the District of Columbia, and five commonwealths and territories. The plaintiffs had sued the tobacco industry to recoup Medicaid costs for the care of persons injured by tobacco use. The suit alleged that the companies had violated antitrust and consumer protection laws, had conspired to withhold information about adverse health effects of tobacco, had manipulated nicotine levels to maintain smoking addiction, and had conspired to withhold lower-risk products from the market.

In the settlement, the companies agreed to pay states \$246 billion over 25 years. But in addition, the settlement agreement contained a number of important public health provisions (see the text box). The agreement placed significant marketing restrictions on the industry by prohibiting direct advertising and promotion aimed at young people, by limiting brand name sponsorship at events that might be frequented by youth, by requiring the removal of street advertising without restrictions on counteradvertising, by placing substantial restrictions on lobbying and on the suppression of research findings, and by requiring major contributions from the industry to cessation and prevention

activities (Wilson 1999). In addition, the agreement dealt with such issues as legal fees, court supervision, civil liabilities restrictions, and public disclosure. Unlike the 1997 settlement, the 1998 settlement contained no provisions regarding FDA authority.

The agreement raised a number of issues for states, but foremost among these has been the competition between tobacco control efforts and other state spending priorities. The National Governors Association issued a policy statement that reaffirmed states' entitlement and asserted that the federal government had no legitimate claim to settlement funds. The association committed to spending "a significant portion of the settlement funds on smoking cessation programs, health care, education, and programs benefitting children" but reserved the right to make funding decisions tailored to states' individual needs (National Governors Association 1999). By mid-1999, 27 states had allocated their first and second settlement payments. Of these, 23 had specified some portion of the money for public health activities, and 16 had specifically designated spending for tobacco control and prevention efforts. Specific issues related to the allocation of Master Settlement Agreement funds to tobacco control efforts in states are discussed in Chapter 7.

Clean Indoor Air Regulation

Introduction

If the regulation of tobacco products themselves has been characterized by slow and incremental advances, the regulation of where and how tobacco products are used—that is, the regulation of exposure, particularly of nonsmokers, to ETS—has encountered comparatively little resistance. Public and private steps to regulate ETS have become both more common and more restrictive over the past several decades.

There are various reasons for this broad and rapid implementation. One reason is that the public health necessity of regulating ETS exposure is manifest: ETS is known to cause acute and chronic diseases in nonsmokers (National Academy of Sciences 1986; USDHHS 1986; National Institute for Occupational Safety and Health 1991; EPA 1992; California EPA 1997). Moreover, this demonstrated health threat is unentangled with legal or ethical issues of "informed

choice" or "informed consent" (see "Product Regulation," earlier in this chapter)—hence a popular name for this exposure, passive smoking. Regulating ETS exposure also has important implications for reducing smoking: studies have shown that restricting smoking in public settings increases the likelihood that smokers in these settings smoke fewer cigarettes or quit smoking entirely (Petersen et al. 1988; Borland et al. 1990a; Stillman et al. 1990; Sorensen et al. 1991a; Woodruff et al. 1993). It has been estimated that the combined effect of general smoking cessation and smoking reduction in public settings could decrease total cigarette consumption by as much as 40 percent (Woodruff et al. 1993), although this conclusion may be questioned based on assessment of worksite interventions (see "Worksite Programs" in Chapter 4). A second reason for the expansion of ETS regulations is that their public support, a key marker for successful

Major Provisions of the Master Settlement Agreement

In addition to the monetary payments from the tobacco industry to states, the settlement provided for other requirements and restrictions:

Youth Access

- No free samples except in an enclosed area where operator ensures that no underage persons are present.
- No gifts to youth in exchange for buying tobacco products.
- No gifts through the mail without proof of age.
- Prohibits sale, manufacture, or distribution of cigarettes in packages of fewer than 20 until December 31, 2001.

Marketing

- No brand name sponsorship of concerts, team sporting events, or events with a significant youth audience.
- No sponsorship of events in which paid participants are underage.
- Bans use of tobacco brand names in stadiums and arenas.
- Bans use of cartoon characters in tobacco advertising, packaging, and promotions.
- Bans payments to promote tobacco products in entertainment settings, such as movies.
- Bans distribution and sale of merchandise with brand name tobacco logos.

Lobbying

- Prohibits industry from supporting diversion of settlement funds to nonhealth uses.
- Restricts industry from lobbying against restrictions of advertising on or in school grounds.
- Prohibits new challenges by the industry to state and local tobacco control laws enacted before June 1, 1998.

Outdoor Advertising

- Bans transit and outdoor advertising, including billboards.
- Tobacco billboards and transit ads to be removed.
- At industry expense, states could substitute advertising discouraging youth smoking.

Cessation and Prevention

- The tobacco industry will contribute \$25 million annually for 10 years to support a charitable foundation established by the National Association of Attorneys General to study programs to reduce teen smoking and to prevent diseases associated with tobacco use. The foundation, since named the American Legacy Foundation, is governed by a board and will carry out a sustained national advertising and education program to counter tobacco use by young people and educate consumers about the health hazards of tobacco use. It will also evaluate the effectiveness of counteradvertising campaigns, model classroom educational programs, and cessation programs and will disseminate the results. Other activities include commissioning and funding studies on the factors that influence youth smoking, developing training programs for parents, and monitoring youth smoking to determine the reasons for increases or failures to decrease tobacco use rates.
- The industry will contribute \$1.45 billion over five years to support the National Public Education Fund, which will carry out a national sustained advertising and education program to counter youth tobacco use and to educate consumers about tobacco-related diseases. The tobacco industry will continue to contribute \$300 million annually to the fund as long as the participating tobacco companies hold 99.05 percent of the market.

implementation, is implicit: national studies suggest that most of the U.S. public experiences discomfort and annoyance from ETS exposure (CDC 1988, 1992b), and smaller-scale surveys have found that the great majority of both nonsmokers and smokers favors smoking restrictions in various public locations, including the workplace, restaurants, and bars (CDC 1991). A third reason is that employers might be expected to support ETS regulations, because prohibiting smoking in the workplace can help employers realize lower maintenance and repair costs of buildings and property, lower insurance costs, and higher productivity among nonsmokers (Mudarri 1994). Employer support, however, may be influenced by other factors (see "Effectiveness of Clean Indoor Air Restrictions," later in this chapter).

Not surprisingly, during the 1980s the tobacco industry identified ETS regulation as the single most important issue confronting the industry's economic future (Chapman et al. 1990). The industry is concerned that the increasing focus on ETS may cause the public and policymakers to view smoking as an environmental issue with broad social consequences instead of as a personal behavior involving individual choice. The tobacco industry is also concerned about legal backlash from possible ETS-related litigation against employers and about revenue losses from possible decreased cigarette consumption due to smoking restrictions (Chapman et al. 1990). An example of the latter concern may be found in California, where workplace restrictions extant in 1990 have reduced consumption by an estimated 148 million packs per year, at a value of \$203 million in pretax sales (Woodruff et al. 1993).

Health Consequences of Exposure to ETS

The detrimental health effects of exposure to ETS are well established (National Research Council 1986; USDHHS 1986, 2000b; EPA 1992; California EPA 1997). The most comprehensive review of the respiratory effects of ETS to date is the 1992 report of the EPA, which states that ETS is a human lung carcinogen that annually accounts for approximately 3,000 lung cancer deaths among adult nonsmokers in the United States. Autopsy reviews (Trichopoulos et al. 1992) and studies of ETS metabolites in body fluids (Hecht et al. 1993) provide biologic support for epidemiologic studies linking ETS and lung cancer. ETS also has subtle but significant effects on the respiratory health (including cough, phlegm production, and reduced lung function) of adult nonsmokers.

Among children, ETS has far-reaching health effects. ETS causes bronchitis and pneumonia, accounting for an estimated 150,000–300,000 annual cases in infants and young children, and causes middle ear diseases (infections and effusions). ETS causes additional episodes of asthma and increases its severity, worsening an estimated 400,000–1,000,000 cases annually. As a risk factor for new cases of asthma, ETS may account for 8,000–26,000 annual cases (EPA 1992; California EPA 1997).

In an important ruling, Judge Osteen of the U.S. District Court annulled Chapters 1–6 and the Appendices to the EPA's 1992 report (EPA 1992; Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Agency, 4 F. Supp. 2d 435 [M.D.N.C. 1998]). The decision was a mix of procedural and scientific concerns. Judge Osteen found that the EPA had not complied with the procedural requirements of the Radon Gas and Indoor Air Quality Research Act of 1986, had acted beyond congressional intent, and had violated administrative law procedure by drawing conclusions about ETS prior to concluding a scientifically sound risk-assessment study. The judge was also concerned with the amount of evidence in the record supporting EPA's final basis for its plausibility hypothesis, with some of the animal laboratory tests that he felt were inconclusive but were cited as compelling evidence of the dangers of ETS, and with the EPA's choice of epidemiologic studies to support its findings.

Considerable information appeared after the EPA's 1992 report that supported its general conclusions (Brownson et al. 1992a; Stockwell et al. 1992; Fontham et al. 1994; Cardenas et al. 1997). A recent meta-analysis of workplace ETS exposure and increased risk of lung cancer also provided needed epidemiologic support (Wells 1998). The ninth EPA report on carcinogens was released in the year 2000 and lists ETS as a known carcinogen for the first time (USDHHS 2000).

Since the 1992 EPA report, further evidence linking ETS and heart disease has been assembled as well. (Glantz and Parmley 1995; Steenland et al. 1996; California EPA 1997; Kawachi et al. 1997; Law et al. 1997; Howard et al. 1998; Valkonen and Kuusi 1998; Wells 1998). If ETS is a causal risk factor for coronary heart disease, it likely accounts for many more deaths from heart disease than from lung cancer (EPA 1992; Wells 1994). A review of 12 epidemiologic studies has estimated that ETS accounts for as many as 62,000 annual deaths from coronary heart disease in the United States (Wells 1994). However, because smoking is but one of the many risk factors in the etiology of heart disease,

quantifying the precise relationship between ETS and this disease is difficult.

Strong evidence is also accumulating that ETS is a risk factor for sudden infant death syndrome (Jinot and Bayard 1994; DiFranza and Lew 1995; Klonoff-Cohen et al. 1995; Anderson and Cook 1997; California EPA 1997; Alm et al. 1998; Dybing and Sanner 1999). In a large U.S. study, maternal exposure during pregnancy and postnatal exposure of the newborn to ETS increased the risk of this syndrome (Schoendorf and Kiely 1992).

Other Consequences of ETS

Separate from their concerns about direct health effects, most nonsmokers are annoyed by ETS exposure (CDC 1988; Brownson et al. 1992b). U.S. survey data have suggested that 71 percent of all respondents, including 43 percent of current smokers, are annoyed by ETS (CDC 1988). Similarly, data from urban St. Louis and Kansas City, Missouri, have shown that 66 percent of all respondents and nearly 40 percent of current smokers were annoyed by ETS exposure (Brownson et al. 1992b). The term "annoyance," a seemingly minor attribute, has some nontrivial ramifications. Public attitudes toward smoking, an amalgam of concerns about health and social interactions, have changed in the past decade, as is discussed in greater detail in the section "Effectiveness of Clean Indoor Air Restrictions," later in this chapter. The findings from one survey suggested that the proportion of Americans who favored a total ban on smoking in restaurants and workplaces increased from less than onefifth in 1983 to almost one-third in 1992 (Gallup Organization, Inc. 1992). The proportion favoring no restrictions fell from as high as 15 percent in 1983 to 5 percent in 1992. Similarly, by 1992, more than 90 percent of respondents favored restrictions or a total ban on smoking in trains and buses as well as in hotels and motels. More than 90 percent "agreed" or "strongly agreed" that ETS is injurious to children, pregnant women, and older adults. Thus, an important consequence of information on ETS has been a changing social norm regarding smoking and an evolving foundation for clean indoor air regulations.

Because of the consequences of ETS, employers are likely to save costs by implementing policies for smoke-free workplaces. Savings include those associated with fire risk, damage to property and furnishings, cleaning costs, workers compensation, disability, retirement, injuries, life insurance, absenteeism, productivity losses, and synergistic occupational risks such as asbestos exposure (Kristein 1989). Such costs were estimated at \$1,000 per smoking employee in 1988

dollars. In a recent report on the savings associated with a nationwide, comprehensive policy on clean indoor air, the EPA estimated that such a law would save \$4 billion to \$8 billion per year in operational and maintenance costs of buildings (Mudarri 1994).

Prevalence of Exposure to ETS

Exposure to ambient tobacco smoke is widespread. The 1988 National Health Interview Survey reported that an estimated 37 percent of the 79.2 million U.S. nonsmoking workers worked in places that permitted smoking in designated and other areas and that 59 percent of these experienced moderate or great discomfort from ETS exposure in the workplace (National Center for Health Statistics 1989). Since the advent of urinary cotinine screening, firmer documentation of ETS has become available. In a study of 663 nonsmokers attending a cancer screening, Cummings and colleagues (1990) found that 76 percent of participants were exposed to ETS in the four days preceding the interview. The authors concluded that the workplace and the home were the primary sources of ETS exposure among these nonsmokers. The best single predictor of urinary cotinine was the number of smokers among friends and family members seen regularly by the study participant. In a study of 881 nonsmoking volunteers, Marcus and colleagues (1992) found that employees in workplaces that were "least restrictive" (i.e., allowed smoking in numerous locations) were more than four times more likely to have detectable saliva cotinine concentrations than employees from smoke-free workplaces were (p. 45).

The largest study of population exposure to ETS with biochemical markers is the CDC's Third National Health and Nutrition Examination Survey, conducted from 1988 to 1991 on a nationally representative sample of 16,818 persons aged 2 months and older (Pirkle 1996). Serum cotinine was measured in 10,642 participants aged 4 years and older. The data indicate high concordance between reported ETS exposure and serum cotinine level. Among nontobacco users, 87.9 percent had detectable levels of serum cotinine, and the level was significantly and independently associated with both the number of smokers in the household and the number of hours of work exposure. The authors concluded that both the work and the household environments make important contributions to the widespread exposure to ETS experienced by children and adults.

Some improvement in ETS exposure has been noted. A study from California found that nonsmokers' self-reported exposure to ETS at work declined from

29 percent in 1990 to 22 percent in 1993 (Patten et al. 1995b). This decline was not as pronounced, however, among some sociodemographic subgroups, such as African Americans, Asian Americans, and persons with less than a high school education. During the same period, the percentage of employees reporting that they worked in smoke-free workplaces greatly increased (from 35 to 65 percent). Survey data from Missouri in 1993 indicated that 41 percent of the population were exposed to ETS in the workplace and 18 percent in the home environment (Brownson et al. 1995a). Among subgroups, younger persons, men, Hispanics, and persons with less than a high school education had more workplace exposure to ETS. Similarly, data from rural Missouri showed higher prevalence of workplace ETS exposure among younger persons, men, African Americans, and persons with less than a high school education (Brownson et al. 1995a). Emmons and colleagues (1992) analyzed entries in diaries recording ETS exposure among 186 persons who were former smokers or had never smoked. Approximately 50 percent of the daily ETS exposure was attributed to the workplace, and 10 percent was attributed to the home environment. However, for persons who lived with a smoker, more exposure occurred in the home than in the workplace.

Relatively few population-based data that specifically examine the levels of ETS exposure in the workplace have been collected. Such data may be important, because exposure levels likely vary greatly by workplace, and recent studies have indicated that higher levels of ETS (measured by intensity or duration of ETS exposure) increase the risk of lung cancer in nonsmokers (Brownson et al. 1992a; Stockwell et al. 1992; Fontham et al. 1994). In a review of existing studies, Siegel (1993) found that ETS concentrations varied widely by location; mean levels of nicotine measured in the ambient air were 4.1 μ g/m³ for offices overall, 4.3 μ g/m³ for residences with at least one smoker, 6.5 μ g/m³ for restaurants, and 19.7 μ g/m³ for bars. In a survey of 25 Massachusetts worksites, Hammond and colleagues (1995) found that the type of worksite smoking policy had a great effect on nicotine concentrations. Levels of nicotine ranged from 8.6 μ g/m³ in open offices that allowed smoking to 0.3 μ g/m³ in worksites that banned smoking.

Legal Foundation for Regulation of Public Smoking

The legal foundation for regulating public smoking is based on case law pertaining mainly to the

protection of the health of workers. Under common law (the body of law based on court decisions rather than government laws or regulations), employers must provide a work environment that is reasonably free of recognized hazards. Courts have ruled that commonlaw duty requires employers to provide nonsmoking employees protection from the proven health hazards of ETS exposure (Sweda 1994).

Three pioneering cases have demonstrated the basis for this protection. In Shimp v. New Jersey Bell Telephone Co. (368 A.2d 408, 145 N.J. Super. 516 [1976]), a secretary who was allergic to cigarette smoke sought an injunction requiring a smoking ban. The court ordered the employer to provide a safe working environment by restricting smoking to a nonwork area. Similarly, in the case of *Smith v. Western Electric Co.* (643 S.W.2d 10 [Mo. App. 1982]), the Missouri Court of Appeals overturned a lower court and forced the employer to "assume its responsibility to eliminate the hazardous conditions caused by tobacco smoke" (p. 13). Finally, in Lee v. Department of Public Welfare (No. 15385 [Mass. Mar. 31, 1983], cited in 1.2 TPLR 2.82 [1986]), a social worker sued her employer, seeking relief from ETS exposure at work. The Massachusetts Superior Court ruled in favor of the plaintiff and required a smoke-free workplace. Additional protections to employees are extended by federal statute, such as the Americans with Disabilities Act of 1990 (ADA) (Public Law 101-336), and by rulings in workers compensation claims.

Status of Restrictions to Limit Smoking in Public Places

Although the health risks of ETS exposure began to be publicized in the early 1970s (NCI 1991), momentum to regulate public smoking increased only in 1986, when reports by the Surgeon General (USDHHS 1986) and the National Academy of Sciences (1986) concluded that ETS is a cause of lung cancer in nonsmokers. Since then, government and private business policies that limit smoking in public places have become increasingly common and restrictive (Rigotti and Pashos 1991). The designation of ETS as a class A (known human) carcinogen by the EPA (1992) stimulated further restrictions on smoking in public places (Brownson et al. 1995a), but a recent court ruling set aside that report (see "Health Consequences of Exposure to ETS," earlier in the chapter).

Although many of the regulatory efforts discussed herein focus on government's passage of a law or an ordinance, other regulations can be implemented by

Table 5.1. Summary of landmark events in the development of U.S. policies for clean indoor air

Year	Event
1971	The Surgeon General proposes a federal smoking ban in public places.
1972	The first report of the Surgeon General to identify environmental tobacco smoke (ETS) as a health risk is released.
1973	Arizona becomes the first state to restrict smoking in several public places and to reduce ETS exposure because it is a health risk.
	The Civil Aeronautics Board requires no-smoking sections on all commercial airline flights.
1974	Connecticut passes the first state law to apply smoking restrictions to restaurants.
1975	Minnesota passes a comprehensive statewide law for clean indoor air.
1977	Berkeley, California, becomes the first community to limit smoking in restaurants and other public places.
1983	San Francisco passes a law to place private workplaces under smoking restrictions.
1986	A report of the Surgeon General focuses entirely on the health consequences of involuntary smoking; ETS is proclaimed a cause of lung cancer in healthy nonsmokers.
	The National Academy of Sciences issues a report on the health consequences of involuntary smoking.
	Americans for Nonsmokers' Rights becomes a national group; it had originally formed as California GASP (Group to Alleviate Smoking Pollution).
1987	The U.S. Department of Health and Human Services establishes a smoke-free environment in all of its buildings, affecting 120,000 employees nationwide.
	Minnesota passes a law requiring all hospitals in the state to ban smoking by 1990.
	A Gallup poll finds, for the first time, that a majority (55 percent) of all U.S. adults favor a complete ban on smoking in all public places.
1988	A congressionally mandated smoking ban takes effect on all domestic airline flights of two hours or less.
	New York City's ordinance for clean indoor air takes effect, banning or severely limiting smoking in various public places and affecting 7 million people.
	California implements a statewide ban on smoking aboard all intrastate airplane, train, and bus trips.
1990	A congressionally mandated smoking ban takes effect on all domestic airline flights of six hours or less.
	The U.S. Environmental Protection Agency (EPA) issues a draft risk-assessment on ETS.
1991	CDC's National Institute for Occupational Safety and Health issues a bulletin recommending that secondhand smoke be reduced to the lowest feasible concentration in the workplace.
1992	Hospitals applying for accreditation by the Joint Commission on the Accreditation of Healthcare Organizations are required to develop a policy to prohibit smoking by patients, visitors, employees, volunteers, and medical staff.
	The EPA releases its report classifying ETS as a group A (known human) carcinogen, placing ETS in the same category as asbestos, benzene, and radon.

Table 5.1. Continued

Year	Event
1993	Los Angeles passes a ban on smoking in all restaurants.
	The U.S. Postal Service eliminates smoking in all facilities.
	Congress enacts a smoke-free policy for WIC (Special Supplemental Food Program for Women, Infants, and Children) clinics.
	A working group of 16 state attorneys general releases recommendations for establishing smoke-free policies in fast-food restaurants.
	Vermont bans smoking in all public buildings and many private buildings open to the public.
1994	The U.S. Department of Defense prohibits smoking in all indoor military facilities.
	The Occupational Safety and Health Administration proposes a rule that would ban smoking in most U.S. workplaces.
	San Francisco passes a ban on smoking in all restaurants and workplaces.
	The Pro-Children's Act requires persons providing federally funded children's services to prohibit smoking in those facilities.
1995	New York City passes a comprehensive ordinance effectively banning smoking in most workplaces.
	Maryland enacts a smoke-free policy for all workplaces except hotels, bars, restaurants, and private clubs.
	California passes comprehensive legislation that prohibits smoking in most enclosed workplaces.
	Vermont's smoking ban is extended to include restaurants, bars, hotels, and motels, except those holding a cabaret license.
1996	The U.S. Department of Transportation reports that about 80 percent of nonstop scheduled U.S. airline flights between the United States and foreign points will be smoke free by June 1, 1996.
1997	President Clinton signs an executive order establishing a smoke-free environment for federal employees and all members of the public visiting federally owned facilities.
	The California EPA issues a report determining that ETS is a toxic air contaminant.
	Settlement is reached in the class action lawsuit brought by flight attendants exposed to ETS.
1998	The U.S. Senate bans smoking in the Senate's public spaces.
	California law takes effect banning smoking in bars unless a bar has a separately ventilated smoking area.

agencies with special authority. An example of a non-government regulatory action is the recent adoption of an accrediting standard that prohibits smoking in hospital buildings (Joint Commission on Accreditation of Healthcare Organizations 1992; Longo et al. 1995).

Government Restrictions

Several of the noteworthy events in clean indoor air regulation are shown in Table 5.1. These events include federal, state, and local activities.

Federal Laws and Regulations

The most notable federal regulation of ETS is the requirement that domestic airline flights be smoke free. The regulation was first enacted in 1988 for domestic flights lasting two hours or less and was renewed in 1989 for domestic flights lasting six hours or less (Table 5.1). Since the early 1970s, the Interstate Commerce Commission (ICC) has required that smoking on interstate buses be confined to the rear of the bus and that smoking sections constitute no more than 10 percent of total seating capacity. Similar ICC regulation for trains was repealed in 1979. In 1987, congressional legislation that threatened to withhold federal funds influenced the State of New York's Metropolitan Transportation Authority to ban smoking on the MTA Long Island Rail Road (USDHHS 1989). Currently, the Occupational Safety and Health Administration is considering regulations that would either prohibit smoking in all workplaces or limit it to separately ventilated areas (Federal Register 1994). Furthermore, the federal government has instituted increasingly stringent regulations on smoking in its own facilities, and the Pro-Children's Act of 1994 (Public Law 103-227, secs. 1041–1044) prohibits smoking in facilities in which federally funded children's services are provided on a regular or routine basis.

State Laws and Regulations

As of December 31, 1999, smoke-free indoor air to some degree or in some public places was required by 45 states and the District of Columbia. These restrictions vary widely, from limited restrictions on public transportation to comprehensive restrictions in worksites and public places (CDC, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data). In 1973, Arizona became the first state in which public smoking was regulated in recognition of ETS as a public health hazard (Table 5.1). Five states (Alabama, Kentucky, New Mexico, North Carolina, and Wyoming) have either no legislation or legislation that preempts localities from enacting any law to restrict smoking in public places (see also Figure 5.2).

As of December 31, 1999, laws restricting smoking in government worksites were present in 43 states and the District of Columbia: 29 limit smoking to designated areas, 2 require either no smoking or designated smoking areas with separate ventilation, and 11 prohibit smoking entirely. Twenty-one states have laws restricting smoking in private worksites: 20 limit smoking to designated areas, and 1 (California) requires either no smoking or separate ventilation for smoking areas. Thirty-one states have laws that

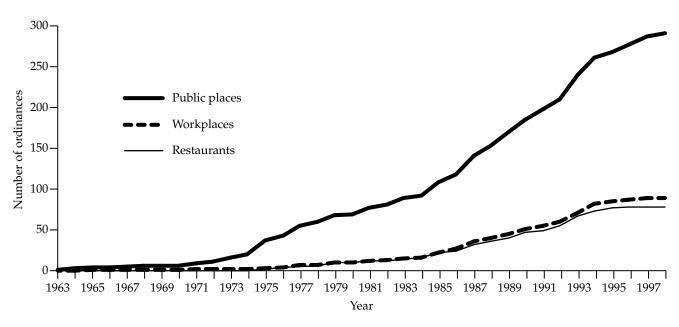


Figure 5.2. Cumulative number of state laws and amendments enacted for clean indoor air, 1963-1998

Note: The category "state" includes the District of Columbia.

Source: National Cancer Institute, State Cancer Legislative Database, unpublished data, August 31, 1998.

regulate smoking in restaurants; of these, only Utah and Vermont completely prohibit smoking in restaurants, and California requires either no smoking or separate ventilation for smoking areas (CDC, Office on Smoking and Health, State Tobacco Activities Evaluation System, unpublished data).

In 1994, Maryland proposed a regulation that would prohibit smoking in most workplaces in the state, including restaurants and bars (Maryland Register 1994). Despite strong support among both nonsmokers and smokers for restrictions on public smoking in the state (Shopland et al. 1995), this proposal was aggressively challenged by the tobacco industry (Spayd 1994), which questioned the state's legal authority to regulate smoking through administrative rule rather than law. In early 1995, the original regulation was modified by legislative action to permit some exceptions for the hospitality industry, and the rules went into effect. In October 1994, the state of Washington also enacted an extensive indoor workplace ban. In this instance, a temporary injunction was dismissed by the state court, and the ban went into effect without litigation (CSH 1994b).

In North Carolina, legislation was enacted on July 15, 1993 (HB 957), that required that smoking be permitted in at least 20 percent of space in state-controlled buildings but also formally required nonsmoking areas. An important preemption clause prohibited local regulatory boards from enacting more restrictive regulations for public or private buildings after October 15, 1993. During that three-month "window of opportunity," 89 local agencies passed new measures providing some increased protection from ETS. Despite the rush to new restrictions, researchers estimated that by the year 2000, the preemption would prevent 59 percent of private employees in North Carolina from being protected from ETS (Conlisk et al. 1995).

Local Ordinances

The modern era of local ordinances for clean indoor air began in the early 1970s (Pertschuk 1993). In 1977, Berkeley, California, became the first community to limit smoking in restaurants and other public places (Table 5.1). After the release of the 1986 Surgeon General's report on the health consequences of ETS, the rate of passage of local ordinances accelerated (Figure 5.3). By 1988, nearly 400 local ordinances to restrict smoking had been enacted throughout the United States (Pertschuk and Shopland 1989). The trend toward smoke-free local ordinances has accelerated since 1989 (Rigotti and Pashos 1991; Pertschuk 1993). As of June 30, 1998, public smoking was restricted or banned in 820 local ordinances. Of those that specified which

agency was responsible for enforcement, 44 percent cited health departments or boards of health, 19 percent named city managers, 5 percent said police departments, and 6 percent identified other agencies (Americans for Nonsmokers' Rights, unpublished data, June 30, 1998). The effectiveness of various enforcement mechanisms and the level of compliance achieved are not known. Data from Wisconsin suggest that implementation may be just as important as legislation in achieving policy goals (Nordstrom and DeStefano 1995).

One study examined the impact a local ordinance had on restaurant receipts (CDC 1995a). Contrary to some prior claims, an analysis of restaurant sales after a ban on smoking in this community (a small suburb of Austin, Texas) showed no adverse economic effect. In a series of ecologic analyses, Glantz and Smith (1994, 1997) analyzed the effect of smoke-free restaurant and bar ordinances on sales tax receipts. Over time, such ordinances had no effect on the fraction of total retail sales that went to eating and drinking places. The authors asserted that claims of economic hardship for restaurants and bars that establish smoke-free policies have not been substantiated.

Private Sector Restrictions on Smoking in Workplaces

Two national data sets are available to ascertain the level of workplace smoking restrictions among private firms in the United States. A survey conducted by the Bureau of National Affairs, Inc. (1991), estimated that 85 percent of large workplaces had policies restricting smoking. The percentage of smoke-free workplaces has increased dramatically, from 2 percent in 1986 to 7 percent in 1987 and to 34 percent in 1991. Similarly, data from the 1992 National Survey of Worksite Health Promotion Activities indicated that 87 percent of workplaces with 50 or more employees regulated smoking in some manner and that 34 percent were smoke free (USDHHS 1993). The 1995 Update of the Business Responds to AIDS Benchmark Survey conducted by CDC also found that 87 percent of worksites with 50 or more employees had a smoking policy of some kind (National Center for Health Statistics 1997).

The prevalence of smoking policies in small workplaces, where the majority of Americans work, is less well studied. A comprehensive examination of workplace smoking policies from the NCI's tobacco use supplement to the Current Population Survey (n = 100,561) indicated that most indoor workers surveyed (81.6 percent) reported that an official policy governed smoking at their workplaces, and nearly half reported that the policy could be classified as

"smoke-free"—that is, that smoking was not permitted either in workplace areas or in common publicuse areas (Gerlach 1997). This proportion varied by sex, age, ethnicity, and occupation: blue-collar and service occupations had significantly less access to smoke-free environments. Though data were not specifically reported by workplace size, the range of occupations suggests that the survey included a substantial proportion of persons who work in smaller workplace environments. But for all workplace sizes, the data suggest that access to smoke-free environments could be substantially improved.

Effectiveness of Clean Indoor Air Restrictions

Although it is generally accepted that regulatory changes influence nonsmokers' exposure to ETS and smokers' behavior, relatively few evaluation studies quantify these effects over time. Evaluating such changes is hampered by the complex interaction of social forces that shape behavior, by the decline in

smoking and smoke exposure in the overall population, and by the overlapping effects of concomitant regulatory policies (e.g., a new law for clean indoor air passed at or around the time of an increase in the cigarette excise tax). Controlling for such potential confounding factors in studies is difficult.

Population-Based Studies

Effects on Nonsmokers' Exposure to ETS

Despite the widespread implementation of restrictions against public smoking, few population-based studies have examined whether these restrictions have reduced nonsmokers' exposure to ETS. One such study from California used data collected in 1990 and 1991 to examine the association between the strength of local ordinances for clean indoor air and cross-sectional data on nonsmokers' exposure to ETS in the workplace (Pierce et al. 1994b). Exposure to ETS in the workplace ranged from 25 percent of workplaces in areas with a strong local ordinance to 35 percent in areas with no local ordinance.

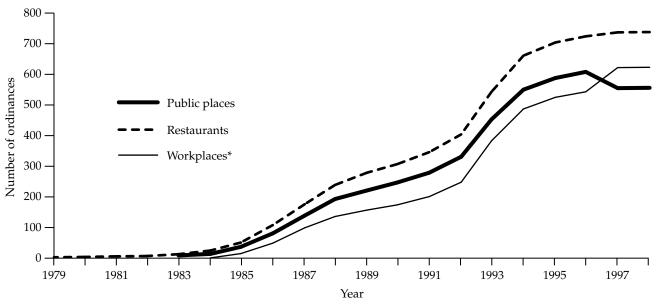


Figure 5.3. Cumulative number of local laws and amendments enacted for clean indoor air, 1979–1998

Note: Ordinances must specifically mention these locations to be counted. Therefore, other ordinances may cover these areas without being included in these figures.

Source: American Nonsmokers' Rights Foundation, unpublished data, June 30, 1998.

^{*}Before 1983, there were four workplace ordinances: one passed in 1975, one in 1979, and two in 1980. These are not included in this chart, because data for consecutive years only became available beginning in 1983 for workplaces.

In measuring the impact of a statewide law for clean indoor air, researchers in Missouri examined selfreported data on ETS exposure from 1990 through 1993 (Brownson et al. 1995a). Nonsmokers' exposure to ETS in the workplace declined slightly the year the law was passed and substantially more after the law went into effect. Exposure to ETS in the home remained constant over the study period; this finding suggests that the declining workplace exposure was more likely linked to the smoking regulations than to the overall declining smoking prevalence observed during the study period. Despite improvements over time, ETS exposure in the workplace remained at 35 percent in the final year of the study (1993). Other data from California indicate that nonsmokers employed in workplaces with no policy or a policy not covering their part of the workplace were eight times more likely to be exposed to ETS (at work) than those employed in smoke-free workplaces (Borland et al. 1992).

Attitudes Toward Restrictions and Bans

Studies of awareness and attitudes toward workplace smoking restrictions and bans have been conducted in cross-sectional samples of the general population and among employees affected by bans. In a 1989 survey of 10 U.S. communities, most respondents favored smoking restrictions or smoke-free environments in all locations, including workplaces, government buildings, restaurants, hospitals, and bars (CDC 1991). Although support for smoking restrictions was higher among nonsmokers, across the 10 communities, 82-100 percent of smokers favored restrictions on smoking in public places. Support was highest for smoking bans in indoor sports arenas, hospitals, and doctors' offices. A 1993 survey from eight states showed greater support for ending smoking in fast-food restaurants and at indoor sporting events than in traditional restaurants and indoor shopping malls (CDC 1994a).

Support for proposed changes may differ from support for actual, implemented changes. Yet in studies of smoke-free hospitals, patients, employees, and physicians have overwhelmingly supported the policy (Rigotti et al. 1986; Becker et al. 1989; Hudzinski and Frohlich 1990; Baile et al. 1991; Offord et al. 1992). In some instances, a majority of smokers support a smoke-free hospital (Becker et al. 1989). Studies of smoking restrictions and bans in other industries also have found that nonsmokers overwhelmingly favor smoke-free workplaces (Petersen et al. 1988; Borland et al. 1990b; Gottlieb et al. 1990; Sorensen et al. 1991b). Time—and consequent habituation—can

make changes more acceptable. In a prospective study of a smoking ban in a large workplace, Borland and colleagues (1990b) found that attitudes of both nonsmokers and smokers toward the smoke-free workplace were more favorable six months after such a policy was implemented. Although most smokers reported being inconvenienced, they also reported that they recognized the overall benefits of the policy. Two studies from Massachusetts found that one and two years after two local laws for clean indoor air were enacted, 65 percent of the businesses surveyed favored the law (Rigotti et al. 1992, 1994). The authors concluded that a self-enforcement approach achieved high levels of awareness (about 75 percent) and intermediate levels of compliance (about 50 percent) (Rigotti et al. 1994).

Effects of Restrictions and Bans on Nonsmokers' Exposure to ETS

As has been found in population-based research, studies conducted in individual workplaces have found that smoke-free workplaces have been effective in reducing nonsmokers' exposure to ETS. Effectiveness has been measured by the perceived change in air quality in the workplace after a smoke-free policy was instituted (Biener et al. 1989; Gottlieb et al. 1990) and by measurement of nicotine vapor before and after such a policy (Stillman et al. 1990). Conversely, workplace policies that allow smoking in designated areas without separate ventilation result in substantial exposure to ETS for nonsmokers (Repace 1994).

An analysis of the effects of a smoke-free workplace in The Johns Hopkins Medical Institutions found that concentrations of nicotine vapor had declined in all areas except restrooms at one to eight months after the ban (Stillman et al. 1990). In most areas, nicotine concentrations after the ban were below the detectable level of $0.24~\mu g/m^3$.

Effects of Restrictions on Smoking Behavior

An additional benefit from regulations for clean indoor air may be a reduction in smoking prevalence among workers and the general public. For example, in a multivariate analysis, moderate or extensive laws for clean indoor air were associated with a lower smoking prevalence and a higher proportion of quitters (Emont et al. 1993). Another study also found an association between local smoking restrictions and smoking prevalence (Rigotti and Pashos 1991).

Table 5.2. Summary of studies on the effects of a smoke-free workplace on smoking behavior

Authors/year	Location	Industry	Sample size
Andrews 1983	Boston, Massachusetts Hospital		965
Rigotti et al. 1986	Boston, Massachusetts Hospital pediatric unit		93
Rosenstock et al. 1986	Puget Sound, Washington	Health maintenance organization	447
Petersen et al. 1988	Connecticut	Insurance company	1,210
Becker et al. 1989	Baltimore, Maryland	Children's hospital	704
Biener et al. 1989	Providence, Rhode Island	Hospital	535
Scott and Gerberich 1989	Midwestern United States	Insurance company	452
Borland et al. 1990b	Australia	Public service	2,113
Centers for Disease Control 1990c	Pueblo, Colorado	Psychiatric hospital	1,032
Gottlieb et al. 1990	Texas	Government agency	1,158
Hudzinski and Frohlich 1990	New Orleans, Louisiana	Hospital	1,946
Stillman et al. 1990	Baltimore, Maryland	Hospital	2,877
Baile et al. 1991	Tampa, Florida	Hospital	349
Borland et al. 1991	Australia	Telecommunications company	620
Sorensen et al. 1991a	New England	Telephone company	1,120
Brenner and Mielck 1992	Germany	National random sample	439
Goldstein et al. 1992	Augusta, Georgia	Hospital	1,997
Offord et al. 1992	Rochester, Minnesota	Hospital	10,579
Wakefield et al. 1992b	Australia	Representative sample	1,929
Jeffery et al. 1994	Minneapolis-St. Paul, Minnesota	Diverse worksites	32 worksites; total number of individuals not reported

Change in individual or overall smokers' consumption	Change in prevalence
Not reported	-8.5% at 20 months follow-up
-2.3 cigarettes per shift (P < 0.01) at 12 months follow-up; no change in overall consumption	No significant change
-2.0 cigarettes per day (P $<$ 0.003) at 4 months follow-up	No significant change
-5.6 cigarettes per day at 12 months follow-up	1.6% at 12 months follow-up
No change at 6 months follow-up	–1.2% at 6 months follow-up
-3.9 cigarettes per day at work at 12 months follow-up	No significant change
22.5% of smokers decreased consumption at 7 months follow-up	–5.1% at 7 months follow-up
-7.9 cigarettes per day in smokers of 25 or more cigarettes per day at 6 months follow-up	–1.0% at 6 months follow-up
-3.5 cigarettes per day at work at 13 months follow-up; –1.8 cigarettes per day over 24 hours	–4.0% at 13 months follow-up
12.0% reduction in consumption of 15 or more cigarettes per day at work at 6 months follow-up ($P < 0.001$)	–3.4% at 6 months follow-up
25% of smokers no longer smoked at work at 12 months follow-up	Not reported
-3.3 cigarettes per day at 6 months follow-up (P = 0.0001)	–5.5% at 6 months follow-up
40% of smokers decreased consumption at 4 months follow-up	–1.5% at 4 months follow-up
-3.5 cigarettes per day at 18 months follow-up ($P < 0.05$)	–3.1% at 18 months follow-up
Not reported	21% of smokers quit at 20 months follow-up
-1.8 cigarettes per day in men, –1.4 cigarettes per day in women	Cessation proportion of 30%
57% of smokers reported they had cut down on number of cigarettes smoked	9% of smokers stated they had quit because of the ban
Not reported	–2.9% at 30 months follow-up
-5 cigarettes per day on workdays vs. leisure days	Not reported
-1.2 cigarettes per day	–2% at 24 months follow-up

In recent years, researchers have increasingly recognized the role of the environment⁵ in influencing individual smoking behavior through perceived cues (NCI 1991; McKinlay 1993; Brownson et al. 1995b), many of which have their origins in generally held rules about acceptable behaviors (i.e., social norms) (Robertson 1977). Smokers frequently respond to environmental cues when deciding whether to smoke at a given time (NCI 1991). For example, a smoker may receive a personal, habit-derived cue to smoke after a meal or on a work break, but this cue may be weakened (and eventually even canceled) by a social, policy-derived cue not to smoke if the person is in a smoke-free restaurant or worksite (Brownson et al. 1995b).

Numerous studies have assessed the potential effects of workplace smoking bans on employee smoking behavior (Table 5.2). These studies have been conducted in health care settings (Andrews 1983; Rigotti et al. 1986; Rosenstock et al. 1986; Becker et al. 1989; Biener et al. 1989; CDC 1990c; Hudzinski and Frohlich 1990; Stillman et al. 1990; Baile et al. 1991; Goldstein et al. 1992; Offord et al. 1992), government agencies (Gottlieb et al. 1990), insurance companies (Petersen et al. 1988; Scott and Gerberich 1989), and telecommunications companies (Borland et al. 1991; Sorensen et al. 1991a) and among random samples of the working population (Brenner and Mielck 1992; Wakefield et al. 1992b). Most of the studies based in hospitals or health maintenance organizations that banned smoking found a decrease in the average number of cigarettes smoked per day. Several of the hospital studies found significant declines in the overall prevalence of smoking among employees at 6-20 months follow-up (Andrews 1983; Stillman et al. 1990). Studies of smoking behavior in other industries have found similar results; in most settings, daily consumption, overall smoking prevalence, or both had decreased at 6-20 months after workplaces were made smoke free.

In a population-based study of California residents, the prevalence of smoking was 14 percent in smoke-free workplaces and 21 percent in workplaces with no smoking restrictions (Woodruff et al. 1993). Consumption among continuing smokers was also lower in smoke-free workplaces, and the percentage of smokers contemplating quitting was higher. In 1992, Patten and colleagues (1995a) followed up a large sample of persons (first interviewed in 1990) to determine the influences a change in worksite setting might have had on smoking. These researchers observed a statistically nonsignificant increase in smoking

prevalence among the group that changed from a smoke-free workplace to one at which smoking was permitted. The prevalence of smoking among other groups was unchanged or had declined. Although these results are tentative, particularly in view of sampling difficulties during the follow-up interview, they signal the potential impact workplace policies can have on smoking behavior.

Case Studies of State and Local Smoking Restrictions

Recent reviews have presented case studies on the passage of state and local laws for clean indoor air (Samuels and Glantz 1991; Fourkas 1992; Jacobson et al. 1992; Traynor et al. 1993). These studies describe the issues that states and local communities dealt with in enacting smoking restrictions in public places.

In a case study of six states, the ability of key legislators to support legislation and the existence of an organized smoking prevention coalition were key determinants of whether statewide legislation was enacted for clean indoor air (Jacobson et al. 1992). Although the enactment of such legislation was not guaranteed when these factors were favorable, enactment was unlikely when they were unfavorable. Two other factors were cited as key in enacting legislation in the six states studied: an active executive branch that pressured the legislature to act, especially by making such legislation an executive policy priority, and existing local ordinances that created a policy environment favorable to the enactment of statewide smoking restrictions.

The study found that coalitions that succeeded in enacting legislation to restrict smoking in public places featured organized commitment, including both a full-time staff and a professional lobbyist. Successful coalitions also had established close working relationships with key legislative sponsors to develop appropriate policy alternatives and to coordinate legislative strategy. Finally, effective coalitions used media and grassroots campaigns to mobilize public support for smoking restrictions.

Another important component in the legislative debate was how the issue of smoking restrictions was framed. In all six states reviewed, the tobacco industry tried to shift the focus from the credibility of the scientific evidence on the health hazards of ETS to the controversial social issue of personal freedom; specifically, the industry lobbied extensively for including nondiscrimination clauses in legislation to restrict smoking (Malouff et al. 1993). Another common strategy that

⁵The term "environment" is defined broadly to include the legal, social, economic, and physical environment (Cheadle et al. 1992).

the tobacco industry has used is to support the passage of state laws that preempt more stringent local ordinances (Brownson et al. 1995b).

Because of the possible countereffect of preemptive legislation and because of the difficulty in enacting statewide legislation, public health advocates have suggested that advocates for reducing tobacco use should devote more resources to enacting local ordinances (Samuels and Glantz 1991; Fourkas 1992;

Jacobson et al. 1992). A local strategy can usually impose more stringent smoking restrictions than statewide legislation does. Like the study of Jacobson and colleagues (1992) on statewide initiatives, a study of local initiatives found that two key ingredients for success were the presence of a strong smoking prevention coalition and sympathetic political leadership within the elected body (Samuels and Glantz 1991).

Minors' Access to Tobacco

Introduction

Minors' access to tobacco products is an area of regulation relatively free from the social and legal debate that often arises from other regulatory efforts. Even the staunchest opponents of reducing tobacco use concede that tobacco use should be limited to adults and that retailers should not sell tobacco products to children and adolescents. Yet as was discussed in detail in the Surgeon General's report on smoking among young people, a significant number of minors use tobacco, and a significant number of them obtain their tobacco through retail and promotional transactions, just as adults do (USDHHS 1994; CDC 1996a,b; Kann et al. 1998). Whether intended exclusively for adults or not, these commercial transactions are supported by vast resources. The multibillion-dollar tobacco industry spends a large proportion of its marketing dollars to support a vast network of wholesale and retail activity. In 1997, cigarette makers spent \$2.44 billion on promotional allowances to the wholesale and retail trade and an additional \$1.52 billion on coupons and retail value-added promotions (FTC 1999). These figures were 42 percent and 26 percent, respectively, of the entire \$5.1 billion spent on advertising and promoting cigarettes in the United States that year.

In general, the availability of cigarettes to the adult population has not been a regulatory issue since the first quarter of the 20th century (see Chapter 2), although recent FDA statements about nicotine levels in cigarettes have raised the possibility of some regulation of adult use (see "Further Regulatory Steps," earlier in this chapter). The primary regulatory focus for cigarette access has been on reducing the sale of tobacco products to minors (Forster et al. 1989;

Hoppock and Houston 1990; Thomson and Toffler 1990; Altman et al. 1992; CDC 1992a; Cummings et al. 1992; *Federal Register* 1993, 1996). Broad-based public support for limiting minors' access to tobacco has developed in the relatively brief time (since the mid-1980s) that this issue has been in the public eye (DiFranza et al. 1987, 1996; CDC 1990a,b,c, 1993a, 1994a, 1996a,d; Jason et al. 1991; Hinds 1992; Keay et al. 1993; Landrine et al. 1994, 1996; USDHHS 1994).

Reducing the commercial availability of tobacco to minors is a potential avenue for reducing adolescent use. Growing evidence suggests that tobacco products are widely available to minors. Uniformly, surveys find that teenagers believe they can easily obtain cigarettes (see, for example, Forster et al. 1989; Johnston et al. 1992; CDC 1996a; Cummings et al. 1998; University of Michigan 1999). As noted, this access is by no means confined to borrowing cigarettes from peers or adults or stealing them at home or from stores; purchase from commercial outlets is an important source for minors who use tobacco. An estimated 255 million packs of cigarettes were illegally sold to minors in 1991 (Cummings et al. 1994), and daily smokers aged 12–17 years smoked an estimated 924 million packs of cigarettes in 1997 (DiFranza and Librett 1999). Between 20 and 70 percent of teenagers who smoke report purchasing their own tobacco; the proportion varies by age, social class, amount smoked, and factors related to availability (Forster et al. 1989; Response Research, Incorporated 1989; CDC 1992a, 1996a,d; Cummings et al. 1992, 1998; Cummings and Coogan 1992-93; Mark Wolfson, Ami J. Claxton, David M. Murray, and Jean L. Forster, Socioeconomic status and adolescent tobacco use: the role of differential availability, unpublished data). In a review of 13 local

over-the-counter access studies published between 1987 and 1993, illegal sales to minors ranged from 32 to 87 percent with an approximate weighted-average of 67 percent. Several local studies published in 1996 and 1997 found somewhat lower over-the-counter sales rates to minors: 22 percent (Klonoff et al. 1997) and 29 percent (CDC 1996) in two separate studies in California and 33 percent in Massachusetts (DiFranza et al. 1996). Nine studies of vending machine sales to minors published between 1989 and 1992 found illegal vending machine sales ranging from 82 to 100 percent with an approximate weighted-average of 88 percent (USDHHS 1994). Comparison of the results of these research studies with the results of later statewide Synar surveys (see below) is problematic for four reasons: (1) the research studies were generally local surveys of a town, city, or county, whereas the Synar surveys are based on statewide samples; (2) the sampling methods vary across the research studies; (3) store inspection methodologies vary; and (4) some of the research studies contain results of several surveys, often pre- and post-intervention (USDHHS 1998a).

Several factors suggest that widespread reduction in commercial availability may result in reduced prevalence or delayed onset of tobacco use by young people: the reported importance of commercial sources to minors, the easy commercial availability that has been demonstrated, and the reductions in commercial availability demonstrated when legal restrictions have been tightened, as outlined below (Jason et al. 1991; DiFranza et al. 1992; Hinds 1992; Forster et al. 1998). One psychological study supports the potential impact of limiting minors' access to cigarettes (Robinson et al. 1997). In this investigation of 6,967 seventh graders of mixed ethnicity, the best predictor of experimentation with cigarettes was the perception of easy availability. Regular smoking was heavily influenced by cost (see Chapter 6).

Direct studies of factors that influence minors' access have produced mixed results, however. Several investigators found that state laws on minimum age for purchasing tobacco products did not by themselves have a significant effect on cigarette smoking among youth (Wasserman et al. 1991; Chaloupka and Grossman 1996). Other studies have provided evidence in single communities (without comparison groups) that compliance with youth access regulations does lead to reductions in regular smoking by adolescents (Jason et al. 1991; DiFranza et al. 1992). In a nonrandomized, controlled community trial (three intervention and three control communities), Rigotti and colleagues (1997) found that although illegal sales rates to minors decreased significantly more in the

control communities than in the intervention communities, there was no difference between control and intervention communities in either self-reported access to tobacco from commercial sources or in smoking behavior among youth. The authors suggest that illegal sales rates were not reduced sufficiently in the intervention communities to cause a decrease in commercial access that was substantial enough to impact youth smoking. Noting that these studies were limited by their scope or sample size, Chaloupka and Pacula (1998) analyzed data from the 1994 Monitoring the Future surveys on 37,217 youths. Using personal and ecologic variables in a two-part multivariate model to estimate cigarette demand by youth and average daily cigarette consumption, the investigators found that adolescents are less likely to smoke and that those who smoke consume fewer cigarettes in the following settings: where prices are higher, in states that use cigarette excise tax revenues for tobacco control activities, where there are stronger restrictions on smoking in public places, and in states that have adopted comprehensive approaches to measuring retailer compliance with youth access laws. The authors concluded that comprehensive approaches, including enforcement of minors' access laws, will lead to a reduction in youth smoking. A large, community-based clinical trial—seven intervention and seven control communities—also found an intervention effect (Forster et al. 1998). In this study, communities that developed new ordinances, changes in merchant policies and practices, and changes in enforcement practices experienced a significantly smaller increase in adolescent smoking than did the control communities. Further exploration of this issue may be required to substantiate the impact of the enforcement of minors' access laws.

As commercial sales to minors are decreased, there is evidence that minors may shift their attempts to obtain cigarettes to "social" sources, e.g., other adolescents, parents, or older friends (Hinds 1992; Forster et al. 1998). One study found that adult smokers aged 18 and 19 years were the most likely group of adults to be asked by a minor for cigarettes (Ribisl 1999). This study did not assess how frequently minors asked other minors for tobacco. There is also evidence, however, that minors who provide tobacco to other minors are more likely to purchase tobacco than other minors who smoke (Wolfson 1997), and in any event, some of the cigarettes provided by minors to other minors were initially purchased from commercial sources (Forster et al. 1997). Whether the source is social or commercial, it is clear that a comprehensive approach to reducing minors' access is needed; smokers of all ages in addition to tobacco retailers must avoid provision of tobacco to minors.

Efforts to Promote Adoption and Enforcement of Minors' Access Laws

Public organizations at the federal, state, and local levels have become active in encouraging state and local jurisdictions to adopt and enforce minors' access laws. The NCI-ACS collaboration known as ASSIST (American Stop Smoking Intervention Study) has identified reducing minors' access to tobacco products as one of its goals for its 17 demonstration states. The Robert Wood Johnson Foundation's SmokeLess States program also encourages funded states to address minors' access. The USDHHS has widely distributed a model state law as a result of an investigation by the Office of Inspector General (OIG) reporting little or no enforcement of state laws on minimum ages for tobacco sales (OIG 1990; USDHHS 1990). Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youth, a report from the Institute of Medicine (IOM), includes an extensive study of minors' access and a series of recommendations about state and local laws in this area (Lynch and Bonnie 1994). A group of 25 state attorneys general formed a working group on the issue and released a set of recommendations regarding retail sales practices and legislation aimed at reducing tobacco sales to minors (Working Group of State Attorneys General 1994).

Efforts to curb illegal sales to minors have also occurred at the federal level. The former FDA program (see description in Chapter 7) was a major effort for several years. Probably the most sustained and widespread attention to the issue of minors' access laws and their enforcement was precipitated by the U.S. Congress, which in 1992 adopted the Synar Amendment as part of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (Public Law 102-321, sec. 1926), which amended the Public Health Service Act. This provision requires states (at the risk of forfeiting federal block grant funds for substance abuse prevention and treatment) to adopt laws establishing minimum ages for tobacco sales, to enforce the law, and to show progressive reductions in the retail availability of tobacco products to minors. The implementation of the Synar Amendment, which initially was to go into effect during fiscal year 1994, was delayed because regulations about how states were to implement the statute had not yet been finalized. During the considerable lag between passage of the amendment and the issuance of final regulations, advocates for Synar-like restriction of youth smoking and those opposed to the Synar approach used the draft regulations to encourage states to adopt laws that in these parties' differing views were the minimum necessary for states to comply with the Synar Amendment (Federal Register 1993; DiFranza 1994c; DiFranza and Godshall 1994). These anticipatory responses, together with the opinions and concerns they elicited, were analyzed in a study conducted in 1995 by Downey and Gardiner (1996). An interim report from the OIG in 1995 indicated that states were finding the implementation process difficult. Although 85 percent of states performed some inspections, the majority did not use a rigorous sampling scheme. Fifty-six percent reported no statewide enforcement activity (OIG 1995).

The draft regulations were finalized in early 1996 after a review of comments from the health community, state agencies, and the tobacco industry. Responsibility for implementation was placed with the Substance Abuse and Mental Health Services Administration (SAMHSA), which in the course of 1996 conducted two technical assistance meetings with states and issued three separate guidance documents. Under these regulations, the Synar Amendment requires the 50 states, the District of Columbia, and U.S. jurisdictions to do the following:

- Have in effect a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any person under the age of 18.
- Enforce such laws in a manner that can be reasonably expected to reduce the extent to which tobacco products are available to persons under the age of 18.
- Conduct annual random, unannounced inspections to ensure compliance with the law; inspections are to be conducted to provide a valid sampling of outlets accessible to underaged youth.
- Develop a strategy and time frame for achieving an inspection failure rate of less than 20 percent among outlets accessible to underaged youth.
- Submit an annual report detailing the state's activities in enforcing the law, the success achieved, methods used, and plans for future enforcement.

In the event of noncompliance with these regulations, the Secretary of Health and Human Services is directed by statute (42 U.S.C. section 300X-26[c]) to make reductions of from 10 percent (for the first applicable fiscal year) to 40 percent (for the fourth

applicable fiscal year) in the noncompliant state's federal block grant for substance abuse programs. Although no additional monies have been appropriated to offset the costs of complying with these regulations, states may use block grant funds for certain Synarrelated administrative activities, such as developing and maintaining a list of retail outlets, designing the sampling methodology, conducting Synar survey inspections, and analyzing the survey results.

In the several years following the issuance of the final Synar regulation, some significant advances have been made in enforcement of youth access laws. All states have laws prohibiting sale or distribution and they are enforcing those laws (USDHHS 1998a). Further, the median rate at which retailers failed to comply with laws prohibiting tobacco sales to minors in 1998 was 24.4 percent compared with the median rate of 40 percent in 1997 and pre-1997 studies that found violation rates ranging from 60 to 90 percent (USDHHS, in press). In the course of implementing Synar, every state has been required to establish a sampling methodology that measures the statewide retailer violation rate within a known confidence interval and to establish inspection protocols for conducting the statewide survey of tobacco retailers. These protocols include restrictions on the ages of minor inspectors and to establish procedures for recruiting and training of both minor inspectors and adult escorts. Additionally, the random, unannounced inspections conducted by the states in compliance with the Synar regulation provide the largest body of statewide data available on the level of retailer noncompliance.

Twenty-two states and two U.S. jurisdictions modified their youth access laws within a year of implementing Synar inspections. These changes improved the states' ability to enforce the law by clarifying responsibility for enforcement, defining violations, clarifying penalties, restricting vending machine sales, and establishing a list of tobacco vendors through retail licensure or vendor registration (USDHHS, in press).

In spite of these advances in enforcement of youth access laws, states also encountered difficulties while attempting to comply with the Synar mandate. The Synar regulation does not allow for the allocation of federal dollars (e.g., the Substance Abuse Prevention and Treatment Block Grant) to be used for enforcement. For many states, this proved to be a significant problem, because enforcement of youth access laws had not been previously viewed as a priority, and states were unwilling to redirect already limited funds for prevention and treatment services to law enforcement. Some states addressed the problem by earmarking

revenue derived from fines, fees, or taxes. Other states implemented collaborative enforcement efforts among several agencies so that the financial burden would be shared. And still other states relied heavily on the use of volunteer youth inspectors and adult escorts (USDHHS 1998a). As the FDA became active in the youth access issue, a few states were able to use FDA funding for enforcement to cover some of the cost of Synar inspections in 1998.

Another obstacle to enforcement involved developing a valid random sample of tobacco outlets in the state when there was no accurate or current list of vendors available. Although a few states addressed this problem by working to pass retailer licensing laws at the state level, states initially had to build lists by relying on information from wholesale tobacco distributors and vending machine distributors and by searching existing lists that inadvertently identify tobacco vendors (e.g., convenience store association membership lists) (USDHHS 1999).

Other less frequently cited obstacles to enforcement included fear of lawsuits from cited vendors, concerns with the liability issues associated with working with youth, and opposition to conducting enforcement from state and local officials, law enforcement, and the general public in regions of the country where the economy is tied to the production of tobacco (USDHHS 1999).

In addition to federal and state efforts targeting illegal tobacco sales to minors, a great amount of local activity has occurred. Many local ordinances have resulted from the work of various groups, particularly in California, Massachusetts, and Minnesota (DiFranza 1994a,b; Kropp 1995; Forster et al. 1996, 1998). These ordinances—which may, for example, prohibit vending machine sales or all self-service sales of tobacco, require the tobacco sellers to be aged 18 years or older, require checking identification before sale, specify civil penalties for violators of the minimum-age law, require posting that law at the point of purchase, and require compliance checks with a specified timetable—permit creative responses at the local level to the minors' access problem. Compared with state officials, local officials deal with fewer retailers and a more limited set of constraints and are freer to tailor their policy to local conditions. Tobacco interests are less influential at the local level, because industry representatives are more likely to be perceived as outsiders, and their campaign contributions are less likely to be important to local officials; moreover, community members and local advocacy groups are often more effective against tobacco interests at this level than they are in statewide policy arenas (Sylvester 1989). Policy implementation is also likely to be more consistent at the local level, because local advocates can monitor the process and because enforcement officials are more likely to have been a part of the policy's adoption. However, many of the policies at the federal, state, and local levels are interrelated: the federal Synar Amendment is implemented through state laws and has led to enforcement at the state and local level (USDHHS 1998a). The former FDA enforcement program operated through contracts with state agencies or organizations to conduct compliance checks in communities across the states. State agencies often fund local coalitions and projects, and local efforts influence and support efforts at the state level. For example, much of the local activity in California and Massachusetts would not have been possible without actions implemented at the state level, specifically designated funding.

Laws enacted by states pertaining to minors' access to tobacco as of December 31, 1999, have been compiled by the CDC (CDC, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data)(Table 5.3). Dates of enactment or amendment indicate that some legislative change occurred in all but one state from January 1990 to December 1997 (National Cancer Institute, State Cancer Legislative Database, unpublished data, October 6, 1998).

Restrictions on Distribution of Samples

Tobacco product samples provide a low-cost or no-cost initiation to their use and thus encourage experimentation at early ages. Many states or other jurisdictions have laws that prohibit not only sales but also any samples distribution of tobacco to minors, whereas some laws specify exceptions permitting parents or guardians to provide tobacco to their children. All states have a specific restriction on the distribution of free samples to minors, and a few states or local jurisdictions prohibit free distribution altogether because of the difficulty of controlling who receives these samples. A ban on product sample distribution can extend to coupons for free tobacco products. In Minnesota, the attorney general levied a \$95,000 civil penalty against the Brown & Williamson Tobacco Corporation for allowing such coupons to be redeemed in the state (Minnesota Attorney General 1994). The reports from both the IOM (Lynch and Bonnie 1994) and the Working Group of State Attorneys General (1994) recommended a ban on the distribution of free tobacco products. The final FDA rules issued in August 1996 would have prohibited the distribution of free samples (see "Further Regulatory Steps," earlier in this chapter). The proposed multistate settlement presumed congressional legislation that would uphold those rules (see "Legislative Developments" and "Master Settlement Agreement," earlier in this chapter).

Regulation of Means of Sale

How tobacco can be sold may also be regulated to make it more difficult for minors to purchase it. Historically, the first such restrictions adopted have been regulations of cigarette vending machines, which are an important source of cigarettes for younger smokers (Response Research, Incorporated 1989; Cummings et al. 1992, 1998; CDC 1996d). These regulations have taken the form of total bans, restrictions on placement (e.g., being within view of an employee instead of in coatrooms or entrances, or not being near candy or soda machines), restrictions on the types of businesses where vending machines may be located (e.g., limited to liquor-licensed businesses, private businesses, or businesses where minors are not permitted), and restrictions on characteristics of the machines themselves (e.g., requiring electronic locking devices or coin slugs purchased over a sales counter) (Forster et al. 1992a; DiFranza et al. 1996). The final FDA rules would have prohibited vending machines except in certain nightclubs and other adults-only facilities totally inaccessible to persons under age 18. The proposed multistate settlement anticipated legislation supporting this prohibition.

Forty-one states and the District of Columbia have laws that restrict minors' access to vending machines, including two states, Idaho and Vermont, that have enacted legislation totally banning vending machines. However, many of the state vending machine laws are weak. For example, 21 states and the District of Columbia do not restrict placement if the machine is supervised, and New Jersey bans vending machines in schools only (CDC, Office on Smoking and Health, unpublished data, 2000). However, more than 290 local jurisdictions, including New York City, have been able to adopt and enforce outright bans on cigarette vending machines or to severely restrict them to locations, such as taverns, where minors are often excluded (American Nonsmokers' Rights Foundation, unpublished data, 2000).

Representatives of tobacco manufacturers and retailers have strongly opposed bans on cigarette vending machines and have argued instead for weaker restrictions, if any, especially for what they term "adult" locations (Minnesota Automatic Merchandising Council 1987; Adkins 1989; Parsons 1989; Grow 1990; Moylan 1990; Pace 1990; Gitlin 1991). Many of these locations, including bars and other liquor-licensed

Table 5.3. Provisions of state laws relating to minors' access to tobacco as of December 31, 1999

State	Minimum age for tobacco sales	Tobacco license required	Vending machine restrictions	Enforcement authority	Sign-posting requirements*	Prohibits purchase, possession, and/or use by minors
Alabama	19	yes	no	yes	no	yes
Alaska	19	yes [†]	yes	no	yes	yes [‡]
Arizona	18	no	yes	no	no	yes
Arkansas	18	yes	yes	yes	yes	yes
California [§]	18	no	yes	no	yes	yes
Colorado	18	no	yes	yes	yes	yes
Connecticut§	18	yes [†]	yes	yes	yes	yes
Delaware§	18	yes	yes	yes	yes	yes
District of Columbi	a 18	yes [†]	yes	no	yes	no
Florida [§]	18	yes	yes	yes	yes	yes
Georgia	18	yes	yes	yes	yes	yes
Hawaii	18	no	yes	no	yes	yes
Idaho	18	no	$\mathrm{yes}^{\scriptscriptstyle\Delta}$	yes	no	yes
Illinois§	18	no	yes	yes	no [¶]	yes
Indiana§	18	no	yes	yes	yes	yes
Iowa§	18	yes [†]	$\mathrm{yes}^{\scriptscriptstyle\Delta}$	yes	no	yes
Kansas	18	yes [†]	yes	no	yes	yes
Kentucky§	18	yes [†]	yes	yes	yes	yes
Louisiana§	18	yes	yes	yes	yes	yes**
Maine	18	yes	yes	yes	yes	yes
Maryland	18	yes [†]	no	no	no	yes
Massachusetts§	18	yes	no	no	yes	no
Michigan§	18	yes	yes	no	yes	yes ^{††}
Minnesota	18	yes	yes	yes	no	yes
Mississippi§	18	yes	yes	yes	yes	yes ^{§§}

^{*}Refers to the requirement to post the minimum age for purchase of tobacco products.

Source: Centers for Disease Control and Prevention, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data.

[†]Excludes chewing tobacco or snuff.

[‡]Except minors at adult correctional facilities.

[§]Some or all tobacco control legislation includes preemption.

^aRequires businesses that have vending machines to ensure that minors do not have access to the machines; however, the law does not specify the type of restriction, such as limited placement, locking device, or supervision.

Signage required for sale of tobacco accessories, but not for tobacco.

^{**}Except persons who are accompanied by a parent, spouse, or legal guardian 21 years of age or older or in a private residence.

⁺⁺A pupil may not possess tobacco on school property.

Table 5.3. Continued

State	Minimum age for tobacco sales	Tobacco license required	Vending machine restrictions	Enforcement authority	Sign-posting requirements	Prohibits purchase, possession, and/or use by minors
Missouri	18	no	no	no	yes	no
Montana§	18	yes	yes	yes	yes	yes ^{‡‡}
Nebraska	18	yes ^{§§}	yes	no	no	yes
Nevada [§]	18	yes §§	yes	yes	no	no
New Hampshire	18	yes	yes	yes	yes	yes
New Jersey§	18	yes [†]	yes	yes	yes	no
New Mexico§	18	no	yes	yes	yes	yes
New York§	18	yes	yes	yes	yes	no
North Carolina§	18	no⁺§§∆∆	yes	no	yes	yes
North Dakota	18	yes ^{§§}	yes	no	no	yes
Ohio	18	yes [†]	yes	no	yes	no
Oklahoma§	18	yes [†]	yes	yes	yes	yes
Oregon§	18	no	yes	yes	yes	yes
Pennsylvania§	18	yes [†]	no	no	no	no ^{‡‡}
Rhode Island	18	yes [†]	yes	yes	yes	yes ^{¶¶}
South Carolina§	18	yes	no	no	no	no
South Dakota§	18	no	yes	yes	no	yes
Tennessee§	18	no	yes	yes	yes	yes
Texas	18	yes	yes	yes	yes	yes
Utah [§]	18	yes	yes	yes	no	yes
Vermont	18	yes	yes	yes	yes	yes
Virginia [§]	18	no	yes	yes	yes	yes
Washington§	18	$\mathrm{yes}^{\scriptscriptstyle \dagger}$	yes	yes	yes	yes
West Virginia§	18	no	no	yes	no	yes
Wisconsin§	18	yes	yes	no	yes	yes
Wyoming§	18	no	yes	no	yes	yes
Total	51	35	44	33	36	42

[‡]A pupil may not possess or use tobacco on school property.

^{§§}Except vending machines.

^{∆∆}A retail license exists for those retailers who manufacture their own tobacco products or deal in nonpaid tobacco products.

^{¶¶}On any public street, place, or resort.

businesses, do not prohibit minors' entry and have been shown to be readily accessible to underaged buyers (Forster et al. 1992b; Wakefield et al. 1992a; Cismoski and Sheridan 1993). Because less-restrictive measures must be consistently implemented to be effective, and because such implementation is difficult, the USDHHS (1994) and the IOM (Lynch and Bonnie 1994) recommend a total ban on cigarette vending machines. The 1996 FDA rules would have excluded locations that are inaccessible to minors, but the multistate settlement proposed a total ban.

Restrictions on vending machines are a category of regulation of self-service cigarette sales. A general ban on self-service would require that tobacco be physically obtained from a salesperson and be stored so that products are not directly accessible to customers. In one study of 489 over-the-counter purchase attempts, minors were successful at purchasing in 33 percent of locations where cigarettes were behind the counter and 45 percent of locations where cigarettes were openly available (Forster et al. 1995). In another study, stores that did not give customers access to tobacco products were less likely to sell to minors (12.8 percent) than stores that permitted direct contact with tobacco products (30.6 percent)(Wildey et al. 1995a). Finally, data suggest that shoplifting is an important commercial source of tobacco to underaged youth (Cummings et al. 1992, 1995; Cismoski and Sheridan 1994; Lynch and Bonnie 1994; Forster et al. 1995; Wildey et al. 1995b; CDC 1996d; Roswell Park Cancer Institute 1997). Shoplifting may be deterred by regulations that specify that until the moment of purchase, single packs, any amount less than a carton, or all tobacco products must be physically handled by an employee only (Cismoski 1994; Wildey et al. 1995a; Caldwell et al. 1996).

Several states have addressed the issue of selfservice sales of tobacco products. For example, Idaho and Minnesota restrict self-service sales to only those stores that do not allow minors to enter and that obtain most of their sales from tobacco. Texas prohibits self-service sales in any location accessible to minors. Three hundred and ten localities have chosen to restrict tobacco sales by prohibiting self-service displays (American Nonsmokers' Rights Foundation, unpublished data, 2000). Opposition to this measure is generally organized by tobacco distributors and retailers, who fear the loss of slotting fees—payments (often substantial) to retailers for advantageous placement of tobacco products and for point-ofpurchase advertising in their business (Gersten 1994; Thomas A. Briant, letter to Litchfield Tobacco Retailers, February 16, 1995; Caldwell et al. 1996). The IOM recommends a ban on self-service displays (Lynch and Bonnie 1994), and the Working Group of State Attorneys General (1994) recommends to tobacco retailers that they eliminate such displays. That this recommendation is not unreasonably burdensome has been demonstrated by one study in which 28 percent of retailers in 14 communities complied voluntarily (Forster et al. 1995) and by another study involving 15 cities in northern California (Kropp 1995). The 1996 FDA rules would also have prohibited self-service displays except in certain adults-only facilities; the proposed national settlement further stipulated that in non-adults-only facilities, tobacco products must be out of reach or otherwise inaccessible or invisible to consumers.

Anecdotal reports have suggested that single or loose cigarettes are sold in some locations. Such sales are often prohibited by state or local law, at least implicitly because single cigarettes do not display the required state tax stamp or federal warning. Frequently, single cigarettes are kept out of sight and are available only by request. Researchers in California found that even after a state law explicitly banned the sale of single cigarettes, almost one-half of tobacco retailers sold them to their customers (Klonoff et al. 1994). The study found that the stores that made loose cigarettes available sold them to almost twice as many minors as they did to adults. That finding lends support to the argument that single cigarette sales are an important avenue to addiction for some youth. A recent study in Central Harlem has produced similar results: 70 percent of the licensed outlets sold single cigarettes to minors (Gemson et al. 1998). The IOM, the 1996 FDA rules, and the proposed multistate settlement have all recommended that the sale of loose or single cigarettes be explicitly prohibited (Lynch and Bonnie 1994).

Regulation Directed at the Seller

All states now have a law specifying the minimum purchaser's age for legal sale of tobacco products. For all but two states, that age is 18; Alabama and Alaska specify age 19. Almost two-thirds of the states and many local jurisdictions require tobacco retailers to display signs that state the minimum age for sale. Some regulations specify the size, wording, and location of these signs. Other regulations specify the minimum age for salespersons; these regulations recognize the difficulty young sellers may experience in refusing to sell cigarettes to their peers.

Most of these laws define violation either as a criminal offense (e.g., misdemeanor or gross misdemeanor), with accompanying penalties, or as a civil offense, with specified civil penalties (e.g., fines and license suspension). Civil offense laws are thought to make enforcement easier and are therefore more likely to be carried out, since they do not generally require court appearances. Many state or local laws specify penalties only against the salesperson. Applying penalties to business owners, who generally set hiring, training, supervising, and selling policies, is considered essential to preventing the sale of tobacco to minors, although tobacco retailers have vigorously opposed these measures (Skretny et al. 1990; Feighery et al. 1991; McGrath 1995a,b).

More than one-half of the states and some local jurisdictions require that tobacco retailers obtain licenses for over-the-counter sales, but smokeless tobacco is exempted by 13 of these states (CDC, Office on Smoking and Health, unpublished data). Licensure sometimes is simply a mechanism for collecting taxes or generating revenue; in other states and cities, conditions are attached that relate to minors' access. In addition to civil penalties, retail licensure for tobacco represents another approach for facilitating youth access law enforcement efforts and strengthening sanctions for violators of the law. Retail licensure can facilitate the identification of retailers. The lack of a current and accurate list of tobacco vendors has been cited by many states involved in Synar enforcement as a serious impediment to efficient enforcement (USDHHS 1999). Retail licensure can also create an incentive for retail compliance. License suspensions or revocations could be imposed as penalties for violation of youth access laws, resulting in revenue loss for retailers. Licensure would also provide a source of funds to pay for enforcement and retailer education when licensing fees or fines for violations are earmarked for such education purposes. Finally, retail licensure provides a mechanism for administrative adjudication of youth access law violations. License holders who fail to comply with the law could be held accountable before the licensing authority.

No published empirical research examines the effects of tobacco retail licensure on either enforcement efforts or retail compliance. Studies on policies targeted to increase retail compliance, however, suggest several specific elements of licensure policies that should be present in order to increase the likelihood of positive effects. The points below outline the ways in which licensure policies could be used to enhance retail compliance efforts.

- Licensure laws must explicitly link the privilege of selling tobacco products to retail compliance with youth access laws (Levinson 1999).
- Licensure should cover both retail stores and vending machines (Levinson 1999).
- License holders should be required to renew their license annually (Levinson 1999; USDHHS 1999).
- License holders should be fined for violation of youth access laws (Levinson 1999).
- Fines should be high enough to encourage vendors to comply with youth access laws but not so high as to risk loss of community or judicial support for the imposition of penalties (Lynch and Bonnie 1994).
- Fines should be graduated so that greater consequences are associated with increased number of violations. Repeated violations should lead to license suspension or revocation (CDC 1995a; NCI n.d.).
- License fees should be sufficient to cover the average cost of compliance checks (CDC 1995a).
- The revenue from fines should subsidize the costs of enforcement (Working Group of State Attorneys General 1994).

In addition to these items, several other policy elements have been suggested for incorporation into licensure laws. These licensure policy components should communicate clear and consistent messages about the illegality of tobacco sales to minors and should promote societal norms intolerant of youth access law violations (Kropp 1996). These elements include mandatory posting of warning signs within clear sight of consumers, mandatory checking of age identification, state provision of merchant and clerk education about youth access law requirements (i.e., consequences for violations and techniques for improving merchants' and clerks' skills at detecting underage youth and refusing sales), restrictions or bans on self-service displays, and ensuring that clerks are at or above the legal purchase age.

Without enforcement provisions, however, licensing laws are not effective measures to restrict minors' access. Before 1996, only 16 states with licensing laws specified the agency with enforcement responsibility, despite recommendations (USDHHS 1990; Lynch and Bonnie 1994; Working Group of State Attorneys General 1994) that states adopt a licensing requirement that has civil penalties and a designated

enforcement agent. In its 1998 report, SAMHSA indicates that all but one state requiring licenses have a designated enforcement agency (USDHHS 1998a; see "Enforcement of Laws on Minimum Ages for Tobacco Sales," later in this chapter).

State laws and local ordinances can be a mechanism for increasing retailer awareness of youth access laws and retailer ability to comply with the law. Often referred to as responsible vendor laws, this type of legislation can require retailer education and training as a condition of retail tobacco licensure or simply require education and training for all tobacco vendors. Numerous studies have shown the potential benefit of comprehensive merchant education and training programs in helping to reduce illegal sales to minors (Altman et al. 1989, 1991, 1999; Feighery 1991; Keay 1993; Cummings et al. 1998). In many instances, representatives of tobacco retailers have supported the passage of responsible vendor laws (McGrath 1995a,b; Thomas A. Briant, Letter to Litchfield Tobacco Retailers, February 16, 1995) when these laws also exempt business owners from penalties or specify lower penalties for tobacco sales to minors if owners have trained their employees. Under such conditions, employee training would relieve retailers of responsibility for ongoing supervision and monitoring of employee behavior and likely result in decreasing the impact of youth access laws. It should be noted, however, that as a result of both Synar and FDA attention to the problem of youth access to tobacco, several states have worked to ensure the modification of youth access and/or retail licensure laws to mandate vendor education and training without the incorporation of clauses relieving retailer responsibility (USDHHS 1998a). These efforts recognize that responsible vendor laws have the potential to be an effective way to increase the ability of retailers and clerks to comply with the law by accurately detecting underage purchases and confidently and safely refusing sales.

The general availability of tobacco products in retail outlets that have pharmacies has led to some concerns. In the United States, stores that have pharmacies usually sell tobacco products, contrary to a 1971 policy recommendation of the American Pharmaceutical Association (1971) that cited the inconsistency of selling cigarettes with their function as health institutions. A few small chains and a growing number of independent stores with pharmacies are tobacco free, but all large chains and most independent stores sell tobacco products. Pharmacies (and stores that have pharmacies) that sell tobacco products are as likely as other outlets to sell to minors (Brown and DiFranza 1992). On the other hand, a study has shown that

pharmacists who work in stores that do not sell tobacco have a better understanding of the dangers of tobacco than do pharmacists who work in stores that sell tobacco, and they also feel more confident that they can help customers who use tobacco stop (Davidson et al. 1988). Two-thirds of pharmacists surveyed in Minnesota believed that members of the profession should not work in stores that sell tobacco products (Martinez et al. 1993), and many felt that the contiguity of tobacco products and pharmaceuticals produces professional dissonance (Taylor 1992; Kamin 1994). Both the Canadian Medical Association and the American Medical Association are opposed to tobacco sales in pharmacies and in stores that have pharmacies (Staver 1987; Sullivan 1989). The Canadian provincial government of Ontario banned such sales in 1994 (An Act to Prevent the Provision of Tobacco to Young Persons and to Regulate its Sale and Use by Others, Statutes of Orleans, ch. 10, sec. 3[6] [1994] [Can.]).

Regulation Directed at the Buyer

State and local jurisdictions are increasingly imposing sanctions against minors who purchase, attempt to purchase, or possess tobacco products (CDC 1996c; Forster et al. 1996). These laws are favored by some law enforcement officials and tobacco retailers because of the potential deterrent value (Parsons 1989; Talbot 1992). Some advocates for reducing tobacco use argue, however, that such laws are part of an effort to deflect responsibility for illegal tobacco sales from retailers to underaged youth; that these laws are not an efficient substitute for laws regulating merchants, because so many more minors than retailers are involved; and that sanctions against minors are more difficult to enforce than those against retailers (Carol 1992; Cismoski 1994; Lynch and Bonnie 1994; Mosher 1995; Wolfson and Hourigan 1997). Other advocates have insisted that some of the responsibility must devolve on the purchaser and that laws prohibiting possession should be vigorously enforced (Talbot 1992). Although not taking a stand on the advisability of purchase and possession laws, the Working Group of State Attorneys General (1994) recommended that such laws should be considered only after effective retail regulations are already in place.

Enforcement of Laws on Minimum Ages for Tobacco Sales

Although laws on the minimum age for tobacco sales have been part of many state statutes for decades, only in the past few years has attention been focused on enforcing these laws by federal, state, or local agencies (Lynch and Bonnie 1994; Federal Register 1996; USDHHS, in press). As more information has become available about the implementation and effects of various minors' access laws, it is becoming clear that organized enforcement efforts are essential to realizing the potential of these laws. Enforcement of minimum-age laws is more likely to occur when enforcement is selfsupporting through license fees and revenues from penalties and when the penalty schedule includes civil penalties that are large enough to be effective but are seen as reasonable and simple to administer (Working Group of State Attorneys General 1994). Law enforcement officials have sometimes balked at applying criminal penalties against clerks and retailers for selling tobacco to minors. Enforcement may be more effective if sanctions can be imposed on managers or business owners rather than, or in addition to, salespersons (Working Group of State Attorneys General 1994).

Moreover, the 1992 enactment of the Synar Amendment (Public Law 102-321, sec. 1926, discussed in the introduction to this section) has forcibly brought this issue to the fore, because the amendment requires states to enact and enforce legislation restricting the sale and distribution of tobacco products to minors. As a result, all states have laws prohibiting the sale and distribution of tobacco to minors and all states enforce these laws through a statewide coordinated program. Additionally, all states have now designated a lead agency and all but one have an agency responsible for enforcing their minimum-age law (Table 5.4) (USDHHS, in press). In addition to federal and state enforcement efforts, a number of local jurisdictions around the country have begun actively enforcing the law against tobacco sales to minors, and local ordinances can include a schedule of required compliance checks (Lynch and Bonnie 1994; Working Group of State Attorneys General 1994; Forster et al. 1996; DiFranza et al. 1998).

Compliance checks are most often carried out by having an underaged buyer, under the supervision of a law enforcement officer, licensing official, or some other designated adult, attempt to purchase tobacco. In jurisdictions where the minor is held legally at fault if a purchase is made (and where no exceptions are made for compliance checks), minors participating in compliance checks are sometimes instructed not to complete the purchase even if the salesperson is willing; in these cases, the retailer is considered to be in noncompliance with the youth access law if the purchase is entered into the cash register (Hoppock and Houston 1990; Cummings et al. 1996).

Several innovative civil enforcement approaches have been attempted in California. The district attorneys in Sonoma and Napa Counties have used the California Business and Professions Code section 17200 to file civil lawsuits against store owners whose outlets repeatedly sold tobacco to minors. Civil enforcement has proved to be more efficient than criminal citations and has resulted in fines and penalties as well as reductions in tobacco sales to minors (Kropp and Kuh 1994).

Increased emphasis on enforcement, coupled with passage of laws against possession of tobacco by minors, may result in enforcement resources being selectively funneled to apprehending underaged smokers rather than penalizing the merchants who sell tobacco to these minors. A survey of 222 police chiefs in Minnesota revealed that although more than 90 percent were enforcing the law against minors' possession, 40 percent reported applying penalties to minors, and only 6 percent reported any enforcement against merchants (Forster et al. 1996).

A vigorous and multidimensional campaign has been mounted by the tobacco industry and its allies to prevent or undermine effective enforcement of minors' access laws and to resist the proposal that retailers be held accountable for their stores' compliance. Since 1992, laws sponsored by the tobacco industry but ostensibly intended to bring states into compliance with requirements of the Synar Amendment have been passed in Georgia, Idaho, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Dakota, and Tennessee (DiFranza 1994c; DiFranza and Godshall 1994). Tobacco industry representatives and their allies have lobbied successfully for the inclusion of language such as "knowingly" or "intentionally" in the law prohibiting sale of tobacco to minors; the impact of such language may be to render the law unenforceable. Industry interests have sought to include various restrictions on how, how often, and by whom enforcement or compliance testing can be conducted. Examples of these restrictions include opposing employing teens in compliance testing or requiring that only very young teens can function as buyers, insisting that enforcement be done only by the alcohol control authority or some other state agency, opposing compliance checks carried out by advocacy groups or for public health research, and opposing requirements that compliance checks occur on a specified schedule. The industry has further proposed immediate reentry and confrontation after an illicit saleprocedure that could compromise collecting evidence. Industry representatives have also consistently maintained that merchants ought not to be responsible for the costs incurred in complying with minimum-age

Table 5.4. Agencies responsible for enforcing state laws on minimum age for tobacco sales as of fiscal year 1998

State/Territory	Lead agency	Enforcement agency
Alabama	Alcoholic Beverage Control Board	Alcoholic Beverage Control Board
Alaska	Department of Health and Social Services, Division of Alcoholism and Drug Abuse	Attorney General's Office
Arizona	Department of Health Services, Office of Substance Abuse and General Mental Health	Department of Health Services, Office of Substance Abuse and General Mental Health
Arkansas	Department of Health, Bureau of Alcohol and Drug Abuse Prevention	Tobacco Control Board
California	Department of Health Services	Department of Health Services
Colorado	Department of Human Services, Alcohol and Drug Abuse Division	State and local law enforcement
Connecticut	Department of Mental Health and Social Services, Office of Addiction Services	Department of Revenue Services
Delaware	Department of Public Safety, Alcoholic Beverage Control Commission	Department of Public Safety, Alcoholic Beverage Control Commission
District of Columbia	Department of Human Services, Addiction Prevention and Recovery Administration	Department of Consumer and Regulatory Affairs and the Metropolitan Police Department
Florida	Department of Business and Professional Regulation, Division of Alcoholic Beverages and Tobacco	Department of Business and Professional Regulation, Division of Alcoholic Beverages and Tobacco
Georgia	Department of Public Safety	Department of Public Safety
Hawaii	Department of Health, Alcohol and Drug Abuse Division	Department of Health with Department of the Attorney General
Idaho	Department of Health and Welfare, FACS Division, Bureau of Mental Health and Substance Services	Department of Health and Welfare, FACS Division, Bureau of Mental Health and Substance Services
Illinois	Liquor Control Commission	No one agency responsible for enforcement
Indiana	Family and Social Services Administration, Division of Mental Health	Indiana Alcoholic Beverage Commission Excise Police
Iowa	Department of Public Health, Division of Substance Abuse and Health Promotion	Department of Public Health, Division of Substance Abuse and Health Promotion
Kansas	Department of Social and Rehabilitation Services, Alcohol and Drug Abuse Services	Department of Revenue, Alcoholic Beverage Control Board
Kentucky	Department of Alcoholic Beverage Control	Department of Agriculture (specified state law) with the Department of Alcoholic Beverage Control (appointed)

Source: U.S. Department of Health and Human Services, in press.

Table 5.4. Continued

State/Territory	Lead agency	Enforcement agency	
Louisiana	Department of Revenue and Taxation, Office of Alcoholic Beverage and Tobacco Control	Department of Revenue and Taxation, Office of Alcoholic Beverage and Tobacco Control	
Maine	Department of Mental Health and Mental Retardation, Office of Substance Abuse	Department of Mental Health and Mental Retardation, Office of Substance Abuse	
Maryland	Department of Health and Mental Hygiene, Alcohol and Drug Abuse Administration	State Comptroller's Office	
Massachusetts	Department of Public Health, Bureau of Substance Abuse Services	Department of Public Health, Tobacco Control Program with the Attorney General's Office	
Michigan	Department of Community Health, Bureau of Substance Abuse Services	Department of Community Health, Bureau of Substance Abuse Services	
Minnesota	Department of Human Services, Chemical Dependency Program Division	Department of Human Services, Chemical Dependency Program Division	
Mississippi	Department of Mental Health, Division of Alcohol and Drug Abuse	Office of Attorney General	
Missouri	Department of Mental Health, Division of Alcohol and Drug Abuse	Department of Mental Health, Division of Alcohol and Drug Abuse	
Montana	Department of Public Health and Human Services, Division of Addictive and Mental Disorders	Department of Public Health and Human Services, Division of Addictive and Mental Disorders	
Nebraska	Department of Health and Human Services	Nebraska State Patrol	
Nevada	Attorney General of the State of Nevada	State Attorney General	
New Hampshire	Department of Health and Human Services, Bureau of Substance Abuse Services	Department of Health and Human Services, Bureau of Substance Abuse Services	
New Jersey	Department of Health and Senior Services	Department of Health and Senior Services with local health agencies	
New Mexico	Department of Regulation and Licensing, Alcohol and Gaming Division	Department of Regulation and Licensing, Alcohol and Gaming Division (statutory), Department of Health and Department of Public Safety (by executive order)	
New York	Department of Health, Office of Alcoholism and Substance Abuse Services	37 local county health units and 10 district offices of the state's Department of Health	
North Carolina	Department of Human Resources, Division of Mental Health, Developmental Disabilities and Substance Abuse Services	Local police and sheriff's departments	
North Dakota	Department of Human Services, Division of Mental Health and Substance Abuse Services	State and local law enforcement agencies are responsible for enforcing state and local laws prohibiting tobacco sales to minors. The Department of Human Services, Division of Mental Health and Substance Abuse Services, is responsible for conducting compliance surveys.	

Table 5.4. Continued

State/Territory	Lead agency	Enforcement agency
Ohio	Department of Alcohol and Drug Addiction Services	Department of Alcohol and Drug Addiction Services
Oklahoma	Alcoholic Beverage Law Enforcement Commission	Alcoholic Beverage Law Enforcement Commission
Oregon	Department of Human Resources, Office of Alcohol and Drug Abuse Programs	Oregon State Police
Pennsylvania	Department of Health, Office of Alcohol and Drug Abuse Programs	Department of Health, Office of Alcohol and Drug Abuse Programs
Rhode Island	Department of Health, Division of Substance Abuse	Department of Health, Division of Substance Abuse (The Division of Substance Abuse transferred from the Rhode Island Department of Health to the Department of Mental Health, Retardation and Hospitals on September 1, 1998.)
South Carolina	Department of Alcohol and Other Drug Abuse Services	Department of Revenue and Taxation
South Dakota	Department of Human Services, Division of Alcohol and Drug Abuse	Division of Alcohol and Drug Abuse coordinates enforcement with the Attorney General's Office and 66 county state's attorneys
Tennessee	Department of Agriculture	Department of Agriculture
Texas	Commission on Alcohol and Drug Abuse and Department of Health	State Comptroller
Utah	Department of Human Services, Division of Substance Abuse	Department of Human Services, Division of Substance Abuse
Vermont	Department of Liquor Control	Enforcement and Licensing Division of the Department of Liquor Control
Virginia	Department of Agriculture and Consumer Services	Alcohol Beverage Control Board
Washington	Department of Social and Health Services, Division of Alcohol and Substance Abuse	Liquor Control Board
West Virginia	Department of Health and Human Resources, Division of Alcoholism and Drug Abuse	Alcohol Beverage Administration
Wisconsin	Department of Health and Family Services, Bureau of Substance Abuse Services	Department of Health and Family Services, Bureau of Substance Abuse Services
Wyoming	Department of Health, Division of Behavioral Health and Substance Abuse Program	Local law enforcement agencies
American Samoa	Department of Human and Social Services, Social Services Division	Department of Public Health
Guam	Department of Mental Health and Substance Abuse	Department of Mental Health and Substance Abuse
Marshall Islands	Office of the Attorney General	Chief Prosecutor of the Office of the Police Commissioner

Table 5.4. Continued

State/Territory	Lead agency	Enforcement agency	
Micronesia	Department of Health	No single agency; enforcement by local police and health departments	
Northern Marianas	Department of Public Health	Department of Public Health	
Palau	Ministry of Justice, Bureau of Public Safety with Ministry of Commerce and Trade (responsible for licensing)	Bureau of Public Safety	
Puerto Rico	Department of Health, Mental Health and Anti-Addiction Services Administration	Department of Treasury	
Virgin Islands	Department of Health, Division of Mental Health, Alcoholism and Drug Dependency Services	Department of Licensing and Consumer Affairs	

laws, such as the costs of making tobacco inaccessible to minors or of having merchants monitor their own staff (DiFranza 1994c; DiFranza and Godshall 1994). Despite, or in some cases in response to, these industry efforts, many states have successfully strengthened their youth access laws and/or removed industryinspired loopholes and provisions for affirmative defense. Six states amended state law to permit minors to participate in compliance checks conducted for enforcement purposes. Twenty-three states now have this provision in their minors' access law. Two states passed legislation that will provide a more accurate list of tobacco retailers for compliance checks and three states added provisions that address funding for enforcement and education programs (USDHHS, in press).

The reports from both the IOM (Lynch and Bonnie 1994) and the Working Group of State Attorneys General (1994) include strong recommendations that active enforcement of minors' access laws be implemented, that merchants be held responsible for sales in their stores, and that access laws supported by the tobacco industry be rejected.

Using another type of enforcement, some private groups and states have conducted lawsuits against commercial outlets that violate minors' access laws. A selection of these cases, one of which also named a tobacco company as a codefendant, is discussed in "Enhancing Prohibitory Regulation by Private Litigation," later in this chapter.

Traditional law enforcement agencies often resist conducting tobacco enforcement for a number of reasons. They believe that tobacco enforcement diverts limited resources from other more pressing crime and

that the public does not support the use of officers for such enforcement. They have also argued that the illfeeling of members of the business community generated by the issuance of citations negatively affects other enforcement efforts. Finally, the officers themselves frequently resist because they do not want to facilitate potential job loss for a clerk for what they perceive to be a "minor" infraction or because they believe that prosecutors and judges will be reluctant to penalize (USDHHS 1999).

Other agencies can be a suitable alternative for the conduct of enforcement. Chief among them are public health departments, which recognize the importance of conducting enforcement, and alcohol beverage control agencies (ABCs), which are highly experienced in conducting undercover compliance checks. ABCs retain a staff of inspectors that are familiar with the protocols that may be employed during retail inspections (i.e., consummated and unconsummated buys). ABCs also tend to recognize a connection between alcohol and tobacco enforcement and accept the importance of conducting tobacco inspection for practical reasons if not for health reasons. This, in turn, results in less of a philosophical resistance to actually issuing citations for violations. Finally, because ABC authorities regularly engage in enforcement directed at retailers, tobacco enforcement conducted by this agency will not likely generate as negative a backlash from retailers and the general public as enforcement conducted by traditional law enforcement (USDHHS 1999).

State Settlements

All four states that settled their lawsuits against the tobacco industry in 1997-1998 won youth access restrictions in their settlement agreements. (The events leading up to these four settlements, along with their implications as a litigational tool for reducing tobacco use nationwide, are discussed in "Recovery Claims by Third-Party Health Care Payers," later in this chapter.) For example, the tobacco industry defendants in the state of Florida case agreed to support new state laws or regulations to prohibit the sale of cigarettes in vending machines, except in adult-only locations or facilities (Florida v. American Tobacco Co., Civil Action No. 95-1466 AH, sec. II.A.2 [Fla., Palm Beach Cty. Aug. 25, 1997]). The industry also agreed to support new state laws in Florida to increase civil penalties for sales of tobacco products to minors (including retail license suspension or revocation) and to strengthen civil penalties for the possession of tobacco by minors. The Florida settlement (sec. II.B) further requires the tobacco industry to pay \$200 million for a two-year pilot program to reduce tobacco use by minors, including enforcement, media, educational, and other youth-directed programs. Youth access provisions of the Texas settlement that pertain to new state laws mirror the terms of the Florida agreement (Texas v. American Tobacco Co., No. 5-96CV-91 [E.D. Tex. Jan. 16, 1998], secs. 7[a-c]).

The state of Minnesota won the most comprehensive array of public health and youth access restrictions to date when it settled its case after a highly publicized trial in 1998 (*Minnesota v. Philip Morris Inc., cited in* 13.2 TPLR 3.39). One provision of the Minnesota settlement forbids tobacco manufacturers from directly or indirectly opposing state statutes or regulations intended to reduce tobacco use by minors. A list of legislative proposals covered by the prohibition is attached to the settlement agreement (Schedule B) and includes the following measures:

- Expansion of self-service restrictions and removal of the current exception for cigars.
- Amendment of the current law for restricting youth access to vending machines to clarify that machines with automatic locks and machines that use tokens are covered.
- "Enhanced or coordinated funding" for enforcement efforts under sales-to-minors provisions of the criminal code or the statute and ordinances involving youth access.

- Laws to "encourage or support the use of technology to increase the effectiveness of age-of-purchase laws" (e.g., programmable scanners or scanners to read drivers' licenses).
- Restrictions on wearing, carrying, or displaying tobacco indicia in school-related settings.
- Establishment or enhancement of nonmonetary incentives for youth not to smoke (e.g., expand community services programs for youth).

Moreover, prohibiting tobacco companies from challenging the enforceability or constitutionality of current Minnesota laws encompasses some key youth access statutes, such as those pertaining to the sale of tobacco to minors (Minnesota Statutes sec. 609.685) and the distribution of samples (Minnesota Statutes sec. 325.77) (Minnesota v. Philip Morris Inc., cited in 13.2 TPLR 3.39, sec. IV.A.2). Another injunctive provision, forbidding the tobacco industry from targeting children through advertising, promotion, or marketing, also prohibits the industry from "taking any action the primary purpose of which is to initiate, maintain or increase the incidence of underage smoking in Minnesota" (Minnesota v. Philip Morris Inc., No. C1-94-8565 [Minn., Ramsey Cty. May 8, 1998], cited in 13.2 TPLR 2.112, 2.113 [1998]).

The Minnesota settlement also includes a large industry-funded program to reduce teen smoking. The program includes counteradvertising, classroom education, community partnerships, research, advocacy, and prevention components (*Minnesota v. Philip Morris Inc.*, cited in 13.2 TPLR 3.39, sec. VIII.A.2).

Although Mississippi (the first state to settle) did not initially secure public health restrictions, it later imported some of those contained in the sweeping Minnesota settlement by exercising the "most favored nation" clause (discussed in "Recovery Claims by Third-Party Health Care Payers," later in this chapter) in its original settlement agreement (PR Newswire 1998a). Intended to ensure that Mississippi would receive the benefits any later similar settlement might receive, the most favored nation clause also enabled the state to substantially increase the dollar amount of its settlement with the industry. Furthermore, although the revised agreement prohibits Mississippi from gaining any additional monetary benefit based on future state settlements, it does not limit the incorporation of additional public health provisions or financial adjustments in the event that Congress adopts national tobacco legislation.

Preemption of Local Action by State Policy

As noted earlier in this section (see "Efforts to Promote Adoption and Enforcement of Minors' Access Laws"), the initiative to address minors' access, as well as many creative solutions, has come from the local level. In state legislatures, the balance of power between forces for and against reducing tobacco use is most often tipped in favor of tobacco use. The reverse is often true at the local level, where jurisdictions have enacted innovative approaches that have been evaluated by researchers. At the state level, however, tobacco industry representatives have sought to preclude legislative or enforcement authority at the local level by including preemption language, usually attached to weak statewide restrictions.

As of 1998, 30 states had preemptive tobacco control laws, although they vary widely in the kind of restrictions they preempt (CDC 1999). No preemptive tobacco control laws have been enacted since July 1996. The tobacco industry has adopted preemption as a main strategy to undermine, overturn, and prohibit future efforts to adopt local policies to reduce tobacco use (Siegel et al. 1997; Gorovitz et al. 1998). For instance, in 1991 and 1992, the tobacco industry spent more than \$2 million to lobby for the repeal of local clean indoor air ordinances (Traynor et al. 1993). In California in one year alone, the industry spent \$18.9 million on an initiative to repeal all local ordinances for reducing tobacco use and to eliminate local authority to enact new ordinances (Siegel et al. 1997).

A memorandum of the 1991 Smokeless Tobacco Council described a strategy to oppose local ordinances and advance statewide antitobacco bills containing preemption clauses (Siegel et al. 1997). In addition, the Tobacco Institute stated that a priority for 1993 was to "encourage and support statewide legislation preempting local laws, including smoking, advertising, sales, and vending restrictions" (Tobacco Institute 1992). This strategy would work against the passage of strong tobacco control laws at the local level and would relieve logistical difficulties of the tobacco industry in devoting resources toward multiple local jurisdictions (Siegel et al. 1997; Gorovitz et al. 1998).

Even when a preemption clause is not specifically included, tobacco industry representatives have argued that state laws that address minors' access are intended to preempt local action, and that argument has been used by at least one court to invalidate more restrictive local ordinances (DiFranza 1993). Both the IOM (Lynch and Bonnie 1994) and the Working Group of State Attorneys General (1994) recommend that state laws include language specifically stating that they are not meant to preempt stronger local ordinances.

One of the U.S. health objectives for 2000 was to reduce to zero the number of states with preemptive smoke-free indoor air laws (Objective 3.25) (National Center for Health Statistics 1997); an objective proposed for 2010 is to reduce the number of states with any preemptive tobacco control laws to zero (USDHHS 2000a). Most states have preemptive tobacco control laws, and 19 have preemptive provisions for minors' access laws. Thus, achievement of the 2000 objective is unlikely (CDC 1999).

Litigation Approaches

Introduction

Society deploys various regulatory controls to confront risks arising from dangerous products or practices. As has been discussed in previous sections in this chapter, these controls include those intrinsic to the practice itself, such as preventive design and safety procedures built into a product or into the technology of its use, as well as external regulation by government agencies and private parties, such as property owners, employers, or insurers. Certain institutions also absorb and spread losses when a practice does

result in injuries, such as relief institutions that assist victims and social and private insurance that compensates the injured. Another regulatory control, introduced here, is private law (referred to generally in this section as litigation and held distinct from the more sweeping legislative scope of public law). In the course of vindicating the claims of injured persons, private law generates, broadcasts, and reinforces safety standards. The various controls are not independent but interact in complex ways. For example, preventive design may stem from the imposition or anticipation either of government regulation or of liability

established through private law; similarly, employers or insurers may institute preventive regulations to limit the cost of remedial measures resulting from private law decisions.

Private Law as a Means of Risk Control

Private law remedies combine existing public standards with a public institution—the courts—that is passive in accepting these standards but is also, accordingly, reactive when the standards change. In private law, the initiative to enforce a change or decision is shifted away from an enterprise or a government to private actors—typically, victims or their surrogates. This diffusion of the enforcement initiative is matched by the decentralized pronouncement of liability standards, which are less often established at a given moment than they are formulated over time, largely by courts responding incrementally to specific cases brought before them. Private law standards are context sensitive, incorporating changing popular values and understandings. In the United States, this incorporation of popular views is accelerated by the use of civil juries.

Tort as a Private Law Control

In the tort system, which applies to actionable wrongful acts other than breach of contract (tort is a Middle English word meaning "injury"), information about instances in which injurers (and their insurers) are forced to compensate victims coalesces slowly into a body of knowledge that, acknowledged by other potential injurers, generates various preventive effects (Calabresi 1970). However, because each instance of remedy involves individualized determination of liability and damages, the production of these preventive effects by the tort system is highly inefficient. The process is also very expensive, because a large portion of the money that the tort system extracts from injurers is consumed by the tort process itself (Kakalik and Pace 1986). Nonetheless, although relatively inefficient for compensating specific classes of injuries, the tort system effectively generates overall preventive effects and is flexible and adaptive (American Law Institute 1991; Galanter 1994).

U.S. Reliance on Private Law Controls

Societies differ in the way they deploy this alternative set of controls. The United States has tended to rely more heavily on private law controls than do other industrialized countries (Kagan 1991; Galanter 1994).

The expansive U.S. system of private remedy is conjoined with a lesser emphasis on administrative controls and social insurance (Pfennigstorf and Gifford 1991).

Where excessive risks are associated with a product or practice, the U.S. tort system typically acts to shift part of the cost of these risks back to the producers and users. Such litigation campaigns follow a familiar course toward preventing particular risks: after a period of innovation and experimentation, a few successful lawsuits provide a model and incentive for other lawyers and plaintiffs; the threat of a mounting tide of litigation (and occasionally an actual tide) leads to a flow of compensation, modifications in the use or design of the product, and occasionally bankruptcy of the defendant; and eventually the litigation abates as product modifications break the link to risk (McGovern 1986; Galanter 1990; Sanders 1992; Hensler and Peterson 1993; Durkin and Felstiner 1994; Schmit 1994).

Potential Public Health Benefits of Tobacco Litigation

As applied to lawsuits against the tobacco industry, private litigation has the potential to do the following:

- Enlist a new cadre of skilled, resourceful, and relentless advocates on the side of reducing tobacco use—the incentive being the contingency fees plaintiffs' attorneys would receive if they won or settled cases against the industry.
- Force the industry to raise prices dramatically to cover their actual or anticipated liabilities. Studies suggest that such higher costs would lower tobacco consumption—especially among children and teenagers, who are more price-sensitive than adults (Daynard 1988; Hanson and Logue 1998). For example, after Philip Morris raised its wholesale cigarette prices by 10 percent in one year to cover legal settlements with four states, a Wall Street stock analyst estimated that these increases reduced overall consumption of [Philip Morris] cigarettes by nearly 3 percent (Hwang 1998).
- Encourage the manufacture of safer (to the extent possible) products, which have lower liability risks. For instance, a noncarcinogenic nicotine delivery device, though retaining the health risks of nicotine, could create less liability both to individual users and to third-party health care payers.
- Discontinue dishonest practices that increase the risk of liability, especially for punitive damages.

Deterring such "intentional torts" is a main goal of the civil justice system.

- Delegitimize the industry politically by exposing patterns of unsavory practices. For example, many politicians discontinued taking tobacco company contributions in the late 1990s, largely because the discovery process in pending lawsuits revealed industry misconduct (Abramson 1998). Loss of political esteem or loyalty would ease the way for effective tobacco control legislation.
- Educate the public about the risks of tobacco use, since lawsuits attract extensive, free media coverage.
- Compensate injured parties, including smokers, afflicted nonsmokers, their families, and the health care compensation system (Daynard 1988).

The First Two Waves of Tobacco Litigation

Starting in the 1950s, injured smokers tried to use the emergence of product liability to secure remedies from the tobacco companies. During the first two waves of tobacco litigation, hundreds of lawsuits were filed against U.S. tobacco companies by individuals claiming tobacco-related injuries to health. (By one count, 808 cases were filed between 1954 and 1984 [Bernstein Research 1994].) Not one of the claims resulted in any plaintiff, or plaintiff's attorney, receiving any financial compensation.

The First Wave

The first wave of tobacco litigation was launched in 1954, inspired by the appearance in the early 1950s of scientific reports and popular magazine articles that indicated that smoking caused lung cancer. Although convinced that this new information would weigh in as evidence of culpability, the plaintiffs' attorneys were overmatched. The tobacco companies presented a concerted defense in every claim, no matter how small the damages sought, and through all stages of litigation. From the earliest cases, the tobacco companies retained lawyers from the country's most prestigious law firms and directed them to spare no expense in exhausting their adversaries' resources before trial (Rabin 1993). Plaintiffs' attorneys, typically operating from small practices under a contingent fee arrangement with clients who could not afford protracted litigation, found themselves both outnumbered and outspent on all fronts.

Only a handful of the first-wave tobacco cases ever came to trial. Those that did found the courts unwilling to impose strict liability on the tobacco industry. Plaintiffs typically brought suit against tobacco companies under one or both of two theories: negligence and implied warranty. Under a theory of negligence, plaintiffs tried to show that the tobacco companies knew enough about the potential harm of tobacco products to induce them to "engage in [further] research . . . adopt warnings, or, at a minimum, refrain from advertising that suggested the absence of any health concerns" (Rabin 1993, p. 114). However, because plaintiffs' attorneys could offer no evidence at that time that the tobacco industry was aware of the potential harm of their products, this negligence theory met with failure.

Most plaintiffs' cases relied on the theory of implied warranty, which imputes strict liability even in the absence of negligence. The mere marketing of a product that was not of merchantable quality or reasonably fit for use would thus support legal recovery of damages (Rabin 1993). The plaintiff's ability to rely on negligence or implied or express warranty was greatly constrained by two circumstances: since 1965, health warnings had been mandated on tobacco products and on some advertising (see "Cigarette Warning Labels," earlier in this chapter), and the tobacco industry had avoided making direct claims that their products had positive health effects. Since early 1966, then, smokers could no longer argue (or at least not easily) that the tobacco companies had not warned them of the hazards posed in using their products (Schwartz 1993). The doctrine of implied warranty, in particular, thus seemed invalid to plaintiffs who were seeking damages from the tobacco industry.

In general, the courts of that time were unreceptive to strict liability arguments. The courts regarded the manufacturer as "an insurer against foreseeable risks—but not against unknowable risks" (*Lartigue v.* R.J. Reynolds Tobacco Co., 317 F.2d 19, 37 [5th Cir. 1963], cert. denied, 375 U.S. 865 [1963]) or against "the harmful effects of which no developed human skill or foresight can afford" (p. 23). The American Law Institute, a prestigious and influential association of lawyers, judges, and academics, adopted this outlook in its 1973 commentary on section 402A of the Restatement (Second) of Torts, which deals with strict liability for defective products. The nonbinding yet authoritative influence of the restatement sounded "the death knell for the first wave of tobacco litigation" (Rabin 1993, p. 117; Givelber 1998).

The Second Wave

A second wave of tobacco litigation began in 1983, inspired by the success that lawyers had recently achieved in suing asbestos companies: they had not only recovered substantial verdicts (and fees) but also effectively ended the production and use of asbestos in the United States.

As was the case with the first wave of tobacco litigation, in the second wave the "lawyers' litigation strategies rather than their legal arguments . . . constituted the first line of defense" (Rabin 1993, p. 121). The tobacco industry continued to successfully pursue the strategy it had developed during the first wave, taking countless depositions and filing and arguing every motion it could, thus threatening to inflict heavy financial losses on any plaintiff's attorney (Daynard 1994a,b). This strategy was summarized by J. Michael Jordan, an attorney who successfully defended R.J. Reynolds Tobacco Company in the 1980s, in an internal memo to his colleagues: "[T]he aggressive posture we have taken regarding depositions and discovery in general continues to make these cases extremely burdensome and expensive for plaintiffs' lawyers. . . . To paraphrase General Patton, the way we won these cases was not by spending all of [RJR]'s money, but by making that other son of a bitch spend all of his" (Haines v. Liggett Group, Inc., 814 F. Supp. 414, 421 [D.N.J. 1993]).

To try to overcome the disparity of legal resources that had overwhelmed the first-wave cases, plaintiffs' attorneys sometimes pooled resources on a case-by-case basis. The Tobacco Products Liability Project, a nonprofit advocacy group established at Northeastern University in 1984 to encourage lawsuits against the tobacco industry as a public health strategy, served as a clearinghouse of relevant information for attorneys, potential plaintiffs, medical experts, and the media. It began holding annual conferences in 1985, at which participants share information about new legal tactics, as well as solve problems about emerging difficulties.

Besides pooling resources and sharing strategies, plaintiffs' attorneys needed to find an effective legal strategy. To find a new theory, plaintiffs' counsel shifted their focus from implied or express warranty to strict liability, which became a more attractive strategy as courts applied strict liability and comparative fault principles to defective product cases concerning many other products (Edell 1987; Rabin 1993). Smokers' awareness of risks and, accordingly, their "freedom of choice" (Rabin 1993, p. 122) became the linchpins of the tobacco industry's defense against these liability tactics. Though consistently denying the

reality of the risks, the tobacco industry paradoxically argued (with great success) that smokers had freely chosen to smoke and had thereby assumed what risks there might be of smoking and had negligently contributed to their own harm. To prove the plaintiff's assumption of risk, counsel for the tobacco industry generally needed to show that the injured smoker, knowing the dangers and risks involved in smoking, chose to smoke anyway. To prove contributory negligence, the tobacco defense typically showed that, by smoking, the injured smoker breached a personal duty to protect himself or herself from injury and thereby contributed to the harm suffered (Kelder and Daynard 1997).

Just as it had aided the tobacco industry in negating charges of negligence and warranty during the first wave of tobacco litigation, the Federal Cigarette Labeling and Advertising Act's imposition of a warning label on cigarette packaging and advertising greatly strengthened the industry's countercharge that plaintiffs had legally assumed their own health risk and were guilty of contributory negligence. As a result, jurors were responsive to the industry's defense. In essence, jurors tended to blame plaintiffs for their disease instead of identifying the tobacco industry as the makers of the product that caused the disease (Daynard 1994a,b). When counsel for plaintiffs pointed to the addictive nature of tobacco, which arguably limited the smoker's ability to make a free choice, defense counsel rebutted by pointing to the large number of former smokers who successfully quit (Rabin 1993).

Taking the freedom-of-choice defense one step further, defense counsel typically drew on, and presented to the jury, information demonstrating that the claimant's lifestyle was overly risky by choice or was even in some way immoral. By presenting this somewhat extraneous material obtained through aggressive pretrial discovery, the defense "appear[ed] to have had considerable success in trying not just the plaintiff's decision to smoke but his or her character more generally" (Rabin 1993, p. 124). The resulting "full-dress morality play" seemed to have effectively negated any jury sympathy for the plaintiff's plight (p. 124).

The case that culminated and best symbolized the uphill battle of second-wave plaintiffs was filed by Rose Cipollone, a dying smoker, in 1983. The case reached the jury in 1988, four years after her death, and the jury awarded the plaintiffs \$400,000. But this verdict, subsequently overturned on appeal, was only one moment in a protracted legal battle. As one analyst describes, in *Cipollone v. Liggett Group Inc.*, ". . . over 100 motions were filed, and most of the motions were argued. There were also four interlocutory applications, one resulting in the grant of an appeal and the Third

Circuit's initial decision on preemption, . . . an appeal from the final judgment to the Court of Appeals following a trial of about four months, . . . and two petitions for *certiorari* to the Supreme Court of the United States, one of which was granted resulting in the historic argument before that Court" (Kelder 1994, p. 4).

After nearly a decade, Cipollone, the quintessential second-wave case, was sent back to the trial court by the United States Supreme Court. The Court ruled that although the Federal Cigarette Labeling and Advertising Act of 1965 did not invalidate any claims in private litigation, its successor, the Public Health Cigarette Smoking Act of 1969, preempted any claims based on the manufacturers' failure to warn after 1969 in its advertising and promotions (Cipollone v. Liggett Group *Inc.*, 505 U.S. 504, 112 S. Ct. 2608 [1992]). However, the Court left open to the plaintiff the option of proceeding under a wide range of legal theories, including theories of breach of express warranty, defective design, fraudulent misrepresentation, and conspiracy to defraud. But the difficulties of mustering a sufficient showing that such violations by the defendants were the proximate cause of Mrs. Cipollone's injuries (as well as the cause of her death in 1984) persuaded the plaintiff's counsel that there was little likelihood of a significant recovery (Lowell 1992). In 1992, five months after the Supreme Court ruling, the New Jersey federal district court approved the request of the Cipollone estate's lawyer to withdraw from the case.

It had been a lengthy, expensive effort for the plaintiff's counsel: \$500,000 in out-of-pocket expenses and approximately \$2 million in attorney and paralegal time (Kelder 1994). Posttrial proceedings cost an additional \$150,000 in out-of-pocket expenses and \$900,000 in attorney and paralegal time. *Time* magazine estimated that the cigarette industry spent at least \$75 million defending the *Cipollone* case (Koepp 1988). Michael Pertschuk, co-director of the Advocacy Institute, a public interest group dedicated to reducing tobacco use, has estimated that altogether tobacco companies were spending approximately \$600 million per year defending the 50 or so cases pending against them (Stone 1994). Tobacco defendants' reputation for relentless legal battle dissuaded many lawyers from entering the fray. Even formidable litigants such as the asbestos producers refrained from trying to embroil the tobacco manufacturers as being jointly responsible for asbestos injuries (Rabin 1993).

The Aftermath of the First Two Waves

The collapse of the *Cipollone* case was widely viewed as signaling the end of the second wave of tobacco litigation. Commentators advanced various explanations for the failure of tobacco litigation, including superior lawyering resources, coordination, and tactics (Rabin 1993), as well as popular resistance in the form of jury reluctance to award damages to smokers (Schwartz 1993). Many observers concluded that product liability litigation had a limited role to play in the regulation of tobacco. Rabin (1993) found that tobacco presents an instance of "the effective limits of tort law," because "tort law and tort process seem to conspire against any effective role for the tobacco litigant" (p. 127). Schwartz (1993) concurred "that tort law does not have a major role to play in the development of public policy for smoking in the 1990s" (p. 132).

At that juncture, tobacco litigation seemed to illustrate that the incidence and outcome of litigation are influenced by the identity, resources, and status of the parties and by the incentives and strategies of their lawyers. Striking differences have been noted between the large organization with a continuing interest in an area of legal controversy and the individual litigant who typically seeks a remedy only once (Galanter 1974). One-time litigants tend to be represented by lawyers who practice in smaller units that have less capacity for coordination and less capacity to invest strategically in litigation. The monetary stakes—and thus the incentives—are also lower for these smaller litigants than for their corporate opponents, who can extract full benefit from the information and experience generated by litigation expenditures (Galanter 1974; Schwartz 1993).

Nonetheless, at the end of the second wave of tobacco litigation, it was argued that the tobacco industry was not untouchable and that its proud record of never, at that point, having paid a penny to its victims masked a high vulnerability to litigation (Daynard 1988, 1993a,b, 1994a,b; Daynard and Morin 1988). The industry's "scorched earth" litigation tactics (Daynard 1994a) had indeed made suing tobacco companies prohibitively expensive for most plaintiffs and their attorneys. Also, the industry's firm and widely publicized policy of never settling cases further discouraged litigation, because plaintiffs' attorneys, working on contingency fees, realized that they could not expect to be paid unless and until they had succeeded at trial and on subsequent appeals. Furthermore, the low volume of cases in the first and second waves allowed the industry to concentrate its legal resources against the few plaintiffs' attorneys who ventured forth against it.

But a very different scenario was also possible. Although the low-volume litigation environment of the first and second waves favored the defendants, a high-volume environment might favor plaintiffs. As happened with asbestos litigation, courts facing the problem of clearing large numbers of tobacco cases off their dockets would need to find ways to expedite them. Firm trial deadlines, case consolidations, and class actions would likely be favored; scorched earth defense tactics would no longer be permitted. Defendants would no longer be able to focus all their attention and legal resources on defeating a few plaintiffs. Some cases thus might break through the industry's defenses, and these victories would provide both practical examples and moral support for plaintiffs' attorneys. At some point, the defendants might realize that their nonsettlement policy had ceased to discourage plaintiffs and would begin settling. At that point, the third wave of tobacco litigation—virtually a tidal wave—would have begun (Daynard 1994a).

Given a pre-1994 legal environment characterized by a low volume of tobacco litigation, few lawyers could afford to ignore the highly unfavorable cost/benefit ratio that would likely meet any effort to bring a lawsuit against the tobacco industry. No single lawyer, however motivated, could hope to change this situation through his or her own efforts. The transition from the low-volume to the high-volume scenario would require public events that signaled clearly to lawyers that the environment was changing (Daynard 1994a).

Paradoxically, although the *Cipollone* case was widely viewed as emblematic of why plaintiffs' attorneys were well advised to avoid tobacco litigation, it was also a crucial forerunner for the events that would soon change the litigation environment. Specifically, the Supreme Court's 1992 decision in the case—though of no avail to the resource-depleted plaintiffs' attorneys—presented other plaintiffs' attorneys with a range of potentially devastating legal theories. The trial itself had provided documentary evidence—which, as it turned out, represented the tip of the iceberg—that could be used to help establish the elements of a plaintiff's claims against the cigarette manufacturers (Daynard and Morin 1988; Daynard 1993a,b).

Among the legal theories advanced in the first two waves that remained viable after *Cipollone* were (1) a theory that cigarettes were defective and unnecessarily dangerous, because evidence discovered by plaintiffs' attorneys and antismoking activists strongly suggested that the tobacco industry had known for many years how to make cigarettes that were less likely to cause cancer; (2) a theory that cigarettes were defective, because they contained tobacco adulterated with many nontobacco carcinogenic substances; (3) a theory that cigarettes were defective, because of the dangers inherent to tobacco; (4) a theory of civil con-

spiracy based on evidence that cigarette manufacturers had joined together beginning in the 1950s to plan and carry out a strategy for marketing cigarettes while concealing the harmful and addictive nature of this product in the face of the developing scientific evidence of their dangers; and (5) a "Good Samaritan" theory, whereby plaintiffs could argue that the tobacco companies, having pledged in 1954 to objectively investigate the possible dangers of smoking, were obliged to carry out their promise and take reasonable action on what they found (Daynard 1988).

Potential support for some or all of these approaches had surfaced during the tortuous process of the Cipollone case. Documents uncovered in the case provided evidence that the tobacco industry had fraudulently misrepresented the safety of their product and deliberately concealed knowledge about the harmful and addictive nature of cigarettes. The evidence suggested that the tobacco industry had conspired to defraud the American public by pretending that it was conducting good-faith efforts to uncover the links between smoking and health and by falsely assuring the public that the results were negative or inconclusive (Daynard and Morin 1988). Some analysts predicted that future fraud and conspiracy claims would be strengthened when the court documents from Haines were released to plaintiffs' attorneys or when other documentary evidence of tobacco industry misdeeds was uncovered (Daynard 1993a,b). In the additional trove of documents reviewed by Judge H. Lee Sarokin in *Haines*—many of them relating to the Council for Tobacco Research's "special projects" division—was information that might support a finding that "the industry research which might indict smoking as a cause of illness was diverted to secret research projects and that the publicized efforts were primarily directed at finding causes other than smoking for the illnesses being attributed to it" (Haines v. Liggett Group, Inc., Civil No. 84-678 [HLS] [D.N.J. 1992], cited in 7.1 TPLR 2.1 [1992]). Calling the tobacco industry "the king of concealment and disinformation" (Haines v. Liggett Group Inc., 975 F.2d 81, 88 [3d Cir. 1992])—a remark that led an appellate court to disqualify Judge Sarokin from further consideration of the case on the grounds that he failed to appear impartial (p. 98)—Judge Sarokin concluded that the documents he had reviewed were not protected by the attorney-client privilege, as the industry had claimed, because the industry's attorneys had been participating in an ongoing fraud, and the documents were therefore discoverable under the well-recognized crime/fraud exception (Haines, cited in 7.1 TPLR 2.1). The same court that disqualified Judge Sarokin from further consideration of the case also agreed that the evidence cited by him would support his conclusion that the crime/fraud exception would apply (*Haines*, 975 F.2d 81).

The Third Wave of Tobacco Litigation

The third wave of tobacco litigation was sparked by two key events. On February 25, 1994, FDA Commissioner David Kessler, relying primarily on a document discovered in the *Cipollone* case, sent a letter to the CSH reporting that the FDA had received "mounting evidence" that "the nicotine ingredient in cigarettes is a powerfully addictive agent" and that "cigarette vendors control the levels of nicotine that satisfy this addiction" (Kessler 1994a). The letter made front-page news. The second event occurred three days later, when an ABC television *Day One* report alleged that tobacco companies manipulated the nicotine levels in cigarettes (Daynard 1994b).

A series of journalistic and congressional investigations ensued in the spring of 1994, and internal Brown & Williamson Tobacco Corporation documents were leaked to the press. These documents indicated that the company had studied nicotine for years, that its internal stance on several issues related to smoking and health differed from what it was telling the public, that it possessed findings regarding the addictiveness of nicotine and the health dangers of smoking and ETS that had been withheld, and that Brown & Williamson attorneys were involved in the management of the research projects (Hanauer et al. 1995). When on April 14, 1994, the chief executive officers of the seven leading U.S. tobacco companies testified under oath before a congressional subcommittee—and a large television news audience that they did not believe that nicotine was addictive, the industry's public credibility plummeted. Suddenly the industry appeared to millions of people, including plaintiffs' attorneys, as dishonest, disreputable, and legally vulnerable (Daynard 1994a; Seattle Post-Intelligencer 1994; see "Nature, Extent, and Focus of the Criminal Investigation," later in this chapter).

Further revelations about the tobacco industry's knowledge of the harmfulness of smoking and the addictiveness of nicotine, as well as about the industry's misbehavior, subsequently surfaced in several forms:

 Philip Morris documents indicated that the company's researchers studied and wrote about the pharmacologic effects of nicotine on smokers (Hilts and Collins 1995).

- Documents obtained from Brown & Williamson and its parent, British-American Tobacco Company, were analyzed (Hanauer et al. 1995).
- Investigative journalists obtained documents from R.J. Reynolds Tobacco Company (Levy 1995).
- In November 1995, Dr. Jeffrey Wigand, Brown & Williamson's former vice president for research, testified under deposition (*Tobacco Products Litigation Reporter* 1995c).
- Sworn statements were given to the FDA (first made public on March 18, 1996) in which three former Philip Morris employees (Ian L. Uydess, Ph.D., a former associate senior scientist; Jerome Rivers, a shift manager at a cigarette manufacturing plant in Richmond, Virginia; and William A. Farone, Ph.D., the director of applied research at Philip Morris' tobacco unit) stated that Philip Morris not only believes it is in the nicotine delivery business but also controls nicotine levels in its brands (*Tobacco Products Litigation Reporter* 1996a,b,c).
- The FDA analyzed both the public evidence and the additional evidence that its investigators gathered about the tobacco industry's past and present knowledge of, and behavior toward, the addictive quality of the nicotine in its products (Federal Register 1995b).
- On March 20, 1997, Liggett Group Inc., the smallest domestic cigarette manufacturer, admitted that nicotine was addictive and that the industry had targeted minors. Liggett turned over incriminating industry documents to the attorneys general and class action attorneys whose cases the company had agreed to settle (Attorneys General Settlement Agreement, cited in 12.1 TPLR 3.1 [1997]).
- Beginning in 1997, first hundreds, then thousands, and finally millions of industry documents began to surface after being uncovered through the discovery process in litigation by the Minnesota attorney general and Blue Cross and Blue Shield. These documents began appearing on Internet Web sites of the Commerce Committee of the U.S. House of Representatives (http://www.house.gov/commerce), Minnesota Blue Cross and Blue Shield (http://www.mnbluecrosstobacco.com), and the Minnesota District Court (http://www.courts.state.mn.us/district). The analysis of these documents has only begun, but they appear to support a wide range of legal claims against the industry.

This third wave of tobacco litigation is more diverse than its predecessors, in part because of the new wealth of factual information available to plaintiffs' attorneys. The series of revelations described above has generated a new set of allegations. For example, the industry has consistently claimed that nicotine is not pharmacologically active, that it is not addictive, and that anyone who smokes makes a free choice to do so. But as was made clear by the FDA's 1995 Statement of Jurisdiction over cigarettes as drug-delivery devices; the documents of Philip Morris Companies Inc., Brown & Williamson-British-American Tobacco Company, and R.J. Reynolds Tobacco Company relating to nicotine; and the information being provided by whistle-blowers such as Jeffrey Wigand and Ian Uydess, the industry was well aware of the pharmacologically active, addictive, and harmful nature of its products and was not forthright with its customers, the public, and public authorities about these facts. There is also evidence that the industry understood its consumers' need for adequate nicotine to sustain their addictions and that the industry designed its products accordingly.

The tobacco industry also has claimed that there is no definitive proof that smoking causes diseases such as cancer and heart disease. Yet the discovered company documents show that by the 1960s various tobacco companies had proved in their own laboratories that cigarette tar causes cancer in laboratory animals (Daynard and Morin 1988; Hanauer et al. 1995). Finally, the industry has claimed that it is committed to determining the scientific truth about the health effects of tobacco by conducting internal investigations and by funding external research. However, the Brown & Williamson-British-American Tobacco Company documents indicate that rather than conducting objective scientific research, Brown & Williamson attorneys have been involved in selecting and disseminating information from internal as well as external scientific projects for decades. An example of the latter is the industry's misrepresenting the work of the Council for Tobacco Research as objective scientific research on smoking and health. All research findings from this council are sent through the industry's attorneys, thereby gaining the protection of attorneyclient privilege and potentially enabling the industry to choose which findings it will release and how it will present those findings to the public. The potential for this practice was suggested when certain Brown & Williamson-British-American Tobacco Company documents were found to include directions for disposing of damaging documents held by the company's research department (Hanauer et al. 1995). This conduct by the industry arguably misled the public and caused them to buy tobacco products; it also deflates the free choice argument the tobacco industry has used to deter further government regulation of its products and to defend itself in products liability lawsuits (Hanauer et al. 1995).

The information outlined above has generated a host of claims put forward by plaintiffs in the third wave of tobacco litigation. Some of these are similar to claims raised in the first two waves but have a much fuller factual support. These common-law (judge-created) legal theories include fraud, fraudulent concealment, and negligent misrepresentation; negligence; negligent performance of a voluntary undertaking; breach of express and implied warranties; strict liability; and conspiracy. Other, statutory (statute-created) claims new to tobacco litigation include violation of consumer protection statutes, antitrust claims, unjust enrichment/ indemnity, and civil violations that invoke prosecution under the federal Racketeer Influenced and Corrupt Organizations Act (Kelder and Daynard 1997).

Common-Law Claims

An illustrative use of currently available evidence to support a common-law legal theory of fraudulent misrepresentation is Count Five of the complaint filed in April 1998 by 21 Blue Cross and Blue Shield plans against the tobacco industry (Blue Cross and Blue Shield of New Jersey v. Philip Morris [E.D.N.Y. Apr. 29, 1998], cited in 13.2 TPLR 3.51 [1998]). Among the allegations listed in Count Five are the following (Blue Cross and *Blue Shield*, p. 3.95):

301. Defendants represented and promised to those who advance and protect the public health and provide or pay for health care and health care services that they would discover and disclose all material facts about the effects of cigarette smoking and other tobacco product use on human health, including addiction.

302. Defendants have made and continue to make representations, statements and promises about the safety of cigarettes, other tobacco products and nicotine in general and their effect on human health and addiction. Such representations, statements and promises were and remain materially false, incomplete and fraudulent at the time Defendants made them, and Defendants knew or had and continue to have reason to know of their falsity. Only Defendant Liggett has recently conceded that the nicotine in cigarettes is addictive; Liggett made this admission for the first time only in March 1997.

303. In testimony before Congress in January 1998, executives of other Tobacco Companies tried to have it both ways concerning the question of addiction. They stated that they personally did not think nicotine was addictive, but conceded that under some definitions, it would be considered addictive.

304. In view of the documentary record establishing that the Tobacco Companies have known for years with certainty that nicotine is addictive, such testimony is dishonest and part of an on-going attempt to disseminate false and misleading information.

305. At all relevant times Defendants intentionally, willfully or recklessly misrepresented material facts about the human health hazards of tobacco use, including addiction, and the association of cigarette smoking and other tobacco product use with various diseases of the heart, lung and other vital organs.

306. Because of Defendants' secret internal research, Defendants' knowledge of the material facts about tobacco use, health and addiction was and is superior to the knowledge of the BC/BS [Blue Cross and Blue Shield] Plans' members who purchased, used and consumed the Tobacco Companies' cigarettes and other nicotine tobacco products. Defendants' knowledge of the material facts about tobacco use, health and addiction was and is also superior to that of the BC/BS Plans, which undertook to provide health care financing for their members. Public access to these facts is limited because such facts are exclusively within Defendants' control.

313. The BC/BS Plans reasonably and justifiably relied on Defendants' materially false, incomplete and misleading representations about tobacco use, health and addiction. As a result of such reliance, the BC/BS Plans did not take, or would have taken sooner, actions to minimize the losses resulting from tobacco-related injuries and diseases and to discourage and reduce cigarette and other nicotine product use and the costs associated therewith by the BC/BS Plans' members.

314. As a direct, foreseeable and proximate result of the foregoing conduct of Defendants, the BC/BS Plans have suffered damages through payments for the costs of medical care due to smoking.

315. As direct and proximate result of Defendants' fraudulent misrepresentations and nondisclosures, the BC/BS Plans have suffered and will continue to suffer substantial injuries and damages for which the BC/BS Plans are entitled to recovery, and for which Defendants are jointly and severally liable.

Statutory Claims

The newer claims include a variety of theories based on federal and state statutes. As with the common-law claims, these statute-based actions are illustrated in the April 1998 complaint that 21 Blue Cross and Blue Shield plans filed against the tobacco industry.

Consumer Protection

Consumer protection claims are based on state statutes, which vary somewhat from state to state but generally forbid unfair methods of competition and unfair or deceptive acts or practices in commerce. A typical set of consumer protection allegations is that of Blue Cross and Blue Shield of Florida (*Blue Cross and Blue Shield*, p. 3.102). It makes the following allegations:

378. In the conduct of trade or commerce, Defendants have engaged and do engage in unfair methods of competition, unconscionable acts or practices and unfair or deceptive acts or practices including but not limited to the following:

a. Intentionally, willfully and knowingly seeking to addict persons, including BC/BS Florida members and their children, to the use of hazardous cigarettes and other nicotine tobacco products, knowing that such addiction physically changes and damages smokers' brain structures and creates and constitutes a substantial unfair impediment or interference in the smokers' ability to choose whether to continue smoking, making the transaction no longer an arm's length one between an equally willing buyer and seller, which is similar to many other deceptive and/or unfair devices

and practices that affect bargaining power or relative information;

- Targeting people with deceptive advertising by misrepresenting the characteristics, ingredients, uses or benefits of Defendants' tobacco products; and
- Engaging for decades in a wide variety of misrepresentations and fraudulent concealment of material facts, directly or by implication, including but not limited to: (1) misrepresentations and fraudulent concealment of the addictive nature of nicotine and of the adverse health consequences of nicotine tobacco products; (2) misrepresentations and fraudulent concealment about Defendants' ability to manipulate and their practice of manipulating nicotine levels and the addictive qualities of nicotine tobacco products; (3) misrepresentations that the Defendants would provide the public and governmental authorities with objective, scientific information regarding cigarettes and other tobacco products; (4) fraudulent concealment of certain aspects of cigarettes and other tobacco products, including the availability of safer, less-addictive products as a substitute to cigarettes and other tobacco products; (5) causing a likelihood of confusion about the source, sponsorship, approval or certification of cigarettes and other tobacco products; (6) misrepresenting that nicotine tobacco products have sponsorship, approval, characteristics, ingredients or benefits that they do not have and that Defendants knew that they did not have; (7) misrepresenting that cigarettes and other tobacco products were of a particular quality or grade, when Defendants knew that they were not; (8) engaging in unconscionable trade practices; (9) fraudulently promoting filter and low-tar cigarettes as safer; (10) fraudulently manipulating scientific research into the health hazards of smoking; and (11) fraudulently creating their "research councils" and using them to spread false information about their products and to promote false information that cigarettes or other tobacco products were safe or that adverse health effects had not been established.

379. The conduct described above and throughout this Complaint constitutes deceptive and

unfair methods of competition, unconscionable acts or practices and unfair or deceptive acts or practices all impacting the public interest, in violation of Fla. Stat. § [section] 501.204.

380. As a direct and proximate result of such wrongful activity, BC/BS Florida has suffered losses and will continue to suffer substantial losses and injuries to its business or property, including but not limited to its being required to pay and paying the costs of medical care for disease, illness, addiction and adverse health consequences caused by cigarettes and other tobacco products.

Antitrust

The federal government and most states have antitrust laws. These are designed to prevent businesses in the same industry from cooperating in ways that deprive consumers or other entities of benefits they would otherwise receive from a competitive marketplace.

Count Three of the complaint by the 21 Blue Cross and Blue Shield plans explains how antitrust theory applies in a tobacco case (*Blue Cross and Blue Shield*, p. 3.93):

281. Since the early 1950s, and continuing until the present date, the Defendant Tobacco Companies, aided and abetted by the other Defendants herein, have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by entering into, adhering to and continuing to observe the terms of a combination or conspiracy in unreasonable restraint of trade and commerce in the market for cigarettes in the United States. Such illegal concerted action has eliminated commercial competition that would have existed but for the conspiracy. Specifically, Defendants have conspired: (1) to suppress innovation and competition in product quality by agreeing not to engage in research, development, manufacture and marketing of less harmful cigarettes and other nicotine products; (2) to suppress output in a market, and to engage in concerted refusal to deal, by agreeing to keep at zero the output of less harmful cigarettes and other nicotine products; and (3) to suppress competition in marketing by agreeing not to take business from one another by making claims as to the relative safety of particular brands, whether or not such claims would have been truthful. But for the conspiracy, competition in the market for cigarettes in the United States would have been far more vigorous, and consumers and others would have reaped enormous benefits.

282. But for the conspiracy, one or more of the Tobacco Companies would have developed a commercially successful, less harmful cigarette; such a cigarette would have garnered a substantial share of the cigarette market; and those who used that product rather than conventional cigarettes would have had significantly fewer health problems. As a consequence of the above, the BC/BS Plans would have incurred substantially lower costs.

283. A relevant market in which Defendants' violations occurred is the manufacture and sale of cigarettes and other nicotine products in the United States. Because, inter alia, such products are physically addictive, they are not reasonably interchangeable with other consumer products, nor are they characterized by cross-elasticity of price with other consumer products. Within this broad relevant market there would have existed, but for Defendants' conspiracy, a relevant submarket for the manufacture and sale in the United States of less harmful cigarettes and other nicotine products which would still have delivered nicotine but which would have had materially less deleterious health effects than the products actually manufactured and sold by Defendants. Such products would have proven attractive to many smokers, who would have chosen to buy them if they had been available.

284. Because Defendants have conspired to suppress output of less harmful cigarettes and other nicotine products, and to refuse to deal in such products, their conduct is unreasonable per se under the Section 1 of the Sherman Act. There is, moreover, no colorable justification for the concerted action alleged herein, which is unrelated to any lawful business transaction, does not promote efficiency, does not advance the interests of consumers and does not promote interbrand or intrabrand competition.

285. Antitrust law protects competition over innovation and product quality just as it protects price competition. Defendants willfully violated antitrust law by agreeing to suppress competition related to the safety of their products. It was clearly foreseeable that this antitrust violation would injure smokers' health, and it was just as foreseeable that the violation would, at the same time,

cause those financially responsible for smokers' health care to suffer an injury in their business or property, by paying increased costs and expenses for health care services and products. These two kinds of injury are inextricably intertwined. Each flows directly from the anticompetitive effects of the illegal conduct. The harm suffered by the BC/BS Plans is the precise type of harm that a conspiracy to suppress competition related to product safety would be likely to cause. Accordingly, this harm reflects the anticompetitive effects of the violation.

Antitrust violations permit the injured party to receive treble damages as well as attorneys' fees.

Federal Racketeer Influenced and Corrupt Organizations (RICO) Act

The federal government and some states have statutes designed to control or eradicate "racketeer influenced and corrupt organizations." "Racketeering" is defined as a pattern of violations of specified criminal statutes ("predicate acts") (18 U.S.C. section 1961[1]). Among these statutes are those criminalizing mail and wire fraud (18 U.S.C. sections 1341, 1343). The evidence put forth that the industry committed these predicate acts is similar to the evidence that it committed common-law fraud (*Blue Cross and Blue Shield*, p. 3.88, para. 260[a]):

The Defendants engaged in schemes to defraud members of the public, including the BC/BS Plans and their members, regarding the health consequences associated with using nicotine tobacco products. Those schemes have involved suppression of information regarding the health consequences associated with smoking, as well as fraudulent misrepresentations and omissions reasonably calculated to deceive persons of ordinary prudence and comprehension. Defendants' misrepresentations and fraudulent concealment of material facts, directly or by implication, include but are not limited to the following: misrepresentations and fraudulent concealment of the addictive nature of nicotine and the adverse health consequences of tobacco products; misrepresentations that such health effects of addictiveness were unknown or unproven; misrepresentations about Defendants' ability to manipulate and about the manipulation of nicotine levels and the addictive qualities of cigarettes; misrepresentations that they would provide the public and governmental authorities with objective, scientific information regarding all phases of smoking and health; and fraudulent concealment of certain aspects of smoking and health, including the availability of safer cigarettes and less addictive cigarettes. Defendants executed or attempted to execute such schemes through the use of the United States mails and through transmissions by wire, radio and television communications in interstate commerce.

The federal RICO Act makes it unlawful to receive income derived, directly or indirectly, from a pattern of racketeering activity or to participate, directly or indirectly, in the conduct of an enterprise's affairs through a pattern of racketeering activity. The relevance of the RICO Act to tobacco litigation was also delineated in the Blue Cross and Blue Shield plans' complaint (*Blue Cross and Blue Shield*, p. 3.92):

271. At all relevant times, the Tobacco Institute, CTR (formerly TIRC) and STRC [the Smokeless Tobacco Research Council] have constituted an enterprise within the meaning of 18 U.S.C. § 1961(4) or, in the alternative, each Defendant has constituted an enterprise within the meaning of 18 U.S.C. § 1961(4). Each enterprise is an ongoing organization. Each enterprise and its activities affect interstate commerce in that the enterprise is engaged in the business of maximizing the sales of cigarettes and other nicotine products.

272. As alleged above, Defendants have engaged in a pattern of racketeering activity that dates from 1953 through the present and threatens to continue into the future. These racketeering acts generated income for Defendants because they contributed to: the suppression and concealment of scientific and medical information regarding the health effects of nicotine products; the suppression of a market for alternative safer or less addictive tobacco products; the manipulation of nicotine to create and sustain addiction to Defendants' products; the targeting of teenagers and children and minorities with marketing and advertising designed to addict them, all to protect and ensure continued sales of Defendants' unsafe and addictive tobacco products; and the avoidance and shifting of smoking related health care costs to others including the BC/BS Plans by the methods stated above, including illicit litigation tactics such as unfounded claims of attorney-client privilege and other means.

273. Defendants have used or invested their illicit proceeds, generated through the pattern of racketeering activity, directly or indirectly in the acquisition of an interest in, or in the establishment or operation of each enterprise, in violation of 18 U.S.C. § 1962(a). Defendants' use and investment of these illicit proceeds in each enterprise is for the specific purpose and has the effect of controlling the material information distributed to the public concerning the health effects of smoking; suppressing and concealing scientific and medical information regarding the adverse health effects of smoking and the alternatives of safer or less-addictive cigarettes; devising means for manipulating nicotine to create and sustain addiction to Defendants' products; directing marketing and advertising toward minorities, teenagers and children to addict them; and enticing more individuals to smoke or to use Defendants' unsafe nicotine tobacco products.

274. Each Defendant also conspired to violate 18 U.S.C. § 1962(a), in violation of 18 U.S.C. § 1962(d). As detailed above, the conspiracy began in 1953, continues to the present and threatens to continue into the future. The object of the conspiracy was and is to protect the Tobacco Companies' business operations by investing their illicit proceeds, generated through a pattern of racketeering activity, in each enterprise. Each Defendant agreed to join the conspiracy, agreed to invest racketeeringgenerated proceeds in each enterprise in order to continue enterprise operations and agreed to the commission of and knowingly participated in at least two predicate acts within ten years of each other. Each Defendant knew that those predicate acts were part of racketeering activity that would further the conspiracy.

275. Defendants' violations of 18 U.S.C. §§ 1962 (a) and (d) have proximately caused direct injury to the business and property of the BC/BS Plans because the BC/BS Plans have been required to incur significant, concrete financial costs and expenses attributable to tobacco-related diseases; have been unable to participate in a market for alternative less harmful or less addictive nicotine products, or to advise, suggest, promote, subsidize or require their members to use alternative products such as safer or less addictive tobacco products or other nicotine delivery devices; and have not been as effective as they would otherwise have been in helping their members not to use hazardous tobacco

products. In absence of the Defendants' violation of 18 U.S.C. §§ 1962 (a) and (d), these costs and expenses would have been substantially reduced.

Finally, the RICO Act provides a civil remedy for entities that have been financially injured as a result of RICO violations (18 U.S.C. section 1964[c]). As with the antitrust laws, the remedy includes treble damages and the recovery of attorneys' fees.

Taken together, the allegations in the case brought by the 21 Blue Cross and Blue Shield plans provide an important summary of the legal approaches that are now available to plaintiffs but were not available to earlier third-wave cases.

Individual Third-Wave Cases

Some third-wave cases involve only minor modifications of standard second-wave product liability claims by individual smokers against cigarette makers. In September 1995, one such case achieved the distinction of being the first clear plaintiff's victory after Cipollone. A state court jury awarded \$2 million, including \$700,000 in punitive damages, to a smoker who had developed mesothelioma (a cancer associated with asbestos exposure) after smoking asbestos-filtered Kent cigarettes in the 1950s. The defendant had won four of these filter cases since 1991. While awaiting appeals, observers speculated whether the result signified a change in public perceptions (Hwang 1995a; MacLachlan 1995c). Ultimately, the jury's awards of both compensatory and punitive damages were upheld on appeal (Horowitz v. Lorillard Tobacco Co., No. 965-245 [Super. Ct. San Francisco Cty. 1995], cert. denied, 118 S. Ct. 1797 [1998]).

In what is perhaps the most important damage recovery case to date (Tobacco Products Litigation Reporter 1996d), on August 9, 1996, a jury in Jacksonville, Florida, awarded \$750,000 to Grady Carter, a former air traffic controller who smoked from age 17 in 1947 until cancer was diagnosed in 1991. Grady and his wife, Mildred, sued Brown & Williamson Tobacco Corporation on the grounds of negligence and strict liability. The jury found that the Lucky Strike cigarettes that were manufactured by the defendant were "unreasonably dangerous and defective" (Tobacco Products Litigation Reporter 1996d, p. 1.114). Of special significance was that the plaintiff's attorney did not have to undergo the burdensome discovery process that industry attorneys had used successfully in the past. The means of avoiding this process was a special court order issued to ease the management of the large number of tobacco liability cases filed in that jurisdiction (*In re Cigarette Cases* [Fla., Duval Cty. Jan. 23, 1996], *cited in* 11.1 TPLR 2.3 [1996]; Ward 1996). Doubt was cast on the impact of the case, however, when a Florida appellate court overturned the jury's findings on the basis that the plaintiff had failed to file his claim within Florida's four-year statute of limitations (*Brown & Williamson Corp. v. Carter*, No. 96-4831, 1998 Fla. App. LEXIS 7477 [Fla. Dist. Ct. App. June 22, 1998]).

In an individual damage recovery action similar to Carter and brought by Norwood Wilner (the same plaintiff attorney who had successfully argued the Carter case), a jury found Brown & Williamson Tobacco Corporation liable for the wrongful death of smoker Roland Maddox and awarded his family just over \$1 million in compensatory and punitive damages (Widdick/Maddox v. Brown & Williamson Tobacco Corp., No. 97-03522-CA, Div. CV-H [Fla. 4th Cir. Jacksonville 1998]). Attorney Wilner has taken two other tobacco cases to trial that have resulted in jury verdicts for the defense, and it is estimated that he had 150 additional cases pending as of July 1998 (Connor v. R.J. Reynolds Tobacco Co., No. 95-01820-CA, Div. CV-H [Fla. Cir. Duval Cty. May 5, 1997]; Karbiwnyk v. R.J. Reynolds Tobacco Co., No. 95-04697-CA, Div. CV-H [Fla. Cir. Duval Cty. Oct. 31, 1997]; *Economist* 1998).

The growth of individual tobacco litigation during the third wave has been exponential. For example, R.J. Reynolds Tobacco Company reported in July 1995 that 68 cases of all sorts were pending against it; the number had risen to 203 cases in July 1996 and to 448 cases as of August 7, 1997 (Daynard 1997).

Aggregation Devices

The third wave got much of its impetus from the use of procedural devices and legal theories that aggregated claims. Aggregation raised the potential value of each case for plaintiffs' attorneys, increasing their willingness to invest large amounts of money and time in pursuing them. This process denied the industry the ability to discourage such cases by escalating litigation costs, a strategy that had served it well during the previous two waves of tobacco litigation (see "The Aftermath of the First Two Waves," earlier in this chapter). The most important of these aggregation devices have been class actions and third-party payer reimbursement actions.

Class Actions

The class action device figures prominently in the third wave of tobacco litigation. This set of procedures

enables a group of persons suffering from a common injury to bring a suit to secure a definitive judicial remedy for that injury on behalf of all members of the group. Class action procedures have two principal forms—one for cases that seek a single remedy for the common benefit of a category of plaintiffs (Federal Rules of Civil Procedure, Rule 23[b][1]), and a somewhat more complicated one known as (Rule 23[b][3] procedures) for cases that seek the resolution of a large number of individual claims that share common factual or legal issues (Federal Rules of Civil Procedure, Rule 23[b][3]).

Tobacco class actions have, in the main, raised two types of issues. One type, exemplified by the claims in the Castano case (Castano v. American Tobacco Co., No. 94-1044 [E.D. La. Feb. 17, 1995], cited in 10.1 TPLR 2.1 [1995], rev'd 84 F.3d 734 [5th Cir. 1996]) and its progeny, seeks recovery for the cost of treating addicted smokers for their addictions and for monitoring their medical condition for signs of impending disease. It does not, however, seek recovery for the cost of treating tobacco-caused diseases, nor for the other costs (tangible or intangible) to smokers and their families that flow from tobacco-caused disease. The other type of issue, exemplified by the claims in the Engle case (Engle v. R.J. Reynolds Tobacco Co., No. 94-08273 CA [20] [Fla., Dade Cty. Oct. 31, 1994], cited in 9.5 TPLR 2.147 [1994], aff'd 672 So. 2d 39 [1996]), seeks damages for the full range of costs that flow from tobacco-caused diseases. The Castano case involves a much larger number of plaintiffs than Engle, but each plaintiff seeks a much smaller recovery.

To date, both Castano- and Engle-type claims have been brought under the more complex Rule 23(b)(3) class action procedures designed for the resolution of individual claims that share common legal or factual issues. Courts have generally been reluctant to allow these procedures for Castano-type claims, with the courts particularly concerned about the individualized proceedings on behalf of millions of addicted smokers, each making relatively small claims, that would follow from a favorable resolution of the common issues (Castano v. American Tobacco Co., 84 F.3d 734 [5th Cir. 1996]; Small v. Lorillard Tobacco Co., 1998 WL 398176 [N.Y.A.D. 1 Dept. July 16, 1998]; Barnes v. American Tobacco Co., No. 96-5903 [E.D. Pa. Aug. 22, 1997], vacated 176 F.R.D. 479 [1997], cited in 12.4 TPLR 2.227 [1997]). The possibility of using the simpler class action procedure for Castano-type claims, which would seek a single judicial order setting up an insurancetype fund that claimants could draw on as they used addiction-related medical or pharmaceutical services, has not been fully explored. By contrast, courts have been more willing to permit Rule 23(b)(3)-type procedures for *Engle*-type claims, where class action procedures promise to simplify the trials of a smaller (but still very large) number of serious individual claims (*Engle*, 672 So. 2d 39; *Broin v. Philip Morris Cos.*, No. 92-1405 [Fla., Dade Cty. Mar. 15, 1994], *cited in* 9.1 TPLR 2.1 [1994]; *Richardson v. Philip Morris*, *Inc.*, No. 96145050/CE212596 [Md. Cir. Ct. Baltimore City Jan. 28, 1998]).

For a class action of either type to be certified, four technical requirements must be met. First, the members of the proposed plaintiff class must be so numerous that joining each plaintiff to the suit would be impractical. Second, the claims of each member of the class must turn on some questions of law or fact that are common to all the members of the class. Third, claims of the class representatives must not be antagonistic to those of the other members of the class. Fourth, the representative plaintiffs and their attorneys must be able to fairly and adequately represent the interests of the entire class (Federal Rules of Civil Procedure, Rule 23[a]). Where members of the class have conflicting interests, the class may be divided into subclasses represented by different attorneys (Federal Rules of Civil Procedure, Rule 23[c][4][A]).

Besides meeting these four requirements, a Rule 23(b)(3) class action needs to surmount two other significant hurdles. First, the court must determine that the action is "manageable," meaning that a reasonable plan for trying the entire case, including the individual claims, can be devised. Second, the common issues must "predominate" over the individual issues, leaving the court to make the judgment whether the benefits likely to be obtained from trying the case as a class action outweigh the difficulties likely to be encountered in doing so (Federal Rules of Civil Procedures, Rule 23[b][3]).

Once a Rule 23(b)(3) class is certified, the class representatives must undertake the onerous and expensive process of notifying each member of the class. This is necessary because Rule 23(b)(3) class members have the significant right to opt out of the class and pursue their claims individually.

The class action device solves the problem of aggregation, reduces the imbalance of resources often found between the parties, achieves economies of scale, and avoids duplicative litigation. The great advantage of the class actions being pursued in the third wave of tobacco litigation is that resources are expended on behalf of thousands or millions of class members rather than on behalf of a single individual (Kelder and Daynard 1997). This advantage provides more of a level playing field and means that the

tobacco companies will not be able to successfully pursue their usual first- and second-wave strategy of forcing opponents to spend exorbitant sums of money until, nearly bankrupted, they are forced to withdraw (Kelder and Daynard 1997). In its unanimous decision, the appellate court in *Broin*, after considering and rejecting defense objections to the plaintiffs' request for class certification, alluded to the great promise that the class action strategy holds for plaintiffs challenging the tobacco industry: "... if we were to construe the rule to require each person to file a separate lawsuit, the result would be overwhelming and financially prohibitive. Although defendants would not lack the financial resources to defend each separate lawsuit, the vast majority of class members, in less advantageous financial positions, would be deprived of a remedy. We decline to promote such a result" (Broin, cited in 9.1 TPLR 2.4).

But with these benefits come new problems. Only common issues can be dealt with in a class proceeding, thus leaving individualized features to be dealt with in separate trials. As noted, some or many potential class members may choose to opt out of the class to pursue individual cases, thereby reducing the advantage of eliminating duplicative litigation. If some class members are more severely injured than others, intractable conflict may arise over distributing the proceeds (Coffee 1986, 1987). If the injury is continuing outside the class, as it is in the case of tobacco use, there is the problem of providing for future plaintiffs (Hensler and Peterson 1993). These problems are overlaid and compounded by issues involving the legal agents representing the plaintiffs. Class actions are organized and managed by entrepreneurial lawyers, and their interests and those of the client class may diverge (Coffee 1986). Finally, there is the danger that the class action device elevates the stakes so high that defendants and plaintiffs settle without resolution of other (nonmonetary) merits of the claim. Just which of these problems are sufficiently salient to discourage use of the class action device in the several varieties of tobacco cases is still an issue.

Castano v. American Tobacco Co., filed March 29, 1994, in federal court in New Orleans (MacLachlan 1994–95), was an unparalleled attempt by a coalition of traditional plaintiffs' lawyers, mass disaster lawyers, and class action specialists from around the country to diminish the organizational advantages enjoyed by the tobacco industry during the first two waves of tobacco litigation. Each of a coalition of 62 law firms pledged \$100,000 annually to fund a massive class action suit, on behalf of millions of nicotine-dependent smokers, charging the tobacco industry with promoting

addiction and thus disabling smokers from quitting (Janofsky 1994a; Shapiro 1994a; Curriden 1995). The plaintiffs requested damages for economic losses and emotional distress, as well as medical monitoring and injunctive relief. In February 1995, the district court granted the plaintiffs' request for class certification conditionally and in part (*Castano, cited in* 10.1 TPLR 2.1). Judge Okla Jones II granted certification for issues of fraud, breach of warranty (express or implied), intentional tort, negligence, strict liability, and consumer protection issues. Certification was denied for other issues, including the questions of causation, injury, and defenses regarding the claims of each smoker.

Normally, a trial judge's decision to certify a class is not subject to review by a higher court until the trial court has reached a final disposition of the whole case, which may be years later. But Judge Jones in Castano granted special permission to allow the defendants to appeal his class certification decision to the United States Court of Appeals for the Fifth Circuit (Collins 1995c). On May 23, 1996, a three-judge panel of the appellate court vacated Judge Jones' decision and remanded the case back to the district court with instructions to dismiss the class action. The court of appeals reasoned that the variations in the state laws of the 50 states in which the injuries occurred classwide, combined with trial management problems not addressed by the district court, justified decertification of the nationwide class (Castano, 84 F.3d 734).

The coalition of lawyers that formed around *Castano* opted to pursue another approach and began to file statewide class actions shortly after the decertification by the court of appeals. By mid-1998, the coalition had filed 26 such cases (Torry 1998).

Another class action, Engle v. R.J. Reynolds Tobacco Co., No. 94-08273 CA (20) (Fla., Dade Cty.), cited in 9.3 TPLR 3.293 (1994), filed in a Florida state court May 5, 1994, on behalf of smokers suffering from "diseases like lung cancer and emphysema," sought billions of dollars in damages from the seven leading tobacco companies, the Council for Tobacco Research U.S.A. Inc., and the Tobacco Institute, a tobacco-financed public relations association (Janofsky 1994a, p. 11). The suit alleged that by denying that smoking is addictive and by suppressing research on the hazards of smoking, the tobacco industry has deceived the public about the dangers of using tobacco products (Janofsky 1994c). On October 31, 1994, *Engle*, filed by a personal injury lawyer who chose to remain apart from the Castano coalition, had the distinction of becoming the first tobacco-related class action lawsuit to be granted class certification (Engle v. R.J. Reynolds Tobacco Co., No. 94-08273 CA [20] [Fla., Dade Cty. Oct. 31, 1994], cited in

9.5 TPLR 2.147 [1994]). When the defendants sought to overturn the class certification, the Florida Supreme Court upheld it, paving the way for the case to go to trial (*R.J. Reynolds Co. v. Engle*, 672 So. 2d 39 [Fla. Ct. App. 1996]). A jury selection for the trial began on July 6, 1998 (*Economist* 1998).

Recovery Claims by Third-Party Health Care Payers

In the late 1970s, a number of scholars and advocates began urging legal theories and statutory reforms that would permit third-party health care payers to collect the expenses of caring for tobacco-caused disease from the manufacturers themselves (Garner 1977; Daynard 1993a,b, 1994a; Gangarosa et al. 1994). Such claims involve complex questions about ascertaining the amount of tobacco-caused injury and the apportionment of damages attributable to each defendant. The stakes in these potential cases are undoubtedly large: one study estimates that 7.1 percent of total medical care expenditures in the United States is attributable to smoking-related illnesses (CDC 1994c). Another study estimates that tobacco use is responsible for about 18 percent of all Medicaid expenses (Clymer 1994). However, calculation of such effects invites the counterargument (albeit amoral) that tobacco's costs to the state are offset in part by the savings afforded by the premature deaths of smokers (Geyelin 1995).

Beginning in 1994, the governments of three states—Minnesota, Mississippi, and West Virginia as well as Blue Cross and Blue Shield of Minnesota, filed lawsuits to secure reimbursement from the tobacco industry for health care expenditures for ailments arising from tobacco use. Three years later, 41 states had filed such legal actions. Since this settlement has not yet been embodied in the congressional legislation necessary to give it the force of law (see "Legislative Developments" and "Master Settlement Agreement," earlier in this chapter), four states— Florida, Minnesota, Mississippi, and Texas—have settled their claims with the tobacco industry. Additional third-party payers—such as labor union pension funds and Blue Cross and Blue Shield plans (whose joint case is described in detail in "Common-Law Claims," earlier in this chapter) in states other than Minnesota—also began to file suit against the industry in 1997 and 1998.

Medicaid Reimbursement Cases

Mississippi filed suit on May 23, 1994, against tobacco manufacturers, wholesalers, and trade groups

on the basis of common-law theories of restitution, unjust enrichment, and nuisance to recover the state's outlays for treating the tobacco-related illnesses of welfare recipients (Janofsky 1994a; Woo 1994c; Moore v. American Tobacco Co., Cause No. 94:1429 [Miss., Jackson Cty. Feb. 21, 1995], cited in 10.1 TPLR 2.13 [1995]). The first state to do so, Mississippi, embraced a strategy that merited the attention of other third-party claimants. Rather than proceeding in a trial court on a theory of subrogation (whereby the state would have acted in the place of injured smokers to recover claims the state had paid to those smokers), Moore chose to proceed in equity (i.e., before a single judge in a nonjury proceeding) on theories of unjust enrichment and restitution (Kelder and Daynard 1997). *Moore's* equity claims were grounded in the notion developed in the literature that the State of Mississippi had been injured directly by the behavior of the tobacco industry because Mississippi's taxpayers had been forced to pay the state's Medicaid costs due to tobacco-related illnesses.

The state planned to use statistical analysis to illustrate the percentage of Medicaid costs that can be attributed to tobacco use. If the lawsuit succeeded, the defendants would pay for Medicaid costs under a formula that calculates liability according to market share (Lew 1994). The lawsuit sought tens of millions of dollars in damages, including punitive damages as well as recovery for future tobacco-related expenditures (Woo 1994c). Lawyers from 11 private plaintiffs' law firms participated in the suit. Instead of promising the private lawyers a percentage of the potential damages, the state sought to compel the tobacco companies to pay the lawyers' fees (Woo 1994c).

Superficially, this state case (and that of other states) resembled subrogation claims, in which a party who pays a claim (typically an insurer) may pursue that claim, acting in the place of the original claimant and subject to the defenses that might be raised against him or her. But the Mississippi complaint avoided asserting the claims of the health care recipients; instead, it asserted the proprietary claims of the state as a health care funder (distinct from any claims of those whose health was injured by tobacco).

This proprietary stance is significant because, as detailed earlier in this section, the tobacco companies won many of the first- and second-wave cases by asserting the defenses of assumption of risk and contributory negligence or by asserting that the smoker's willfulness, not the industry's misbehavior, was the proximate cause of the smoker's smoking and consequent illness. These defenses should not be available to the tobacco industry in medical cost reimbursement

suits because these suits are not brought on behalf of injured smokers. They are brought, instead, on behalf of the states themselves to recover the medical costs they have been forced to pay to care for indigent smokers. The tobacco industry cannot plausibly argue that the states chose to smoke or that they contributed to the financial harm caused to them (Daynard 1994b; Kelder and Daynard 1997).

The decision in the Mississippi medical cost reimbursement suit demonstrates that this commonsense argument can prevail, even in states that lack special legislation that creates an independent cause of action for the state. The tobacco industry defendants in *Moore* v. American Tobacco Co. filed a motion for judgment on the pleadings on October 14, 1994. The defendants argued that, under Mississippi law, assignment/subrogation was the state's exclusive remedy for pursuing the recovery of medical benefits from potentially liable third parties. Further, the defendants argued that because Mississippi's counts for restitution, indemnity, and nuisance in the complaint did not assert a subrogation claim, they had to be dismissed. Alternatively, the defendants argued that the case should be transferred to a Mississippi circuit court, where thousands of jury trials would have to be conducted (Kelder and Daynard 1997).

In response, Mississippi Attorney General Mike Moore pointed out that "this 'remedy,' as the industry knows, would be cost prohibitive and exhaustive of our State's limited judicial resources" (Moore v. American Tobacco Co., No. 94:1429 [Miss., Jackson Cty. Oct. 14, 1994], cited in 9.5 TPLR 3.597, 3.598 [1994]). He argued that "although the Medicaid Law did further codify the State's right to be subrogated, this right is in addition to, and not in derogation of, the State's statutory and common law remedies. There is no language in the Medicaid Law that implies an exclusive remedy, and well-settled rules of statutory interpretation require a construction that the Medicaid Law expanded, not contracted, the State's remedies [emphasis in original]" (p. 3.598).

On February 21, 1995, Chancellor William H. Myers, presiding over the Chancery Court of Jackson County, denied the tobacco industry defendants' motions to obtain a judgment on the pleadings and to remove the claim from the chancery court to a Mississippi circuit court. The court simultaneously granted the state's motion to strike the affirmative defenses of the defendants; the tobacco industry thus could not rely on the defenses of assumption of risk and contributory negligence, which have proved a mainstay in earlier battles—and which might have

been allowed had the state proceeded on a theory of subrogation (*Tobacco Products Litigation Reporter* 1995a).

On July 2, 1997, Mississippi settled its claims so that it would receive at least \$3.3 billion over 25 years, with annual payments of at least \$135 million continuing in perpetuity. A provision of the settlement agreement guaranteeing Mississippi most favored nation (MFN) treatment, which meant that Mississippi would get the benefit of any better agreement that another state might achieve, was little noticed at the time but has since proved immensely important; additional settlement terms from later industry arrangements with the other three states have been granted to Mississippi.

The second state to bring suit against the tobacco industry was Minnesota (Minnesota v. Philip Morris Inc., No. C1-94-8565 [Minn., Ramsey Cty. Nov. 29, 1994], cited in 9.3 TPLR 3.273 [1994]). Minnesota's suit alleged an antitrust conspiracy and an elaborate course of fraudulent behavior on the part of the defendants. Specifically, the tobacco companies were alleged to have violated the state's laws against consumer fraud, unlawful trade practices, deceptive trade practices, and false advertising, as well as violated the duty they voluntarily undertook to take responsibility for the public's health, to cooperate closely with public health officials, and to conduct independent research and disclose to the public objective information about smoking and health. The suit sought various damages, including restitution, forfeiture of tobacco profits, attorneys' fees, and treble damages for several statutory violations. Blue Cross and Blue Shield of Minnesota, the state's largest private medical insurer, joined as a co-plaintiff with the state (Woo 1994b). Like most other states that brought Medicaid reimbursement cases, Minnesota and the insurer retained private counsel to provide representation under a contingency fee arrangement.

Following a three-month trial and in the midst of closing arguments, Minnesota settled its case—the last of the four states to do so—on May 8, 1998. The industry agreed to pay about \$6.1 billion to Minnesota and \$469 million to Blue Cross and Blue Shield of Minnesota (which was also a plaintiff) over 25 years, an amount substantially larger proportionately than the three earlier state settlements, resulting in substantial increases in their settlement packages under the MFN clauses. The industry also agreed to the following public health concessions (*Minnesota v. Philip Morris Inc.*, cited in 13.2 TPLR 2.112):

• Disband the Council for Tobacco Research.

- Not pay for tobacco placement for movies (a provision that inherently extends beyond Minnesota's borders).
- Stop offering or selling in Minnesota nontobacco merchandise, such as jackets, caps, and T-shirts, bearing the name or logo of tobacco brands.
- Remove all tobacco billboards in Minnesota within six months and eliminate such ads on buses, taxis, and bus shelters.
- Refrain from targeting minors in future advertising and promotions.
- Refrain from misrepresenting the evidence on smoking and health.
- Refrain from opposing in Minnesota certain new laws designed to reduce youth tobacco use, as well as clean indoor air laws that could adversely affect the industry.
- Institute new lobbying disclosure rules for Minnesota.
- Release internal indexes to millions of previously secret industry documents, thereby providing a means for attorneys and researchers to find relevant information more easily.
- Maintain at industry expense for 10 years a depository of millions of tobacco documents in Minneapolis and another such depository in Great Britain.
- Instruct retailers in Minnesota to move cigarettes behind the counter to restrict minors' access to those cigarettes.
- Pay out \$440 million in fees to the private attorneys who represented the plaintiffs.
- Give Minnesota its own MFN clause, limited to improved public health provisions in future state settlements.

Through the MFN process, many of the public health concessions that Minnesota obtained from the industry are also being incorporated in the prior state agreements (Branson 1998).

The Florida case (*Florida v. American Tobacco Co.*, No. 95-1466AO [Fla., Palm Beach Cty. Feb. 21, 1995], *cited in* 10.1 TPLR 3.1 [1995] [Complaint]; Geyelin 1995) was the first conforming with a statute tailored for the purpose of establishing such a claim. In May 1994, Florida amended this little-used statute, which provided for recovery by the state from third parties responsible for Medicaid costs, to permit the state to

sue on behalf of the entire class of smokers on Medicaid, to use statistical proof of causation, to bar assumption of risk as a defense, and to permit recovery according to the defendants' share of the cigarette market (Rohter 1994; Woo 1994a). Apparently having second thoughts about the statute (which had passed by a wide margin), the state legislature considered repealing it, eliciting a vow from Florida's Governor Lawton Chiles to veto a repeal (Hwang 1995a). After an unsuccessful last-minute attempt by the tobacco companies to have the Florida Supreme Court bar state agencies from initiating a lawsuit under the statute, Florida filed its medical cost reimbursement suit on February 21, 1995, seeking \$4.4 billion (*Florida*, *cited in* 10.1 TPLR 3.1; Geyelin 1995).

The complaint in the Florida lawsuit contains extended factual allegations regarding the defendants' knowledge (or lack of knowledge) about the harmfulness of tobacco. Raising the familiar causes of action, the complaint also emphasizes the tobacco industry's alleged violations of consumer protection laws. Specifically, it criticizes the industry's use of advertising to target minors.

The Florida Supreme Court narrowly upheld the liability law, on which the state's case is based, in a 4 to 3 ruling that produced equivocal results for both sides. The court agreed with the defendants that the state could only use the law to recover damages incurred since July 1, 1994, and that the names of individual Medicaid recipients would have to be supplied so that the tobacco companies could challenge their claims (Agency for Health Care Administration v. Associated Industries of Florida, 678 So. 2d 1239 [Fla. 1996]). But the majority decision left most of the law's key provisions intact. The presiding state circuit court judge, Harold J. Cohen, next ordered both parties to try to resolve the dispute by engaging in mediation, which broke off after four days and produced no results (Kennedy 1996). Judge Cohen then dismissed 15 counts of the state's 18-count claim against the tobacco industry in a ruling issued September 1996 (Florida v. American Tobacco Co., No. CL 95-1466 AH [Fla., Palm Beach Cty. Sept. 16, 1996]). The following month, however, he rejected the defendants' request to depose the hundreds of thousands of Medicaid recipients supplied to the court by the state in compliance with the supreme court decision. The judge held that the hundreds of thousands of recipients need only be identified by case number, not by name (Florida v. American Tobacco Co., No. CL 95-1466 AH [Fla., Palm Beach Cty. Oct. 18, 1996], cited in 11.7 TPLR 2.236 [1996]). In yet another setback for the defendants, Judge Cohen permitted the state to add a count of racketeering to its claim (MacLachlan 1996–1997).

Florida settled its case on August 25, 1997, for at least \$11 billion over 25 years, with annual payments of at least \$440 million continuing thereafter. It obtained its own MFN clause, as well as an additional \$200 million for a two-year initiative to reduce youth smoking, an agreement to ban cigarette billboards and transit advertisements, and an agreement by the industry to lobby for a ban on cigarette vending machines. As a consequence of Mississippi's MFN clause, Florida received similar benefits.

The Texas suit was innovative in that it was brought in federal rather than state court. The case was also the first to include claims under the federal RICO Act. On January 16, 1998, Texas settled its claims for at least \$14.5 billion over 25 years, with annual payments of at least \$580 million continuing thereafter, as well as public health provisions similar to those negotiated by Florida and its own MFN clause.

Although West Virginia was one of the first three states to file a suit against the tobacco companies, its case did not fare as neatly as those of Mississippi, Minnesota, and the later-arrived Florida and Texas. Filed on September 20, 1994 (McGraw v. American Tobacco Co., No. 94-1707 [W.Va. Cir. Ct. Kanawha Cty. Sept. 20, 1994], cited in 9.4 TPLR 3.516 [1994]), West Virginia's suit named 23 defendants, including Kimberly-Clark Corporation, developer of a process once used in Europe—but never, according to a company spokesperson, in the United States—to control nicotine levels in tobacco products (Hwang and Ono 1995), and United States Tobacco Company, the largest manufacturer of chewing tobacco and snuff. The West Virginia action "asks the Court for damages to cover what West Virginia has paid providing medical care to people afflicted with tobacco-related illness, and what the state will pay in the future for tobacco victims. The lawsuit also seeks punitive damages to prevent a repetition of such conduct in the future" (West Virginia Attorney General 1994, p. 2). Citing an "intentional and unconscionable campaign to promote the distribution and sale of cigarettes to children," the complaint also requires that the defendants be enjoined from "aiding, abetting or encouraging the sale . . . of cigarettes to minors" (p. 4) and be fined \$10,000 for each violation of the injunction. West Virginia's complaint is signed by lawyers from five private firms, including a prominent asbestos litigation firm that is also involved in the Mississippi case.

Unlike the Mississippi and Minnesota claims, the West Virginia case met with early difficulties. On May 3, 1995, Kanawha County Circuit Court Judge Irene C. Berger dismissed 8 of the suit's 10 counts, including fraud, misrepresentation, and conspiracy, as being outside of the state attorney general's powers. Ironically, Berger's decision is based in part on a decision that Attorney General Darrell V. McGraw Jr. himself, the named plaintiff in the suit, authored when he served on West Virginia's Supreme Court, holding that the state attorney general lacked common-law authority (i.e., he could bring only statutory claims). The two remaining counts of the West Virginia action dealt with consumer and antitrust charges (MacLachlan 1995a).

On May 13, 1996, Judge Berger permitted the West Virginia Public Employees Insurance Agency Finance Board to join as co-plaintiffs. This ruling "essentially revived" (*Mealey's Litigation Reports: Tobacco* 1996a) the case by providing the state with a means of hiring legal counsel after the tobacco companies won an October 1995 order barring the attorney general from retaining private law firms on a contingency fee basis (MacLachlan 1995a,b,c).

Among the numerous other states currently trying to recoup Medicare expenditures, Oklahoma stands out for an innovation in its suit. The Oklahoma suit names, among other defendants, three industry law firms: Shook, Hardy and Bacon of Kansas City, Missouri; Jacob, Medinger and Finnegan of New York; and Chadbourne and Parke of New York. Shook, Hardy and Bacon has represented tobacco companies since 1954 (Kelder and Daynard 1997). The suit accuses the law firms of helping the tobacco companies conceal the health risks of smoking and alleges they kept documents confidential by falsely claiming they were protected by attorney-client privilege (Oklahoma v. R.J. Reynolds Tobacco Co., No. CJ961499L [Okla., Cleveland Cty. Aug. 22, 1996], cited in 11.7 TPLR 3.901 [1996]).

Other notable settlements mentioned earlier in this chapter include the Liggett Group Inc.'s 1997 settlement with most of the states, in return for a fraction of future profits, public admissions of the dangers and addictiveness of nicotine and the past misbehavior of the industry, and disclosure of secret industry documents (Tobacco Products Litigation Reporter 1997a). The same year brought in another key settlement—that of R.J. Reynolds Tobacco Company and a dozen California cities and counties, which had alleged that R.J. Reynolds' Joe Camel campaign was aimed at minors (see "A Critical Example: Joe Camel," earlier in this chapter). R.J. Reynolds agreed to discontinue the campaign in California and to give the plaintiffs \$9 million for a counteradvertising campaign (Mangini, cited in 12.5 TPLR 3.349). In October 1997,

the industry settled the first phase of a class action brought on behalf of nonsmoking flight attendants for substantial money and other concessions (*Broin, cited in* 12.6 TPLR 3.397). This case is discussed in detail in "Claims of Nonsmokers," later in this chapter.

Finally, at the time of writing, a group of state attorneys were holding discussions about settling some or all of the remaining state cases. According to published reports, as a starting point "the states have decided to use the [public health] concessions gained by Minnesota as part of its \$6.5 billion settlement" (Meier 1998a).

Other Third-Party Reimbursement Cases

Although the parties seeking recovery in Medicaid reimbursement cases are public officials, the cases are based on private law theories of recovery—that is, the officials proceed not as authoritative public regulators but as holders of rights conferred by the general law. Such use of private law recovery as an instrument of state policy suggests further possibilities of analogous suits by private funders of health care and may provide incentives for attorneys to organize such suits. Health insurers, widely seen as reluctant to enforce their rights to recoup from third parties, may be mindful of such opportunities in an increasingly competitive health care setting.

Indeed, Blue Cross and Blue Shield of Minnesota was a co-plaintiff with the State of Minnesota in its action against the tobacco industry. In 1996, the Minnesota Supreme Court unanimously rejected an industry challenge that co-plaintiff Blue Cross and Blue Shield could not remain in the case. This ruling permitted the insurance company and the state to pursue their claims directly against the defendants, rather than on behalf of individual smokers (*Minnesota v. Philip Morris Inc.*, 551 N.W.2d 490 [Minn. 1996]). When the industry settled with the State of Minnesota in May 1998, it also settled with Blue Cross and Blue Shield of Minnesota—for \$469 million to be paid over a five-year period (Weinstein 1998a).

In March 1998, two Minnesota health maintenance organizations filed a separate suit against the industry, with claims paralleling those in the Minnesota case that was still in trial (Howatt 1998). The following month, Blue Cross and/or Blue Shield Plans in 37 states combined in three legal actions to sue the major tobacco companies and their public relations firms to recover damages allegedly caused by a conspiracy to addict their insurance plan members to cigarettes (e.g., *Blue Cross and Blue Shield*, *cited in* 13.2 TPLR 3.51; *National Law Journal* 1998).

These plans are alleging that tobacco companies conducted an "ongoing conspiracy and deceptive, illegal and tortious acts" that have resulted in the plaintiffs suffering "extraordinary injury in their business and property," having been required to expend many millions of dollars on costs attributable to tobaccorelated diseases caused by defendants who "knowingly embarked on a scheme to addict millions of people, including members of the [Blue Cross and Blue Shield] Plans, to smoking cigarettes and other tobacco products—all with the intent of increasing their annual profits . . . [and forcing] others to bear the cost of the diseases and deaths caused by the conspiracy" (Blue Cross and Blue Shield, p. 3.52).

The plans allege a conspiracy to hide the health effects of tobacco products, violations of federal racketeering laws and of antitrust laws, and unjust enrichment, among other theories (*Tobacco Products Litigation Reporter* 1998). They request damages in the forms of payments for treatments of tobacco-related diseases, court orders to require corrections of unlawful behavior, damages in excess of \$1 billion for past and future harm, and other forms of relief.

Bankruptcy trusts representing the interests of injured plaintiffs who have made claims against the asbestos industry filed suit against the tobacco industry in late 1997 (Bourque 1997). The trusts allege that they paid claims to victims of asbestos exposure whose injuries were substantially caused by either active or passive exposure to cigarette smoke. Alleging the unjust enrichment of the tobacco companies at the expense of the trusts, the latter seek to recover expenditures and payments made to the asbestos settlement class and seek punitive damages against the defendants (*Tobacco Products Litigation Reporter* 1997b).

The trusts allege that among persons exposed to asbestos, direct or indirect exposure to tobacco smoke is a substantial contributing factor in both the development of cancer and the frequency and severity of symptoms of asbestosis, a disease from which many asbestos workers suffer. The trusts also allege that tobacco companies knew or should have known that their products would cause these injuries (*Falise v. American Tobacco Co.*, No. 97-CV-7640 [E.D.N.Y. Dec. 31, 1997], *cited in* 12.8 TPLR 3.504 [1997]).

The asbestos trusts accuse the tobacco companies of suppressing the truth concerning the nature of their products and their carcinogenic effects. They allege that tobacco industry products were at least partly responsible for the illnesses suffered by asbestos plaintiffs. The trusts thus want the tobacco companies to pay a share of the billions of dollars in damages awarded to those plaintiffs (Bourque 1997).

Small Claims Tribunals to Recover the Cost of Quitting

Related to these expansive addiction suits are a series of more limited claims based on the addictive properties of cigarettes. As with large suits, small claims for the recovery of costs related to quitting tobacco use depend on whether judges and juries accept the addiction argument that underlies the product liability portion of the third wave of tobacco litigation. In this scaled-down version, claims for modest amounts might be brought in small claims courts, obviating some of the litigation advantages enjoyed by the manufacturers. In one case, an individual smoker sued Philip Morris Companies Inc. for \$1,154 in a Washington State small claims court to recover the costs of consulting a doctor, buying nicotine patches, and joining a health club—all activities undertaken to help the plaintiff quit smoking cigarettes (Hayes 1993; Janofsky 1993). Because the court rejected the suit on the preliminary ground that the statute of limitations had expired, the substantive merits of the claim were not considered (Montgomery 1993).

In July 1998, an Australian appellate court allowed a formerly addicted smoker to proceed before the New South Wales consumer claims tribunal with a \$1,000 claim for the cost of a stop-smoking program, as well as for mental suffering caused by the addiction and the effort to quit (Australian News Network 1998). Were a timely small claims case to succeed, the recovery would be small. Incentives for lawyers to supply and plaintiffs to consume the legal services needed to pursue such a claim might be provided by statutory provision allowing winning plaintiffs to recover attorneys' fees. Or if such claims could be sufficiently standardized and simplified, they might proceed without lawyers (e.g., by preparing "kits" to enable plaintiffs to represent themselves).

Other Cost Reduction Procedures

Several other procedures have been used or may be available to reduce the costs—for plaintiffs, their attorneys, and the courts—of resolving individual claims. One such procedure is to combine pretrial and perhaps trial proceedings for several, or even many, cases. In July 1998, a California court ordered that proceedings in a variety of actions pending in various California courts be combined (Associated Press 1998). Earlier, a Tennessee court ordered several pending individual cases to be combined for trial (*Mass Tort Litigation Reporter* 1998). Asbestos trials have occasionally combined hundreds and even thousands of individual

claims (*Acands, Inc. v. Abate*, 710 A.2d 944 [Md. Ct. Spec. App. 1998]). These procedures permit courts to achieve substantial efficiencies with the formalities of class action certification. Efficiencies can also be obtained by case management orders that set firm schedules for trials and pretrial proceedings (*In re Cigarette Cases, cited in* 11.1 TPLR 2.3).

Another procedure available in some jurisdictions is "offensive collateral estoppel," which exempts future plaintiffs from retrying issues on which specific defendants have lost in prior trials (*Blonder-Tongue Laboratories v. University of Illinois Foundation*, 402 U.S. 313, 91 S. Ct. 1434 [1971]). This device has not yet been used in tobacco litigation.

Claims of Nonsmokers

ETS Claims Against Manufacturers

Although most litigation involving adverse health effects from exposure to ETS has not directly involved tobacco companies, a line of cases has developed during the 1990s naming tobacco companies as defendants and targeting the companies' behavior in attempting to, as a British-American Tobacco Company Ltd. document from 1988 put it, "keep the controversy alive"—referring to the industry's common strategy of shifting the focus from personal health to personal freedom (Boyse 1988; Chapman 1997).

Claims of nonsmokers asserting damages from ETS have been filed on behalf of both individual and class plaintiffs. As nonsmokers, alleged victims of ETS are not vulnerable to the defense that they knowingly subjected themselves to the dangers of tobacco use. Butler v. American Tobacco Co. ([Miss., Jones Cty. May 12, 1994], cited in 9.3 TPLR 3.335 [1994] [Amended Complaint]), filed May 13, 1994, seeks damages from six tobacco companies and others for the lung cancer death of Burl Butler, a nonsmoker and "paragon of clean living" (Greising and Zinn 1994, p. 43), who allegedly contracted the disease after inhaling customers' tobacco smoke for 35 years while working at his barber shop (Kraft 1994). Butler became the first case in which documents allegedly stolen from Brown & Williamson Tobacco Corporation by one of its former employees were admitted into evidence, despite objections by the defendants that attorney-client privilege prohibited disclosure. Lawyers for Butler's estate contend that "the documents will show, among other things, that tobacco companies manipulated and suppressed scientific research for years to mislead their customers about smoking's dangers" (Ward 1996). State Circuit Court Judge Billy Joe Landrum postponed

commencement of the trial on motion by the plaintiffs to allow new defendants to be added to the action. The amended complaint now contends that manufacturers of talcum powder used by Butler in his barber shop "knew or should have known that Environmental Tobacco Smoke can act synergistically with . . . Talc, to cause respiratory diseases, including lung cancer, and other health problems" (Butler v. Philip Morris Inc., Civil Action No.:94-5-53 [Miss., Jones Cty. Mar. 4, 1996], cited in 11.3 TPLR 3.307, 3.315 [1996] [Second Amended Complaint and Request for Trial by Jury]). A new trial date has not yet been set.

Another case involved a woman who had never smoked but who was subjected to prolonged and repeated exposure to ETS since childhood and died of lung cancer in 1996 at the age of 44 (Buckingham v. R.J. Reynolds Tobacco Co., 713 A.2d 381 [N.H. 1998]). Two years before her death, Roxanne Ramsey-Buckingham sued the major tobacco companies and a local store in strict liability and under Restatement (Second) of Torts, section 389. She alleged "that the defendants knew or should have known that it was unlikely that their products would be made reasonably safe prior to their customary and intended use, and that it was foreseeable that Ms. Ramsey-Buckingham would be endangered by ETS from the defendants' cigarettes" (p. 383). A superior court judge dismissed her lawsuit in 1995 on the basis that New Hampshire does not recognize a strict liability cause of action under section 389. However, the New Hampshire Supreme Court reinstated the lawsuit in May 1998, ruling that "section 389 is not a form of strict liability because it requires the defendant's knowledge of the product's dangerous condition and does not require that the product be defective. . . . The comments to section 389 make it clear that a bystander, assuming he is within the scope of foreseeability of risk, is owed a duty under law and may recover on a showing of breach, damage, and causation" (p. 385). The case was sent back to the trial court for further proceedings.

One case that was tried before a jury in March 1998 resulted in a verdict for the defendants. In that case, *RJR Nabisco Holdings, Corps. v. Dunn* (657 N.E.2d 1220 [Ind. 1995]) a nonsmoking nurse who worked for 17 years at a Veterans Administration Hospital died of lung cancer at the age of 56. Her widower sued a group of tobacco companies, claiming that her exposure to ETS from her patients at the hospital had killed her. A six-person jury returned a verdict for the defendants. Interviewed after the trial, some of the jurors explained that they had had doubts as to whether the cancer that killed Mrs. Wiley had originated in the lungs or, as

the tobacco companies' lawyers had argued, in the pancreas and had then spread to the lungs (Dieter 1998).

The most prominent ETS case with tobacco company defendants has been Broin v. Philip Morris Cos., which was brought against the six major cigarette manufacturers in 1991. Seven current and former nonsmoking flight attendants, who contracted lung cancer or other ailments and who face an increased risk of disease as a result of exposure to ETS on airplanes, filed a class action suit on behalf of thousands of flight attendants harmed by exposure to ETS on flights that predated the federal ban on smoking on domestic airline flights. In 1992, a Dade County circuit judge dismissed the class action aspect of the complaint, but two years later, a three-judge panel of the District Court of Appeal of Florida, Third District, unanimously reversed the order of dismissal and ordered that the class action allegations be reinstated (*Broin, cited in* 9.1 TPLR 2.1).

In late December 1996, the Circuit Court for Dade County authorized the mass notification of some 150,000 to 200,000 flight attendants so they could either sign up as plaintiffs or exclude themselves from the case to pursue their own suits if they wished. In June 1997, jury selection in the trial began. More than three months later, midway through the companies' presentation of their defense, the parties announced a proposed settlement whereby the defendants would pay \$300 million to establish the Broin Research Foundation. The settlement would permit flight attendants harmed by ETS exposure aboard airlines to sue the tobacco companies, regardless of statute of limitations issues. In the event of such individual actions, the defendants would assume the burden of proof on the issue of whether ETS exposure is capable of causing disease in nonsmokers. Dade County Circuit Judge Robert P. Kaye approved the proposed settlement on February 3, 1998, calling it "fair, reasonable, adequate and in the best interests of the class," but challengers to the settlement have appealed (Broin v. Philip Morris Cos., No. 91-49738 CA [22] [Fla., Dade Cty. Feb. 3, 1998], cited in 13.1 TPLR 2.79 [1998]). As of August 1998, the appeal was pending.

One workplace setting that has generated substantial exposure to ETS has been casinos. In 1997, nine casino dealers filed a class action lawsuit against 17 tobacco companies and organizations. The lawsuit seeks tens of millions of dollars in damages and class certification of up to 45,000 casino dealers working in Nevada, along with their estates and family members. The plaintiffs in this case, *Badillo v. American Tobacco Co.* (No. CV-N-97-00573-DWH [D. Nev. 1997]), are also seeking to get medical monitoring for the dealers who have had years of exposure to ETS on the job. In April

1998, a federal judge denied all of the motions to dismiss by the defendants, except for The American Tobacco Company, which has merged with Brown & Williamson Tobacco Corporation.

In April 1998, a group of nonsmoking casino workers filed a lawsuit in New Jersey Superior Court against several tobacco companies and the industry's trade association, the Tobacco Institute, because the workers were being made sick by their exposure to ETS at work (Smothers 1998).

Suing Tobacco Companies Over Failure to Disclose Harm From ETS

In a unique case from California, the City Attorney of Los Angeles filed suit in July 1998, against 16 tobacco companies (those that sell cigarettes, cigars, or pipe tobacco) and 15 retailers on the grounds that they are violating Proposition 65, an initiative statute passed by the voters of California in 1986. That law, known as the Safe Drinking Water and Toxic Enforcement Act of 1986 and contained in California Health and Safety Code section 25249.6, provides that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."

The lawsuit specifically lists 46 chemicals referred to as carcinogenic constituents of tobacco smoke and 8 (arsenic, cadmium, carbon disulfide, carbon monoxide, lead, nicotine, toluene, and urethane) as reproductive toxicants. The city attorney's complaint cites a number of prominent government studies: The Health Consequences of Involuntary Smoking, the 1986 report of the U.S. Surgeon General on smoking and health; Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects, published in 1986 by the National Research Council; Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, a report issued by the U.S. Environmental Protection Agency in January 1993; and Health Effects of Exposure to Environmental Tobacco Smoke, published by the California Environmental Protection Agency in September 1997. The complaint alleges that "Notwithstanding this overwhelming body of governmental information, and notwithstanding their own knowledge of these facts since at least 1981, the Tobacco Defendants have each knowingly and intentionally concealed from, and thereby deceived, every nonsmoking individual exposed to environmental tobacco smoke by the sale and use of tobacco products in California. By these acts of knowing and intentional concealment and deception, the Tobacco Defendants, and their agents, the Retailer Defendants, have each individually violated Proposition 65" (*California v. Philip Morris Inc.*, No. BC194217 [Calif., Los Angeles Cty. July 14, 1998], *cited in* 13.4 TPLR 3.195 [1998]).

The City of Los Angeles' lawsuit will likely benefit from a court decision rendered in 1997 in a federal court located some 3,000 miles away. A nonsmoker in Florida filed a lawsuit against various tobacco companies, alleging that she suffers from severe emphysema and an array of other injuries as a result of prolonged exposure to ETS from the normal and foreseeable use of the companies' products. The companies filed a motion to dismiss her case, contending that the Federal Cigarette Labeling and Advertising Act preempts claims based on state law duties to disseminate information relating to smoking and health. A judge in the U.S. District Court for the Southern District of Florida denied the motion to dismiss, concluding that the federal act's preemption of state regulations "based on smoking and health" does not preempt regulations involving ETS. "The Court finds it unlikely that Congress intended the word 'smoking' to mean inhaling second-hand smoke," since the "Congressional reports make clear the purpose of the [federal act] is not to inform non-smokers of the hazards of breathing second-hand smoke but rather to inform smokers and potential smokers of the dangers of actively smoking" (Wolpin v. Philip Morris, Inc., No. 96-1781-CIV-KING, 1997 WL 535218 [S.D. Fla. Aug. 18, 1997]). The court also ruled that the federal act did not by implication preempt a claim based on harm from ETS (Sweda 1998).

ETS Cases Against Nontobacco Parties

Injunctive relief from ETS. In 1976, Donna Shimp (see "Legal Foundation for Regulation of Public Smoking," earlier in this chapter), an office worker in New Jersey, sought intervention from the courts to provide her relief from exposure to ETS at her worksite (Shimp, 368 A.2d 408). The court ruled that the evidence was "clear and overwhelming. Cigarette smoke contaminates and pollutes the air, creating a health hazard not merely to the smoker but to all those around her who must rely upon the same air supply. The right of an individual to risk his or her own health does not include the right to jeopardize the health of those who must remain around him or her in order to properly perform the duties of their jobs" (p. 415). In granting an injunction to ensure that Shimp be provided a smoke-free workplace, the New Jersey Superior Court provided a clear example of taking seriously the health concerns of nonsmokers who are forced to breathe ETS.

The *Shimp* decision preceded most of the medical studies that have demonstrated the adverse health effects of ETS. In the 22 years since *Shimp*, lawsuits designed to protect nonsmokers from the health hazards caused by involuntary exposure to ETS have escalated.

A 1982 decision from the Missouri Court of Appeals gave additional momentum to nonsmoking workers seeking legal relief from on-the-job exposure to ETS. In Smith (643 S.W.2d 10), the Missouri Court of Appeals reversed a trial court's dismissal of a lawsuit brought by a nonsmoking worker who was seeking an injunction—a form of direct intervention by a court—to prevent his employer from exposing him to tobacco smoke in the workplace. The court of appeals ruled that if Paul Smith were to prove his allegations at trial, then "by failing to exercise its control and assume its responsibility to eliminate the hazardous condition caused by tobacco smoke, defendant [Western Electric Co.] has breached and is breaching its duty to provide a reasonably safe workplace" (p. 13). Although the nonsmoking worker eventually lost his case after it was sent back to the trial court, the court of appeals decision remains as a precedent that will help similar cases survive motions to dismiss (Sweda 1998).

The following year, a nonsmoking social worker in Attleboro, Massachusetts, was granted a temporary restraining order (which by law could last no more than 10 days) against smoking in the open office area where she worked with about 39 coworkers, 15 of whom smoked. In Lee (cited in 1.2 TPLR 2.82), a superior court judge denied a motion by the employer to dismiss the case, ruling that "an employer has no duty to make the work place safe if, and only if, the risks at issue are inherent in the work to be done. Otherwise, the employer is required to 'take steps to prevent injury that are reasonable and appropriate under the circumstances'.... Accordingly, this court cannot say that plaintiff's claim fails to make out a legally cognizable basis for relief" (p. 2.83). The case was settled in January 1985 when the employer, the Commonwealth of Massachusetts, agreed to provide the plaintiff, Marie Lee, and the other nonsmoking workers there, with a separate nonsmoking area with ventilation separate from the ventilation in the smoking area. As it turned out, only 4 of the office's 40 workers chose to work in the smoking area (Sweda 1998).

Handicap Discrimination/Americans With Disabilities Act

A new theory for ensuring ETS protection for nonsmokers involved using the ADA. As the rationale for applying the ADA to the workplace, Parmet and colleagues (1996) explained: "The ADA was enacted in 1990 to provide a 'clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities' [42 U.S.C. section 12101(b)(1)]. The act prohibits discrimination against individuals with disabilities on the job [42 U.S.C. section 12112(a)] and in places of 'public accommodation' [42 U.S.C. section 12182(a)], as well as by state and local governments [42 U.S.C. section 12132]" (p. 909).

Initially, some plaintiffs did not succeed in acquiring relief from ETS under the ADA. For example, in Harmer v. Virginia Electric and Power Co. (831 F. Supp. 1300 [E.D. Va. 1993]), an employee suffering from bronchial asthma sued his employer, contending that in failing to ban smoking at the workplace, the company had violated the ADA by discriminating against him because of his disability. Harmer contended that after he requested a smoke-free work environment, the company retaliated against him by reducing his job authority and failing to promote him. Though recognizing Harmer's disability, the district court dismissed the claim, saying that he "still must show that he is entitled to a complete smoking ban as a reasonable accommodation to his disability, and he is unable to do so" (p. 1306). This was so "because the many smoking limitations that the employer had put in place, coupled with improvements such as the installation of air filtration devices, were sufficient to enable the plaintiff to work. Of course, a patient more severely disabled might have required further accommodations" (Parmet et al. 1996, p. 912).

In *Emery v. Caravan of Dreams, Inc.* (879 F. Supp. 640 [N.D. Tex. 1995]), two women hypersensitive to ETS filed suit under the ADA, contending that they were effectively precluded from attending musical performances at the defendant's establishment because smoking was permitted there. After a one-day, jurywaived trial, a federal judge ruled against the plaintiffs, but noted that they should have brought their claim under the ADA's reasonable accommodation provision, instead of the section of the act that bars the establishment of rules that "screen out" disabled people (p. 643).

A different result had occurred in a case from Connecticut. In *Staron v. McDonald's Corp.* (51 F.3d 353 [2d Cir. 1995]), plaintiffs brought an action under the ADA, 42 U.S.C. section 12101, saying that the presence of tobacco smoke in the defendants' restaurants was preventing the plaintiffs from having the opportunity to benefit from the defendants' goods and services. The plaintiffs, all of whom have adverse reactions to ETS, also alleged that the defendants' restaurants are places of public accommodation under 42 U.S.C. section 12181.

After a district judge granted the defendants' motion to dismiss the case, the United States Court of Appeals for the Second Circuit reversed, ruling that "we find that plaintiffs' complaints do on their face state a cognizable claim against the defendants under the Americans with Disabilities Act" (p. 355). The court noted that "the determination of whether a particular modification is 'reasonable' involves a fact-specific, case-by-case inquiry that considers, among other factors, the effectiveness of the modification in light of the nature of the disability in question and the cost to the organization that would implement it [p. 356]. . . . We see no reason why, under the appropriate circumstances, a ban on smoking could not be a reasonable modification" (p. 357).

An Illinois woman suffering from chronic severe allergic rhinitis and sinusitis sought a smoke-free work environment and sued her former employer after it "repeatedly refused to provide" the plaintiff with a reasonable accommodation to her disability. After filing an ADA claim with the Equal Employment Opportunity Commission and a worker's compensation claim, she was terminated. A federal judge in Homeyer v. Stanley Tulchin Associates, Inc. (No. 95 C 4439, 1995 WL 683614 [N.D. Ill. Nov. 17, 1995]) granted the defendants' motion to dismiss, saying that the plaintiff "does not, and cannot, allege that her sensitivity to [ETS] substantially limits her ability to find employment as a typist generally. Thus, Homeyer is not a qualified individual with a disability, and, accordingly, is not entitled to the protection of the ADA" (p. 3).

However, the United States Circuit Court of Appeals for the Seventh Circuit unanimously reversed the district court's ruling and sent the case back for trial. Noting that the district court had ignored Homeyer's claim that she was disabled in that her breathing, an essential life activity, was affected by ETS, the court of appeals ruled that "we cannot say at this stage that it would be impossible for her to show that her chronic severe allergic rhinitis and sinusitis either alone or in combination with ETS substantially limits her ability to breathe" (Homeyer v. Stanley Tulchin Associates, Inc., 91 F.3d 959, 962 [7th Cir. 1996]).

In October 1997, a New York jury awarded \$420,300 to an asthmatic prison guard, Keith Muller (Muller v. Costello, No. 94-CV-842 (FJS) (GJD), 1996 WL 191977 [N.D.N.Y. May 20, 1996]), who had been fired after he had made numerous complaints about the effect of ETS exposure on his health. While serving as a correctional officer, Muller had become seriously illincluding numerous occasions when he had to be taken to a hospital directly from the prison where he worked—after being exposed to ETS. After Muller's treating physician had recommended that he work in a smoke-free environment, the New York State Department of Correctional Services instead provided him with a mask that, according to Muller, made him even more ill. Furthermore, wearing the mask had subjected Muller to widespread ridicule, putting him in even greater personal danger from the breakdown in the respect that the inmates had for him. Whereas a judge in 1996 had barred the plaintiff's negligence and civil rights claims in Muller v. Costello, the court allowed Muller's ADA claim to proceed.

Ruling on posttrial motions, the judge reduced the award to \$300,000 because of the cap on compensatory damages contained in 42 U.S.C. section 1981a(b)(3). The court also rejected the defendant's motion to vacate or reduce the verdict as excessive, ruling that the "plaintiff submitted evidence of discrimination that had taken place over a period of years during which time he was forced to endure mental suffering, embarrassment, economic hardship, actual termination and physical injury. In view of this evidence, the Court finds that the jury award of \$300,000 is not excessive and does not shock the conscience as a matter of law" (Muller v. Costello, 997 F. Supp. 299, 303 [N.D.N.Y. 1998]).

In a more recent case, three asthmatic women sued Red Lobster and Ruby Tuesday restaurants under the ADA. The plaintiffs in Edwards v. GMRI, Inc. (No. 119S93 [Md., Montgomery Cty. Nov. 26, 1997], cited in 13.1 TPLR 3.1 [1998]) said that they attempted to patronize the defendants' restaurants but were forced to leave because of the ETS there. In their complaint, the plaintiffs stated that the defendants' "failure to establish a policy prohibiting smoking in their restaurants throughout the state discriminates against the Plaintiffs on the basis of their disability in their use and enjoyment of" the restaurants (p. 3.3).

Seepage of Smoke From One Dwelling Unit to Another

The 1990s have seen the development of cases in which a nonsmoker living in an apartment or condominium unit is being adversely affected by smoke entering his or her dwelling space from elsewhere. In June 1998, a Boston Housing Court judge ruled in favor of nonsmoking tenants who were being evicted for nonpayment of rent (50-58 Gainsborough Street Realty Trust v. Reece and Kristy Haile, No. 98-02279, Boston Housing Court [1998]). After pleading with the landlord for several months to do something about the problem of smoke from a first-floor nightclub constantly entering their second-floor apartment and disrupting their ability to use and enjoy their

apartment, the tenants got no relief. After they withheld their monthly rent payments of \$1,450, the landlord brought an action in housing court seeking their eviction. The court ruled that "the evidence does demonstrate to the Court that the tenants' right to quiet enjoyment [of their apartment] was interfered with because of the second hand smoke that was emanating from the nightclub below" (p. 34). The court ruled that "as the tenants describe the second hand smoke within their apartment at nighttime, the apartment would be unfit for smokers and non-smokers alike" (p. 7). That interference with the quiet enjoyment of the tenants' apartment was a defense to the effort to evict them. Also, the court found for the tenants in the amount of \$4,350—the same amount that the tenants had withheld over the course of three months.

In Dworkin v. Paley (93 Ohio App. 3d 383, 638 N.E.2d 636 [Ohio Ct. App. 1994]), Dworkin, a nonsmoker, entered into a one-year lease with Paley to reside in a two-family dwelling; the lease was later renewed for an additional one-year term. During the second year, Paley, a smoker, moved into the dwelling unit below Dworkin's. Two weeks later, Dworkin wrote to Paley to tell her that her smoking was annoying him and causing him physical discomfort, noting that the smoke came through the common heating and cooling systems shared by the two units. Within a month, Dworkin vacated the premises. Eight months later, he brought a legal action to terminate the lease and recover his security deposit from Paley. The lawsuit, which alleged that Paley had breached the covenant of quiet enjoyment and statutory duties imposed on landlords (including doing "whatever is reasonably necessary to put and keep the premises in a fit and habitable condition," p. 387) was dismissed on a motion for summary judgment. However, the Cuyahoga County Court of Appeals reversed the dismissal, concluding that a review of the affidavits in the case "reveals the existence of general issues of material fact concerning the amount of smoke or noxious odors being transmitted into appellant's rental unit" (p. 387). The case was thus sent back to the trial court.

In June 1998, a prominent New York law firm, Weil, Gotshal & Manges LLP, sued the owner and landlord of the office building where it is located, as well as the tenant located one floor below, because of ETS seepage into its office space. The firm alleges in its lawsuit, that as a result of the smoke infiltrating into its 29th floor offices, "some of WG&M's partners, associates and employees have suffered illness, discomfort, irritation and endangerment to their health and safety, and/or have been unable to use or occupy their offices or workstations on the WG&M 29th Floor

Premises" (Weil, Gotshal & Manges LLP v. Longstreet Associates, L.P. [N.Y., N.Y. Cty. June 12, 1998], cited in 13.4 TPLR 3.188 [1998]).

Many landlords are not waiting to be sued. The Building Owners and Managers Association International, a trade association for 16,000 office landlords and owners, has been advising its members to lessen their risk of ETS liability by banning smoking whenever possible. During the past two years, the proportion of member office buildings that banned smoking increased from 68 to 80 percent (White 1998).

United States Supreme Court Ruling on ETS in Prisons—Eighth Amendment Issues

Perhaps the most frequent area of litigation involving exposure to ETS has come in a setting where the exposure is both involuntary and inescapable prisons. A landmark case that eventually reached the United States Supreme Court started in Nevada when a nonsmoking prisoner was housed in the same cell as a heavy smoker (McKinney v. Anderson, 924 F.2d 1500 [9th Cir. 1991]). The nonsmoker brought a civil rights lawsuit against the prison officials, claiming that his Eighth Amendment right to be protected from cruel and unusual punishment was being violated due to his constant exposure to ETS. Although his case was thrown out initially by a district court in Nevada, the lawsuit was reinstated by the United States Court of Appeals for the Ninth Circuit. The court ruled that even if the inmate could not show that he suffered from serious, immediate medical symptoms caused by exposure to ETS, compelled exposure to that smoke is nonetheless cruel and unusual punishment if at such levels and in such circumstances as to pose an unreasonable risk of harm to the inmate's health.

On June 18, 1993, the Supreme Court ruled in a 7 to 2 decision that McKinney's case could go forward. The Court affirmed "the holding of the Court of Appeals that McKinney states a cause of action under the Eighth Amendment by alleging that petitioners [the prison officials] have, with deliberate indifference, exposed him to levels of ETS that pose an unreasonable risk of serious damage to his future health" (*Helling v. McKinney*, 113 S. Ct. 2475 [1993]).

ETS and Child Custody Cases

Disagreements between parents who are divorcing can, of course, cover a wide variety of subjects. One of the issues that has increasingly become a significant subject of disputes that have ended up before a judge in probate court has been the exposure to ETS on the part of a child or children caught up in a

custody battle. Over the past 11 years, there have been recorded cases in at least 20 states (Sweda 1998). One of the earliest was *Wilk v. Wilk* (*In re Wilk v. Wilk*, 781 S.W.2d 217 [Mo. App. 1989]). The trial court in this case granted primary custody of the children to the mother, who had been advised by a doctor that the children, one of whom was asthmatic, should not be taken to the father's home because he smoked. The Missouri Court of Appeals ruled that the trial court did not err in awarding custody of the minor children to the mother.

In a case from Kansas, an ex-wife with custody sought permission to move with her children to another state; the ex-husband responded with a motion to obtain custody. The district court did make the change by awarding custody to the ex-husband after finding that the ex-wife's smoking had harmed the children. The ex-wife appealed, arguing that there had been no evidence to prove that her smoking had caused her children's health problems. The court of appeals affirmed the district court's change of custody, noting that there was evidence that her smoking had harmed the children: "That finding is supported by the testimony of three doctors that second-hand smoke aggravated the children's health problems and placed them at risk for further health problems" (In re Aubuchon, 913 P.2d 221 [Kan. Ct. App. Mar. 22, 1996]).

In some cases, the smoking issue is not sufficient to produce a change of custody. For example, in *Helm* v. Helm (01-A-01-9209-CH00365, 1993 WL 21983 [Tenn. App. Feb. 3, 1993]), the trial court awarded custody of a five-year-old child to the father. The mother appealed the divorce decree, arguing before the Court of Appeals of Tennessee that the father smoked around the child. The court said that "Other than exposure to violent movies and cigarette smoke, no evidence is cited that the father has neglected or mistreated the child" (p. 2). The trial court's judgment was affirmed, with the mother being accorded visitation rights. In Baggett v. Sutherland (No. CA 88-224, 1989 WL 5399 [Ark. App. Jan. 25, 1989]), a nonsmoking father attempted to obtain a change in custody on the basis of, among other things, the fact that the mother smoked in the presence of children who were allergic to smoke. Although the lower court had found that circumstances were not so changed as to warrant a change in custody, it did acknowledge that smoking was detrimental to the children. The mother was forbidden to smoke in the home or allow anyone else to smoke in the home; the judge "made it clear that he would exercise continuing jurisdiction over the parties to insure compliance with that order" (p. 3).

Rulings in other cases have been the product of compromise. In *Northcutt v. Northcutt*, a 1997 case, a nonsmoking father objected to ETS around his 2-year-old son, who has asthma and has had repeated respiratory infections, bronchitis, allergies, and earaches (Sweda 1998). As part of a joint custody agreement, a Warren County, Tennessee, judge ordered the mother to keep her son away from ETS. Each parent was to have custody for six months per year.

Victims of Smoking-Related Fires

Smoking is the leading cause of deaths and injuries by residential fire. According to the Building and Fire Research Laboratory of the National Institute of Standards and Technology, cigarettes start more fatal fires than any other ignition source, causing about 30 percent of all fire deaths in this country. For example, in 1989, 44,000 cigarette-ignited fires caused 1,220 deaths, 3,358 injuries, and \$481 million in property damage (Karter 1993).

In 1984, Congress passed the Cigarette Safety Act (Public Law 98-567), creating a Technical Study Group to assess the feasibility of developing a less incendiary cigarette. The group concluded that changing a standard cigarette's diameter, paper porosity, and tobacco density would produce a cigarette that would not transfer enough heat to cause a fire when dropped on most upholstery (Technical Study Group on Cigarette and Little Cigar Fire Safety 1987). The tobacco industry maintains that even if such cigarettes could be manufactured, when smoked they would not burn as thoroughly as current brands, meaning that fire-safe cigarettes would deliver more tar, nicotine, and carbon monoxide to the smoker (Levin 1987).

The prospect of technologies for making less incendiary cigarettes raises the question of whether the manufacturers might be held liable for failure to incorporate such a feature. Until now, product liability litigation for fires caused by cigarettes has met with no more success than smokers' claims for injuries to health. The first such case to produce a judicial decision, Lamke v. Futorian Corp. (709 P.2d 684 [Okla. 1985]), involved a fire started when a cigarette ignited a sofa, resulting in severe burns to much of the plaintiff's body. The Oklahoma Supreme Court applied the socalled consumer expectation test to find that the cigarettes in question were not dangerous to an extent beyond what would be expected by the ordinary consumer. The consumer expectation test, which evolved from comments to section 402A of the Restatement (Second) of Torts, today survives as the law in a minority of jurisdictions (American Law Institute 1995). The prevailing view, endorsed by the current draft of the Restatement (Third) of Torts, would determine liability for defective product design by a risk-benefit standard that evaluates the quality of the manufacturer's design decision by reviewing whether the manufacturer properly weighed the comparative costs, safety, and mechanical feasibility of one or more alternative designs (Green 1995). In Lamke, the court found that evidence regarding the feasibility of manufacturing a less incendiary cigarette was irrelevant to considerations of consumer expectation, but such evidence might be found persuasive in a jurisdiction following a risk-benefit standard for determining design defects. Whether the tobacco companies suppressed research and product development regarding fire-safe cigarettes is under investigation by the antitrust division of the U.S. Department of Justice (Shapiro 1994c).

Fire claims by smokers would face many of the familiar obstacles to recovery but, as two pending claims illustrate, many of the potential plaintiffs in fire litigation are not smokers but third parties untainted by the decision to smoke. In Kearney v. Philip Morris Cos. ([D. Mass. May 11, 1992], cited in 7.2 TPLR 3.65 [1992]), suit was brought on behalf of a woman who died in a fire started by her husband's cigarette. The plaintiff's attorneys focused "on the issue of additives and other manufacturing techniques that cigarette makers use to ensure that cigarettes will stay lit even if they aren't being smoked" (Wilke and Lambert 1992). On February 16, 1996, Judge Robert E. Keeton granted summary judgment⁶ in favor of Philip Morris, holding that even under the more forgiving standard of liability for design defect, "fatal gaps" existed in evidence submitted by the plaintiff in supporting her claim that adoption of an alternative design by the company would have prevented the fire started by Mr. Kearney's cigarette (Kearney v. Philip Morris Inc., 916 F. Supp. 61, 66 [D. Mass. 1996]).

Another cigarette-caused fire claim seeks recovery based on the fire-related injuries received by a 21-month-old infant trapped in her child car seat (*Shipman v. Philip Morris Cos.*, Cause No. 26294 [Tex., Johnson Cty. Oct. 7, 1994], *cited in* 10.1 TPLR 3.91 [1995]).

Enhancing Prohibitory Regulation by Private Litigation

Enforcing Minors' Access Laws

Although selling cigarettes to minors is prohibited in all states and the District of Columbia, retail store employees frequently ignore the law (Lew 1992).

Enforcing these widespread and important statutes is typically left to government officials who have competing commitments and limited sanctioning powers. A pioneering suit, brought by tobacco activists against a Massachusetts convenience store chain, sought to supplement this ineffectual arrangement by private enforcement. The initiative first took the form of a test case, sponsored by the Tobacco Products Liability Project, charging that Philip Morris was engaged in a "civil conspiracy" with the convenience store chain to sell cigarettes to minors. A divided Massachusetts Supreme Court found the conspiracy unproven (Kyte v. Philip Morris Inc., 408 Mass. 162, 556 N.E.2d 1025 [Mass. 1990]). The plaintiffs then refocused the suit directly against the convenience store chain, alleging that it had violated the Massachusetts Consumer Protection Act, which allows consumers to bring civil suits directly against vendors for money damages and injunctions. The suit terminated in a settlement in which the chain agreed to demand proof of age from wouldbe cigarette purchasers. In 1992, the Tobacco Products Liability Project launched a project to research the legal basis for such suits in all 50 states and to provide informational and strategic support for such litigation (Lew 1992).

After the settlement in *Kyte*, the attorney general in Massachusetts, acting under the state's consumer protection laws (Mass. Ann. Laws ch. 93a, sec. 1) began to conduct tests using minors posing as customers to gauge retailer compliance with state bans on tobacco sales to persons under 18 years of age (Mass. Ann. Laws ch. 270, sec. 6). Settlements were reached with several supermarket chains in 1994 for monetary damages as well as implementation of measures designed to reduce the risk of further illegal tobacco sales to minors (Tobacco Products Liability Project 1996). By 1998, state attorneys general offices in 26 states began working with the National Association of Attorneys General and the Tobacco Control Resource Center (1998) to develop approaches to prevent illegal tobacco sales to minors.

Kyte presents an instance of a lawyer functioning as a private attorney general to secure the enforcement of underenforced public standards. This case suggests that restrictions on sales to minors might be enforced more effectively by establishing informational networks and incentives (such as the recovery of attorneys' fees) to facilitate widespread and routine

⁶ A summary judgment is a judgment granted without a formal trial when it appears to the court that there is no genuine issue of fact and that the moving party is entitled to judgment as a matter of law.

exertions by lawyers. Such private enforcement is a well-established feature of a number of regulatory regimes, including consumer credit regulations, securities laws governing insider trading, and bounties paid for apprehending persons who defraud the government. In devising such strategies, the risks of underuse, overuse, and abuse must be identified to frame a scheme of incentives that yields optimum results.

One state's highest court has upheld the legal validity of using the civil provisions of consumer protection statutes to enforce penal laws prohibiting to-bacco sales to minors. The California Supreme Court held that a private and for-profit enterprise had standing under that state's consumer protection laws to maintain a private action in the public interest, even though the underlying penal statute contained no provisions for a private right of action (*Stop Youth Addiction, Inc. v. Lucky Stores, Inc.,* 17 Cal. 4th 553, 557, 71 Cal. Rptr. 2d 731 [1998]).

Restrictions on Advertising

State and local laws restricting the advertising and promotion of tobacco products (see "Advertising and Promotion," earlier in this chapter) provide another occasion for private initiatives. The California Supreme Court held that federal preemption did not extend to bar a suit claiming that the "Joe Camel" advertising campaign targeted minors and thus violated California's ban on unfair business practices (see "A Critical Example: Joe Camel," earlier in this chapter) (Mangini, 875 P.2d 75). This suit, like Kyte, invites consideration of the benefits and costs of the private attorney general device. Such an evaluation must compare the performance of private efforts with actual rather than idealized governmental regulatory activity. For example, the FTC did secure a consent decree against the Pinkerton Tobacco Company (In re Pinkerton Tobacco Co., 115 F.T.C. 60, 1992 F.T.C. LEXIS 35 [Jan. 9, 1992]) to cease promotion of its smokeless products at a televised tractor pull. On the other hand, after FTC staff lawyers recommended in 1994 that the FTC charge R.J. Reynolds Tobacco Company with using the Joe Camel campaign to promote cigarettes to children, the commissioners voted 3 to 2 to take no action (FTC:Watch 1994).

The presence of private attorneys general may add to the limited resources of public regulators. The U.S. Department of Justice recently settled a lawsuit against Madison Square Garden for circumventing the 1971 federal ban on broadcast advertising of cigarettes by placing cigarette advertising where it would be displayed in television broadcasts. The case ended with

a consent decree in which the arena admitted no wrongdoing but agreed to remove cigarette advertising from sites where it would be seen on television (Thomas and Schwartz 1995). The government's enforcement capacity in this area could be amplified if there were sufficient incentives for private litigants.

The International Dimension of Tobacco Litigation

Tobacco Litigation Abroad

The first and second waves of tobacco litigation were uniquely U.S. phenomena, but the third wave has an international dimension that its predecessors lacked. Only a few years after a 1990 survey reported that "there has been no history of tobacco litigation in the [European Community]" (Cooper 1990, p. 291), counterparts of many of the third-wave litigation initiatives have appeared in other countries. In Australia, employees injured by ETS have recovered substantial damages from their employers (Daynard 1994a). A public interest group, the Consumer's Federation of Australia, secured a judicial declaration that the Tobacco Institute of Australia Ltd. had falsely claimed that "there is little evidence and nothing which proves scientifically that cigarette smoke causes disease in non-smokers" (Daynard 1994a, p. 60). A French public interest group, acting as private attorneys general, successfully enforced bans against tobacco advertisements on radio and television (Gourlain v. Societe Nationale D'Exploitation Industrielle des Tabacs et Allumettes [SEITA] [Tribunal de Grande Instance de Montargis Dec. 19, 1996], cited in 11.8 TPLR 3.1073 [1996]). In Canada, a class action suit based on addiction was filed against Canada's three largest tobacco manufacturers. To show that the tobacco companies knew of nicotine's addictiveness, the suit relied on documents uncovered in the United States (Van Rijn 1995). In England, the Legal Aid Board granted certificates of eligibility for legal aid to fund 200 cases brought by smokers alleging that tobacco manufacturers had failed to meet their legal duty to minimize the risks of smoking (PR Newswire 1995). Legal Aid's willingness to finance the litigation comes after a threeyear battle for funding, led by the British group Action on Smoking and Health (Milbank 1995).

Foreign Plaintiffs in the American Courts

Overseas sales are an increasingly important sector of the American tobacco industry: exports grew from 8 percent of total production in 1984 to 35 percent in 1996 (MacKenzie et al. 1994; U.S. Department of Agriculture 1996). The absence of warnings on the

packaging of exports and the aggressive promotional activity might help foreign plaintiffs who brought claims in U.S. courts overcome some of the barriers that have protected tobacco companies from domestic plaintiffs. However, such litigation would face other formidable obstacles, including the problem of establishing a substantive right to recover according to foreign law and an expanded notion of the responsibilities of multinational corporations for merchandise sold overseas. Such an expansion seems unlikely in the light of the reluctance of U.S. courts to provide a forum for foreign victims of corporate misconduct. This reluctance was dramatized in the litigation arising from the 1984 chemical plant explosion in Bhopal, India (Jasanoff 1985; Cassels 1993; Galanter 1994). Although the U.S. courts decided that the case should be tried in India rather than in the United States (In re Union Carbide Corp. Gas Plant Disaster at Bhopal, India in December, 1984, 634 F. Supp. 842 [S.D.N.Y. 1986], aff'd in part 809 F.2d 195 [2d Cir. 1987], cert. denied, 484 U.S. 871, 108 S. Ct. 199 [1987]), the U.S. parent company was required, as a condition of moving the case to India, to submit to the jurisdiction of the Indian courts. A number of rulings in the Bhopal litigation also created the basis for enhanced liability of U.S. multinational corporations for their overseas operations. In a later proceeding, a U.S. court acknowledged that a foreign government might establish itself as the exclusive representative of victims of a mass tort (Bano Bi v. Union Carbide Chems. & Plastics Co., 984 F.2d 582 [2d Cir. 1993]). If any of the current third-wave claims flourish, foreign claims will likely be presented to U.S. lawyers and filed in U.S. courts.

On May 12, 1998, the Republic of Guatemala became the first nation to file a lawsuit against the U.S. tobacco industry for the recovery of public health care expenses (Davis 1998) (*Guatemala v. Tobacco Institute* [D.C. May 12, 1998], *cited in* 13.3 TPLR 3.121 [1998]).

Counterthrust: Tobacco Industry Initiation of Litigation and Other Tactics

The Tobacco Industry Response to the Science of ETS

In its 1993 lawsuit filed in U.S. District Court in Greensboro, North Carolina, the tobacco industry accused the EPA of using improper procedures, including statistical manipulation, to arrive at a predetermined conclusion and sought "a declaration that EPA's classification of ETS as a Group A [known human] carcinogen and the underlying risk assessment are arbitrary, capricious, violative of the procedures required by law, and unconstitutional" (*Flue-Cured Tobacco*

Cooperative Stabilization Corp. v. United States Environmental Protection Agency [M.D.N.C. June 22, 1993], cited in 8.2 TPLR 3.97 [1993]). As discussed earlier in this chapter (see "Health Consequences of Exposure to ETS"), on July 17, 1998, U.S. District Judge William L. Osteen Sr. issued a ruling whereby the court annulled Chapters 1–6 and the Appendices to EPA's Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders (EPA 1992; Meier 1998b). The judge reached his conclusion only after having denied the EPA's motion to dismiss the case even though the EPA had never taken, and indeed had no authority to take, final agency action (e.g., the adoption of a regulation restricting smoking) based on its report (Flue-Cured Tobacco Cooperative Stabilization Corp. v. United States Environmental Protection Agency, 857 F. Supp. 1137 [M.D.N.C. 1994]).

This lawsuit, filed in 1993, was not the first instance of the tobacco industry attacking scientists and their work on ETS. Internal industry memos were cited in an article in April 1998 in the Wall Street Journal: "Determined to keep reports about second-hand smoke from mushrooming, the tobacco industry mobilized a counter attack in the mid-1980s to systematically discredit any researcher claiming perils from passive smoke" (Hwang 1998). In a February 25, 1985, letter, Anthony Colucci, who was a top scientist at R.J. Reynolds Tobacco Company, wrote to H.E. Osmon, a director of public affairs at R.J. Reynolds: "... we anticipate that if [then-EPA scientist James] Repace runs true to form there will be a good deal of media copy written about their [Repace's and naval researcher Alfred Lowrey's] analyses and thus we should begin eroding confidence in this work as soon as possible" (Hwang 1998).

A British-American Tobacco Company memo from 1988 details a meeting at which Philip Morris unveiled its plans to organize the "selection, in all possible countries, of a group of scientists either to critically review the scientific literature on ETS to maintain controversy, or to carry out research on ETS. In each country a group of scientists would be carefully selected, and organized by a national coordinating scientist" (Boyse 1988, p. 2). The Philip Morris plan begins by drawing up a list of "European scientists who have had no previous association with tobacco companies" (p. 2). The scientists are then contacted and

asked if they are interested in problems of Indoor Air Quality: tobacco is not mentioned at this stage. CVs are obtained and obvious "anti-smokers" or those with "unsuitable backgrounds" are filtered out. The remaining scientists are sent a literature pack containing approximately 10 hours of

reading matter, including "anti-ETS" articles. They are asked for a genuine opinion as independent consultants, and if they indicate an interest in proceeding further a Philip Morris scientist makes contact. Philip Morris then expects the group of scientists to operate within the confines of decisions taken by PM scientists to determine the general direction of research, which apparently would then be "filtered" by lawyers to eliminate areas of sensitivity (p. 2).

As this observer notes, "Although the industry is in great need of concerted effort and action in the ETS area, the detailed strategy of Philip Morris leaves something to be desired. The excessive involvement of external lawyers at this very basic scientific level is questionable" (Boyse 1988, p. 275). Chapman (1997) has described this 1988 memo as one that "promises to blow apart the façade that the tobacco industry carries out neutral research into passive smoking" (p. 1569).

A study published in May 1998 in the Journal of the American Medical Association (Barnes and Bero 1998) concluded that of the 37 percent (39 out of 106) of articles reviewed that concluded that ETS is not harmful to health, 74 percent (29 out of 39) of these were written by authors with tobacco industry affiliations. In this survey, the authors included articles whose stated or implied purpose was to review the scientific evidence that ETS is associated with one or more health outcomes. Articles were excluded if they did not focus specifically on the health effects of ETS or if they were not written in English. The authors noted, "In multiple logistic regression analyses controlling for article quality, peer review status, article topic, and year of publication, the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry" (p. 1566). The authors also found that the "conclusions of review articles are strongly associated with the affiliations of their authors. Authors of review articles should disclose potential financial conflicts of interest, and readers should consider authors' affiliations when deciding how to judge an article's conclusions" (p. 1566).

Other Industry-Sponsored Opposition to State Tobacco Control Initiatives and Advocates

Tobacco interests have used the courts proactively against other measures to prevent smoking. The proliferation of third-wave litigation against the tobacco industry has been matched by a more aggressive use of litigation by tobacco interests. For example, the industry and its allies filed a preemptive challenge, on state constitutional grounds, to the

Florida legislation authorizing the state to recover tobacco-related health spending; the suit was ultimately unsuccessful (Agency for Health Care Administration v. Associated Industries of Florida, No. 86,213 [Fla. June 27, 1996], cited in 11.4 TPLR 2.113 [1996]). Similarly, the Governor of Mississippi, along with the tobacco industry, brought unsuccessful proceedings in the Mississippi Supreme Court to stop the Mississippi Medicaid reimbursement suit from going forward (*In* re Kirk Fordice as Governor of Mississippi [Miss. S. Ct.], cited in 12.1 TPLR 2.5 [1997]; In re Corr-Williams Tobacco Co. [Miss. S. Ct.], cited in 12.1 TPLR 2.1 [1997]). The tobacco industry also filed preemptive challenges on federal constitutional grounds to other state lawsuits even before these suits were filed (e.g., *Philip Morris* Inc. v. Harshbarger, Civil Action No. 95-12574-GAO [Mass. Nov. 22, 1996], cited in 11.8 TPLR 2.259 [1996]; Philip Morris Inc. v. Graham, Case No. 960904948 CV [Utah Dist. Ct. Salt Lake Cty.], cited in 12.1 TPLR 2.46 [1997]; Philip Morris Inc. v. Blumenthal, No. 97-7122 [2d Cir. 1997], cited in 12.5 TPLR 2.305 [1997]), and the industry has tried to remove these suits from state to federal court once they were filed (e.g., Massachusetts v. Philip Morris Inc., No. 96-10014-GAO [D. Mass. May 20, 1996], cited in 11.3 TPLR 2.33 [1996]; Louisiana v. American Tobacco Co., No. 96-0908 [La. July 16, 1996], cited in 11.5 TPLR 2.164 [1996]; Maryland v. Philip Morris Inc., No. CCB-96-1691 [Md. July 31, 1996], cited in 11.5 TPLR 2.167 [1996]; Connecticut v. Philip Morris Inc., No. CV960153440S [Conn. Oct. 9, 1996], cited in 11.7 TPLR 2.238 [1996]).

Arguably, the most sweeping litigation measure taken by the tobacco industry was initiated on August 10, 1995, when Philip Morris and others filed suit to block the FDA from regulating the sale, promotion, and distribution of cigarettes to minors. Discussed earlier in this chapter (see "Further Regulatory Steps"), the suit challenged the agency's authority to regulate cigarettes under the Federal Food, Drug, and Cosmetic Act. The lawsuit further charged that the proposed regulations would violate the tobacco companies' freedom of speech and would impair their ability to compete (Collins 1995b).

Tobacco companies have also used litigation tactically to impede the flow of damaging information. Brown & Williamson Tobacco Corporation brought suit against a paralegal aide accused of stealing confidential and potentially incriminating documents (*Wyatt, Tarrant & Combs v. Williams*, 892 S.W.2d 584 [Ky. 1995]). The documents, some of which were ultimately obtained by members of Congress, have shown that the tobacco manufacturers not only knew of both the addictive and the carcinogenic properties of tobacco

use but also concealed the evidence for decades (Shapiro 1994b). R.J. Reynolds brought suit (R.J. Reynolds Tobacco Co. v. John Does, 94-CVS-5867 [N.C., Forsyth Cty. 1994], cited in 9.4 TPLR 2.95 [1994]) to stop the solicitation of damaging information from tobacco insiders (National Law Journal 1994). In March 1994, Philip Morris filed a \$10 billion libel suit in Virginia circuit court against the American Broadcasting Company (ABC) television network, a reporter, and a producer of the network's magazine program Day One. The suit concerned a broadcast segment that focused on Philip Morris' chief competitor, R.J. Reynolds Tobacco Company, and that accused R.J. Reynolds (and, in effect, the entire tobacco industry) of increasing the levels of nicotine in cigarettes to cause addiction among smokers (Chamberlain 1994; Janofsky 1994b). R.J. Reynolds subsequently filed a similar suit. In August 1995, after a siege of unusually aggressive discovery (Frankel 1995), ABC agreed to apologize for its "mistake" in accusing the manufacturers of "spiking" nicotine and to pay for Philip Morris' legal expenses, reportedly some \$15 million (Freedman et al. 1995). ABC preferred to avoid the rigors of further litigation even though "the network's own lawyers felt they had a 65 percent chance of winning the case" (Landler 1995). Philip Morris subsequently took out full-page advertisements in the New York Times, Washington Post, Wall Street Journal, and other newspapers, proclaiming ABC's capitulation. That Philip Morris chose to respond to the news report with legal action, rather than mounting an aggressive advertising campaign as it has done in the past, is seen as reflecting the company's decision to turn over responsibility for public relations to its lawyers (Landler 1995).

Tobacco companies have heavily funded organizations that oppose smoke-free laws and policies. The National Smokers Alliance (NSA), for example, purports to be a membership organization on behalf of smokers. When NSA's Senior Vice President Gary Auxier was asked why his organization, which boasts that it is "a nonprofit, grass-roots membership organization with more than 3 million members," in fiscal year 1996 collected only \$74,000 from dues (enough for 7,400 members) while its total receipts were more than \$9 million, Auxier chose not to answer (Levin 1998). The NSA has vigorously attacked the smokefree bar law in California, including publicizing bar owners who have engaged in civil disobedience (PR Newswire 1998b). Regarding this and other mediaattracting actions, Morain (1998) points out, "Assisting that group is one of the world's largest public relations firms, Burson-Marsteller. The company has a long-standing account with the tobacco industry and is renowned for its ability to generate news coverage. As the organizers tell it, they're merely tapping the grass roots of the body politic, giving a voice to every-day people. Opponents deride the [supposed grass-roots] campaign as 'Astroturf'" (p. A23).

In opposing a lawsuit based on harm from ETS, Philip Morris tried to subpoena scientific researchers' raw data that support epidemiologic research on the link between ETS and lung cancer. A state judge rejected the company's attempt to get the raw data, citing a 1990 Louisiana privacy law. The court found that "enforcement of the subpoenas would leave the researchers with the knowledge throughout continuation of their studies [that] the fruits of their labors had been appropriated by and were being scrutinized by a not unbiased third party whose interests were arguably antithetical to theirs" (*In re Philip Morris Inc.*, 706 So. 2d 665, 1998 La. App. LEXIS 138 [4th Cir. Jan. 28, 1998]).

One important industry tactic is to attack the integrity of leading tobacco control researchers and advocates (Sweda and Daynard 1996). For example, a group called Californians for Scientific Integrity (CSI) sued the University of California in 1997, in part, over Dr. Stanton Glantz's 1994 study on the economic impact of smoke-free restaurant laws. Public officials around the country have used that study to support passage of clean indoor air laws in their cities and towns. Funded by the NSA (Sullivan 1997), the CSI lawsuit alleged that public funds were used improperly in supporting the study. Earlier in 1997, the NSA had paid \$10,000 to Michael Evans, clinical professor of managerial economics at the J.L. Kellogg Graduate School of Management at Northwestern University, to write a report that attacked the Glantz study on smokefree restaurants (Price 1997). In November 1997, Sacramento County Superior Court Judge Joe S. Gray dismissed the CSI lawsuit, saying that "there were no grounds for the case" (Weinstein 1997b). A lawyer for the university wrote in a brief that led to the dismissal that the "true agenda of this action was patently obvious—to muzzle scientists whose research publications and speech on subjects relating to tobacco, tobacco control and the politics of tobacco have been a thorn in the side of the tobacco industry for decades" (Weinstein 1997b).

Industry-Sponsored Litigation Against Local Tobacco Control Efforts

The tobacco industry has used litigation, as well as the threat of litigation, to try to thwart local measures to reduce tobacco use. For example, R.J. Reynolds Tobacco Company financed a 1994 lawsuit filed by local restaurant owners in Puyallup, Washington (Suttle

1994). The suit alleged that the recently enacted ordinance requiring that restaurants be smoke free was preempted because state law permitted smoking sections in restaurants and that the city had unlawfully and substantially deprived the plaintiffs of their rights guaranteed by the U.S. Constitution. Even though the legal arguments seemed dubious, the City Council decided to repeal the ordinance rather than expend the funds necessary to fight the lawsuit (Sweda and Daynard 1996).

In contrast, a board of health regulation banning all public smoking in Northampton, Massachusetts, was unsuccessfully challenged in 1994 (*Alexander's Restaurant, Inc. v. City of Northampton,* Civil Action No. 94-307 [Mass. Super. Ct. Oct. 25, 1994]).

Philip Morris joined with some local businesses to file a lawsuit on February 1, 1994, against the city of San Francisco to try to block an ordinance banning smoking in public buildings (Holding 1994; Schmeltzer and Arndt 1994). The plaintiffs argued that the ordinance was preempted by state rules governing workplace health and safety. However, five months later, California Governor Pete Wilson signed into law a measure banning smoking in most indoor workplaces and allowing local governments to enforce even stricter antismoking ordinances. The tobacco industry shifted away from its lawsuit against San Francisco and sponsored Proposition 188, an initiative that would eliminate local smoking laws and replace them with a weaker statewide standard (Epstein and Russell 1994). Although the tobacco industry spent \$18.9 million on behalf of Proposition 188, about 18 times the amount spent by opponents, California voters resoundingly rejected the measure. Proposition 188 garnered less than 30 percent of the vote (Morain and Ellis 1994).

Local restrictions against cigarette vending machines have increasingly come under attack by cigarette distribution companies suing in several states (Schmit 1994; Sullivan 1994). In one such instance, the Massachusetts Supreme Judicial Court unanimously upheld a Provincetown bylaw that banned cigarette vending machines from that town (*Take Five Vending*, *Ltd. v. Town of Provincetown*, 415 Mass. 741, 615 N.E.2d 576, 1993 Mass. LEXIS 440 [Mass. Mar. 4, 1993]).

In addition to the above-mentioned cases, other local ordinances forbidding tobacco use in public places and regulating various forms of outdoor advertising have been challenged. As discussed earlier in this chapter (see the case description of *Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore* in a subsection of "Constitutionality of Regulating Tobacco Advertising"), the outcomes of these challenges have been mixed.

Anticipatory Effects

Law works not only by coercive imposition but also by signals about authoritative (and potentially changeable) norms and about the potential disposition of legal coercion. Litigation may have an effect not only on those who are parties to it but also on other potential legal actors (plaintiffs, defendants, and attorneys who learn about the litigation) (Galanter 1983). Depending on the outcome of a litigation, similarly situated injured parties, for example, may abandon or modify—or conversely, may decide to continue—their risk-creating behavior or may be either encouraged to make a legal claim or discouraged from claiming. Lawyers may be encouraged to mount or discouraged from mounting claims or defenses. Uninvolved actors (such as potential business partners) who anticipate dealing with parties or potential parties may respond to litigation signals by modifying (or even terminating) their dealings with those parties. Such signals may be derived not only from authoritative decisions but also from the process of the litigation itself, which may exhibit advantages to be gained or costs to be avoided. For example, news organizations viewing the fierce and expensive industry response to critical depiction may hesitate to portray industry practices negatively (Freedman and Stevens 1995).

More often, third-wave tobacco litigation provides dramatic evidence of the indirect, anticipatory effects of litigation on reducing tobacco use. In early 1995, three prominent manufacturers recoiled from business dealings with cigarette makers to avoid the risk of getting embroiled in liability litigation. The Manville Corporation sued R.J. Reynolds Tobacco Company for a declaratory judgment that the corporation does not have a contract to supply fiberglass for cigarette filters (Appleson 1995). A few days later, Harley-Davidson, Inc., responding to a 1993 suit by the Lorillard Tobacco Company to enforce an agreement licensing the motorcycle maker's name for a brand of cigarettes, countersued, alleging that tobacco liability risks reduced Lorillard's ability to fulfill its contract (Rose and Hwang 1995). Papermaker Kimberly-Clark Corporation (which had been named a defendant in the West Virginia health care provider suit), the world leader in tobacco papers, decided to sell its cigarette paper business. The company denied that liability fears or shareholder activism played any part in its decision, but analysts said that such concerns were dominant factors (Collins 1995a). Other companies, such as Pfizer, have adopted policies "prohibiting units from doing business with Big Tobacco and its suppliers" (Mallory 1995, p. 39).

Another set of actors responsive to signals about liability are insurers. Presumably, virtually all of the suppliers and professionals who serve cigarette makers carry liability insurance. The tobacco manufacturers themselves have been insured for at least some liability risks, although the amount of insurance coverage of the tobacco companies is unknown (Reidy and Carter 1995). If any of these insured parties are found liable for promoting or selling tobacco products, the insurers can be expected to contest coverage, using as defenses against liability to the insured many of the same arguments that plaintiffs use to establish the liability of the insured. If, for example, liability involves attribution to the industry of knowledge of a causal link to disease or concealment of that information, then to defeat coverage, the insurer may likewise claim that the insured had wrongfully and knowingly obtained coverage for a business practice whose dangers were concealed from the insurer. "In effect," note two analysts, "the insurance industry will have to prove the very thing the policyholder is trying to deny in the tobacco-related suits" (Reidy and Carter 1995, p. S38). Thus a "breakthrough" by tobacco plaintiffs may lead to a "second front" of liability battles between tobacco defendants and their insurers.

Indeed, in 1996, Imperial Tobacco Limited (No. 500-05-014084-964 [Canada S. Ct., Prov. of Quebec, Dist. of Montreal Jan. 12, 1996], cited in 11.1 TPLR 3.39 [1996]) filed suit in the Superior Court of Quebec against two Toronto-based liability insurance companies—American Home Insurance Company and Commercial Union Assurance Company of Canada—demanding that they pay legal costs and any damages arising from a class action suit filed against Imperial in Ontario by Mr. David Caputo and three other persons in 1995. The Canadian class action suit, which has not yet been resolved, seeks damages on behalf of nicotine-addicted persons who have suffered because of their addiction to nicotine. Imperial claims to have had policies issued by the insurers obligating them to reimburse Imperial for legal costs incurred in the class action and to pay any further costs they may incur in this matter. The tobacco company is, in essence, asking the Superior Court of Quebec for a declaration that the two named insurance companies must pay all of Imperial's legal fees and all sums awarded by an eventual finding of liability by the Ontario court (*Tobacco Products Litigation Reporter* 1995b).

Finally, the investment community is greatly interested in the potential effects of legal liability on the future profitability and solvency of the tobacco companies. Tobacco cases are closely tracked by investment analysts, and "even interim events in peripheral

cases can propel share prices in one direction or another" (Orey 1995, p. 70). The overhang of potential liability casts a shadow on tobacco stocks. Opinions differ about just how much these stocks are discounted for liability, but there is general agreement that the removal of the liability shadow would be worth many billions in increased stock value. This volatile combination of possible liability and latent value means that any breach in the previously impregnable liability ramparts would inaugurate a period of pronounced instability among tobacco investors. Some analysts imagine a zone of agreement that would locate a comprehensive settlement, which would in turn unlock the unrealized value of tobacco stocks while providing generously for the victims of tobacco. However, because present litigants cannot preclude future plaintiffs, it remains unclear whether litigation can provide the finality and closure that a comprehensive settlement would require. Litigation can set off ramifying effects and in general advance a formerly sluggish or obstructed state of affairs, but it is not clear whether it can contain these effects or design an all-encompassing resolution or policy.

Criminal Proceedings

Another arena in which attention is being given to the activities of the tobacco industry is the criminal justice system. Since 1995, the U.S. Department of Justice has conducted an ongoing investigation of the alleged violation of federal criminal laws by tobacco companies, tobacco company executives, tobacco industry-supported trade and scientific associations, and other entities that have conducted business with the tobacco industry.

The Justice Department initiated a formal investigation of the tobacco industry in response to the filing in 1994 of a comprehensive legal analysis, referred to as a prosecution memorandum, by Representative Martin T. Meehan (D-MA) with the U.S. Attorney General (Hohler 1994; Mallory 1994, 1995; Meehan 1994; Schwartz 1994; Miga 1995; Reuters 1996; Rodriguez and Taylor 1998). The prosecution memorandum petitioned the Justice Department to consider allegations that tobacco companies, tobacco company executives, and others had violated multiple criminal laws by providing false information to the FDA and the U.S. Surgeon General (18 U.S.C. section 1001), committing perjury in testimony before Congress (18 U.S.C. section 1621), perpetrating mail and wire fraud (18 U.S.C. sections 1341 and 1343, respectively), engaging in deceptive advertising practices (15 U.S.C. section 52), and violating federal conspiracy and racketeering laws (18 U.S.C. sections 371 and 1962, respectively) (Meehan 1994; Shane 1997; *Corporate Crime Reporter* 1998; Clifford E. Douglas. The criminal investigation of the tobacco industry. Speech to the 13th Annual Conference of the Tobacco Products Liability Project; May 31, 1998; Boston; unpublished data).

Nature, Extent, and Focus of the Criminal Investigation

The Justice Department's investigation began as a preliminary inquiry focused on alleged perjury arising out of testimony delivered under oath by seven tobacco company executives who stated before a congressional subcommittee on April 14, 1994, that they did not believe that nicotine is addictive. The initial inquiry was later expanded to a formal grand jury investigation to address broader allegations that tobacco companies had, among other things, violated 18 U.S.C. section 1001.

Section 1001 prohibits the making of false statements to agencies and officials of the federal government (Hilts 1995; Novak and Freedman 1995; Appleson 1996; Blum 1996; Freedman 1996; Thomas and Schwartz 1996; Stohr 1997). In contrast to the level of proof required for a showing of perjury, section 1001 does not require a showing that a person knowingly lied under oath. It also allows prosecution for the withholding of information. Besides addressing potential section 1001 violations, the investigation continues to focus on other allegations of criminal conduct, including fraud, conspiracy, and racketeering (Cole and Taylor 1998; Corporate Crime Reporter 1998; Davis and Duffy 1998; Douglas, unpublished data; Duffy and Taylor 1998; Meier 1998c).

As of mid-1998, two federal grand juries were considering evidence of alleged tobacco industry wrongdoing. One grand jury was assigned to hear evidence presented by prosecutors from the Fraud Section of the Justice Department's Criminal Division regarding the broad allegations of criminal misconduct described above. The second grand jury was assigned to review information presented by the U.S. attorney for the Eastern District of New York. The work of the second grand jury concerned a related criminal investigation whose focus is an alleged conspiracy by major tobacco manufacturing companies to suppress legitimate medical research and promote biased research through the industry-sponsored Council for Tobacco Research. The Justice Department coordinated these complementary investigations (Cohen and Geyelin 1996; Thomas and Schwartz 1997; Davis and Duffy 1998).

A third criminal investigation was begun in 1995 to determine whether a major cigarette manufacturing company may have committed securities fraud by failing to disclose all it knew about nicotine. Under securities laws, companies are required to disclose significant information that may affect their stock price. The third investigation was initiated by the U.S. attorney for the Southern District of New York, following the publication of an investigative news article that reported that, based on a review of 2,000 pages of previously undisclosed documents, Philip Morris Companies Inc. had conducted many years of secret research into the pharmacologic effects of nicotine on the human brain and central nervous system (Freedman and Lambert 1995; Hilts and Collins 1995). The securities fraud investigation subsequently was consolidated with the main Justice Department investigation (Philip Morris Companies Inc. 1998).

Federal prosecutors have interviewed witnesses, compiled comprehensive company dossiers, and issued subpoenas, all under the supervision of the U.S. Attorney General. Several of the major cigarette manufacturing companies, such as R.J. Reynolds Tobacco Company and Philip Morris Companies Inc., as well as others, confirmed publicly that they are the subject of federal criminal investigations relating to the matters described above and that employees of the companies have received requests for information, including orders to produce internal documents and subpoenas to testify before the grand juries (Goshko 1995; Hilts 1995; Miga 1995; Associated Press 1996a,b; Bloomberg Business News 1996a,b; Federal Filings-Dow Jones News 1996; Johnston 1996; Jones 1996; Reuters 1996; Thomas and Schwartz 1996; Tribune News Services 1996; Weiser and Schwartz 1996; Shaffer 1997; Philip Morris Companies Inc. 1998).

In an April 1998 announcement that it had reached a cooperation agreement with a cigarette manufacturing company in support of the criminal investigation, the Justice Department identified five main subject matter areas on which it was focused (U.S. Department of Justice 1998). These were industry knowledge of the health consequences of smoking cigarettes and the addictive nature of nicotine; the targeting of children and adolescents by the industry; the manipulation of nicotine by the industry; control of research by the Council for Tobacco Research, including special projects conducted under the auspices of the council; and lawyer involvement in directing research or crafting false or misleading statements by any of the tobacco companies to the Congress, the FDA, and the American consumers concerning the above.

The announcement of the cooperation agreement was interpreted by legal experts as a sign that the criminal investigation was accelerating and the Justice Department was likely to file broad conspiracy charges against major cigarette companies in the future (Cole and Taylor 1998; *Corporate Crime Reporter* 1998; Douglas, unpublished; Duffy and Taylor 1998; Keil 1998; Levin and Ostrow 1998; Schwartz 1998a).

Key Sources of Evidence

The gathering of evidence by the Justice Department was advanced by the increased availability of an array of outside resources. These included the results of the extensive investigation of the tobacco industry conducted by the FDA from 1994 to 1996. The FDA's administrative record and investigative files were made available to the Justice Department, providing prosecutors and investigators with a significant body of information concerning tobacco manufacturers' knowledge of the addictive nature of nicotine and of the manipulation and control of the substance (*Federal Register* 1995b, 1996).

Another important source of information for Justice Department officials was the voluminous hearing record produced over a 10-month period in 1994 by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce in the U.S. House of Representatives (1995a,b,c,d). The subcommittee, chaired by U.S. Representative Henry A. Waxman (D-CA), held numerous hearings in which testimony was obtained from a variety of witnesses, including the commissioner of the FDA, other federal government health officials, experts in nicotine addiction, tobacco company representatives, and former tobacco company scientists, among many others. In addition, Representative Waxman made available hundreds of previously secret nicotine research documents from the largest cigarette manufacturer by reading them into the public record on the floor of the House of Representatives in July 1995 (Associated Press 1995; Congressional Record 1995a,b; Schwartz 1995).

A third significant source of evidence in support of the Justice Department's criminal investigation was the emergence of internal tobacco company documents and testimony obtained in private lawsuits brought against tobacco industry defendants. Starting in 1994, these civil cases were initiated by state attorneys general, private classes of allegedly addicted and injured smokers, and individual plaintiffs, as described earlier in this chapter (see "The Third Wave of Tobacco Litigation"). The simultaneous litigation of numerous civil suits and the Justice Department's

pursuit of its criminal investigation have produced a notable synergy. Millions of previously undisclosed tobacco industry documents that were obtained through the discovery process in civil lawsuits became, in many instances, readily accessible to federal prosecutors (Curriden and Rodrigue 1997; Geyelin 1998; Meier 1998c; Rodriguez and Taylor 1998; Scherer and Rybak 1998; Schwartz 1998c).

Initial Results of the Criminal Investigation

The Justice Department's ongoing investigation resulted in a first conviction in 1998. Under the terms of an agreement with the government, a biotechnology company, DNA Plant Technology Corporation, pleaded guilty to a misdemeanor charge of conspiring to break a law that had made it illegal to export tobacco seeds. The company was found to have engaged in such unlawful conduct in cooperation with a leading cigarette manufacturing company, identified as an unindicted coconspirator, with whom it had contracted to patent and develop a genetically altered tobacco code-named Y-1, which contained approximately twice the nicotine of ordinary tobacco. According to the Justice Department, the prosecution memorandum submitted by Representative Meehan, and the FDA, one of the goals of the cigarette company in conspiring with the biotechnology company was to develop a reliable source of supply of highnicotine tobaccos that could then be used to control and manipulate the nicotine levels in several popular cigarette brands (Meehan 1994; Federal Register 1995b, 1996; Meier 1998d; Neergaard 1998; Schwartz 1998b; Schwartz and Connolly 1998; Taylor 1998; Taylor and Rodriguez 1998; Weinstein 1998b).

Beginning in 1997, the threat of criminal liability led certain individuals associated with the tobacco industry, such as Thomas S. Osdene, Ph.D., former Director of Research for Philip Morris Companies Inc., and Roger R. Black, current Director of Leaf Blending for Brown & Williamson Tobacco Corporation, to decline to answer questions under oath, choosing instead to invoke the Fifth Amendment right against self-incrimination (Geyelin 1997; Meier 1997; Weinstein 1997a; Anderson 1998). Some officials sought immunity from prosecution in exchange for their cooperation. Such offers were met with mixed responses from the Justice Department. Typically they were rejected, but in one publicized instance a request for immunity was granted (Geyelin 1997; Stohr 1997; Weinstein 1997a). The Justice Department granted immunity to Janis A. Bravo, a scientist formerly with DNA Plant Technology Corporation and coholder of the patent for a high-nicotine tobacco plant called Y-1, developed for Brown & Williamson Tobacco Corporation.

Prognosis for Future Actions Through the Criminal Justice Process

Federal prosecutors possess considerable discretion both in terms of bringing charges against alleged wrongdoers and, in the event a strong case is developed, in seeking concessions from criminal targets in the plea-bargaining process. In light of these options, the Justice Department may seek to require tobacco manufacturing companies to modify their advertising and marketing practices so as to render them unappealing to young people, stop manipulating nicotine or using nicotine-enhancing chemicals, pay the federal government significant monetary penalties, and submit to regulation by the FDA (*Corporate Crime Reporter* 1998; Douglas, unpublished data).

Given the breadth and complexity of the criminal investigation of the tobacco industry, as well as the substantial burdens of proof that prosecutors must satisfy pursuant to the federal criminal statutes noted above, it is not possible to predict the outcome of the current criminal investigative process. From its inception, the investigation was anticipated to be a lengthy, complicated operation, in part because of the government's responsibility to process and review millions of pages of documents obtained from the tobacco industry and other sources (Thomas and Schwartz 1996).

With the Justice Department's accumulation of a growing body of evidence, including company documents and grand jury testimony, as well as the cooperation of the Liggett Group Inc. in support of the government's investigation, some legal experts have described the investigation as likely to result in further action (Cole and Taylor 1998; Corporate Crime Reporter 1998; Douglas, unpublished data; Duffy and Taylor 1998; Keil 1998; Levin and Ostrow 1998; Schwartz 1998a). One recent indicator that the issuance of indictments might be near was the delivery by Justice Department officials of letters to Brown & Williamson Tobacco Corporation and its officials, formally notifying them that they are the targets of a criminal investigation and that they face possible prosecution (Davis and Duffy 1998; Meier 1998c; Wall Street Journal 1998).

Further criminal action against the tobacco industry also raises the likelihood of diluting the influence of the industry's political lobby, thereby strengthening the ability of public health proponents to advocate for more stringent regulation of the

manufacture, sale, distribution, advertising, and promotion of tobacco products (Douglas 1998).

Comment

After 40 years in which two waves of product liability litigation proved unavailing, there has been a recent upsurge of investment and innovation in tobacco litigation. This third wave of litigation departs from its predecessors in various ways:

- It moves away from exclusive reliance on smokers as plaintiffs, because so many cases have been decided against them as the victims of their own, informed behavior choices. Plaintiffs now include states, cities, pension funds, private health care providers, and persons exposed to ETS, none of whom can be blamed for smoking in the face of warnings.
- It multiplies the range of legal issues. Instead of focusing exclusively on common-law tort doctrine, third-wave litigation also invokes various statutory claims under consumer, antitrust, and other protective legislation.
- It expands from the classic private lawsuit by a discrete plaintiff to the class action device.
- It expands from solely seeking monetary damages to including claims for injunctive relief, medical monitoring, and the recovery of attorneys' fees.
- It shifts from a pure model of private law to mixed strategies in which private law is used to effectuate public policy by defending public fiscal interests and by enhancing the performance of statutory and regulatory controls of tobacco.
- It enlarges the roster of claimants' lawyers from those who specialize in representing individual plaintiffs in personal injury cases to include mass tort specialists and entrepreneurial securities class action lawyers. These attorneys, who typically practice in larger firms than individual plaintiff attorneys and have greater financial resources, are joined in more complex coalitions, including alliances with government lawyers.

Considerable uncertainty surrounds each of the several third-wave litigation initiatives and their potential contribution to reducing tobacco use. The prospect of using private law in these ways has captured attention only recently. In a wide-ranging 1993 review of tobacco policy (Rabin and Sugarman 1993), virtually all of the attention to private law was devoted

to smokers' product liability litigation. The newer legal theories that are now available to plaintiffs have considerable potential. Just how these initiatives will fare depends both on developments within the legal system and on forces outside it.

Normally, law incorporates and reflects public opinion. In a setting where smoking declines and becomes disreputable, particularly among the educated and influential (Zimring 1993), where smokers are increasingly viewed either as victims of coercion and addiction or as a minority group becoming more distanced from others (Gusfield 1993), and where evidence accumulates that the tobacco companies aggressively recruit new smokers and suppress knowledge of harmful effects of smoking, the law can be expected to respond to pressures to extend accountability and to provide remedies, if not to smokers then to those who are otherwise adversely affected by smoking.

However, other forces are working against an enlarged role for the civil justice system in the effort to reduce tobacco use. Important groups, displeased with the expansion of legal accountability, have mounted a protracted and influential campaign to curtail the civil justice system and weaken the position of claimants within it (Galanter 1993, 1994). Apart from these external constraints, the very magnitude of tobacco injury—the vast number of potential claimants involved—raises apprehension about the courts' institutional capacities to respond. Driven by the desire to conserve their scarce resources, courts will find ways to ration the judicial attention bestowed on any sizable set of related cases (Sanders 1992). As the size of the potential victim class increases, the chances for individualized judicial resolution decrease. It has been argued that the litigation about Agent Orange, the Bhopal disaster, and asbestos-related injury should be viewed as instances in which the sheer number of claims "simply overwhelm[ed] the capacity of legal institutions to meet victim compensation needs" and led to improvisation of formulaic administrative solutions (Durkin and Felstiner 1994, p. 159; cf. Henderson and Twerski 1991, on judicial aversion to such massive projects).

A balanced assessment of the possible contribution of private law initiatives to the effort to reduce tobacco use must consider not only the costs and benefits of the various initiatives but also the likelihood of accomplishing similar results by other institutional means (Komesar 1994). Typically, private law involves high transaction costs (Galanter 1994). Private law is by definition the creature of independent actors whose operations are not centrally managed and are at most partially and intermittently coordinated; each actor is trying to maximize its own gains as it defines them. No single initiative or the sum of such efforts will necessarily produce an optimal policy to reduce tobacco use. Yet private law may be a valuable component in reducing tobacco use precisely because it is an arena in which multiple courses of action are advanced by energetic champions who are open to new ideas and who, independent of government, can undertake innovative and even risky initiatives without securing official approval or competing for priority with other political commitments. Such initiatives may thus be able to stimulate and shape policy solutions. Other than as an agent or catalyst, however, it seems unlikely that the judicial forum, in a setting involving politically powerful actors and an unpredictable number of inchoate future claimants, will itself provide the ultimate policy resolution.

Conclusions

Advertising and Promotion

- Since 1964, numerous attempts to regulate advertising and promotion of tobacco products have had only modest success in restricting such activity.
- 2. Current regulation in the United States is considerably less restrictive than that in several other countries, notably Canada and New Zealand.
- Current case law supports the contention that advertising does not receive the protections of free speech under the First Amendment to the Constitution that noncommercial speech does.

Product Regulation

- 1. Warning labels on cigarette packages in the United States are weaker and less conspicuous than those of other countries.
- Smokers receive very little information regarding chemical constituents when they purchase a tobacco product. Without information about toxic constituents in tobacco smoke, the use of terms such as "light" and "ultra light" on packaging and in advertising may be misleading to smokers.
- Because cigarettes with low tar and nicotine contents are not substantially less hazardous than higher-yield brands, consumers may be misled by the implied promise of reduced toxicity underlying the marketing of such brands.
- 4. Additives to tobacco products are of uncertain safety when used in tobacco. Knowledge about the impact of additives is negligible and will remain so as long as brand-specific information on the identity and quantity of additives is unavailable.
- Regulation of tobacco product sale and promotion is required to protect young people from influences to take up smoking.

Clean Indoor Air Regulation

- Although population-based data show declining ETS exposure in the workplace over time, ETS exposure remains a common public health hazard that is entirely preventable.
- Most state and local laws for clean indoor air reduce but do not eliminate nonsmokers' exposure to ETS; smoking bans are the most effective method for reducing ETS exposure.
- Beyond eliminating ETS exposure among nonsmokers, smoking bans have additional benefits, including reduced smoking intensity and potential cost savings to employers. Optimal protection of nonsmokers and smokers requires a smoke-free environment.

Minors' Access to Tobacco

- Measures that have had some success in reducing minors' access include restricting distribution, regulating the mechanisms of sale, enforcing minimum age laws, having civil rather than criminal penalties, and providing merchant education and training. Requiring licensure of tobacco retailers provides both a funding source for enforcement and an incentive to obey the law when revocation of the license is a provision of the law.
- 2. The effect of reducing minors' access to tobacco products on smoking prevalence requires further evaluation.

Litigation Approaches

- 1. Two historic waves of tobacco litigation were initiated by private citizens, were based largely on theories of negligence and implied warranty, and were unsuccessful.
- A third wave has brought in new types of claimants, making statutory as well as common-law claims and using more efficient judicial procedures. Although several cases have been settled for substantial money and have yielded public health provisions, many other cases remain unresolved.
- 3. Private law initiative is a diffuse, uncentralized activity, and the sum of such efforts is unlikely to produce optimal results for a larger policy to reduce tobacco use. On the other hand, the litigation actions of individuals are likely to be a valuable component in some larger context of strategies to make tobacco use less prevalent.

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Introduction

This chapter reviews recent research on economic aspects of tobacco production and the use of tobacco products in the United States. Much of the chapter focuses on the impact of various governmental policies related to tobacco. As was the case with the regulatory effects examined in Chapter 5, the "interventions" recounted here require a broader definition and a different set of measurement tools (see Chapter 1).

The chapter first considers the supply of tobacco and tobacco products. The history of tobacco and the evolution of the cigarette industry in the United States are briefly discussed. More comprehensive summaries can be found in the 1992 Surgeon General's report Smoking and Health in the Americas (U.S. Department of Health and Human Services [USDHHS] 1992) and in several sources cited herein. Tobacco-related supplyside policies are reviewed in more detail. In particular, the tobacco support program is closely examined, and its economic implications are discussed. That section is followed by a discussion of the impact of tobacco taxes and other prevention policies on prices in the highly concentrated U.S. cigarette markets. U.S. trade policy relating to tobacco and tobacco products is reviewed, followed by a discussion of the domestic and international impact of these policies. Finally, the economic impact of tobacco on the U.S. economy and its implications for policy are described.

In the second part of the chapter, economic studies of the demand for tobacco are reviewed. Although several factors affect the demand for tobacco products, this section focuses on the effects of tobacco prices (particularly as they are raised by increasing tobacco taxes) on demand. Recent econometric and other informative studies of the demand for tobacco products are described. (A more detailed review of early studies is contained in the 1989 Surgeon General's report *Reducing the Health Consequences of Smoking: 25 Years of Progress* [USDHHS 1989].)

The third part of the chapter focuses on the most important economic policy in the campaign to reduce tobacco use—higher cigarette excise taxes. This section reviews the alternative rationales for imposing cigarette and other tobacco taxes, including a historical or comparative approach, one based on the economic costs of cigarette smoking, one focused on the health benefits of higher taxes, and one based on the revenue potential of the taxes. Discussion of the appropriate level of the taxes suggested by each approach follows its review.

Supply of Tobacco and Tobacco Products

Tobacco is a truly American plant. The first known evidence of tobacco use is depicted in carvings on a Mayan temple in Chiapas, Mexico, that date from A.D. 600–900 (Wagner 1971). Europeans were first introduced to tobacco in 1492 when American Indians presented gifts of the substance to Christopher Columbus. On Columbus' return home, tobacco was introduced to Spain and throughout Europe. Tobacco was widely grown by early English settlers in America and was exported from the colonies to England, where it was reexported to many other destinations. Colonial tobacco exports to England grew from 100,000 pounds in 1620 to 100 million pounds just before the Revolutionary War, making tobacco the single most important

commodity exported from the colonies to England (Johnson 1984). Indeed, tobacco was so important in some colonies that it was sometimes used as the unit of account (Johnson 1984).

The high tariffs imposed by England on tobacco and other imports from the colonies contributed to the start of the Revolutionary War. In the newly formed United States, tobacco soon became the leading agricultural export commodity. The tobacco industry played a significant part in the U.S. economy of the 19th and early 20th centuries. Although tobacco consumption has declined in recent years, it is still economically important in major tobacco-producing states.

In many ways, tobacco is an ideal crop to grow. It grows under a variety of soil and climatic conditions and thrives under specific but fairly common circumstances. The tobacco plant has prodigious leaf growth yet takes up relatively little field space, and the financial return for tobacco is both absolutely and relatively high compared with other agricultural commodities (Goodman 1993). For example, in 1993, the per acre value of tobacco in the United States, \$3,780, was well above the values for other crops (Grise 1995). Because of these factors, tobacco is grown in more than 120 countries and thus is the most widely grown nonfood crop in the world (cotton acreage substantially exceeds that of tobacco, but tobacco is grown in about twice as many countries as cotton is). In the United States, tobacco is a highly profitable crop for other reasons, including agricultural price supports that guarantee relatively high prices; the availability of loans from government, or tobacco companies, or both; the provision of seed, fertilizer, and other agricultural input from external sources; and export subsidies (Food and Agriculture Organization of the United Nations 1990). Counter to these profitable arrangements, tobacco growing is relatively labor-intensive, demands heavy use of fertilizers and pesticides, and often requires the use of fuel for tobacco curing.

Tobacco is a storable product, and its quality initially improves with age. After being harvested, tobacco goes through several steps in a processing course, including sorting and grading (according to type and quality) and curing and drying by various techniques (including flue, fire, sun, and air curing). Most of this processing is done on the tobacco farm before the product is sold to the producers of cigarettes and other tobacco products.

Several types of tobacco are grown in the United States and throughout the world. Burley and flue-cured tobacco, the primary ingredients in cigarettes, are the most important of the domestically grown types of tobacco; they account for about 93 percent of total production (Tables 6.1 and 6.2). Most burley tobacco is grown in Kentucky and flue-cured tobacco is grown primarily in North Carolina. These two states account for about two-thirds of domestically grown tobacco.

Although several other types of tobacco are grown in 14 other states, about one-quarter of the total domestic production is concentrated in Georgia, South Carolina, Tennessee, and Virginia. Other important types of domestically grown tobacco include Maryland tobacco, an important component of cigarettes because it burns slowly; fire-cured tobacco, which is used in snuff; dark air-cured and sun-cured tobaccos, which are used in chewing tobacco and small

dark cigars; and other types used for cigar leaf (Johnson 1984).

In 1992, the United States had about 124,000 farms producing tobacco, down sharply from 330,000 in 1964 (U.S. Department of Agriculture [USDA] 1998a). Tobacco was grown on an estimated 644,000 acres in 1999, down sharply from its recent peak of 836,000 acres in 1997. In 1998, tobacco farms produced almost 1.5 billion pounds of tobacco at a total value of approximately \$2.7 billion. After inflation is accounted for, however, the value of domestically grown tobacco has fallen since 1980. More than 1.4 billion pounds of domestically grown tobacco were used in 1998, with less than two-thirds of this used domestically, while the remainder was exported (Table 6.3).

Domestic consumption of domestically grown, unmanufactured tobacco fell steadily from the 1950s through the early 1990s, from a peak of almost 1.6 billion pounds in 1952 to about 900 million pounds in 1993 (Table 6.3). After rising for a few years, domestic consumption of domestically grown tobacco fell to just over 900 million pounds in 1998. Declining prevalence of tobacco use is not the only—or even the main factor behind the long-term decrease; domestically produced cigarettes contain about 35 percent less tobacco than they did 40 years ago (Womach 1994b). Furthermore, the use of imported tobacco in domestically produced cigarettes has greatly increased in recent years. In 1950, the imported tobacco content of domestically produced cigarettes was approximately 6 percent. By 1993, this proportion had risen to about 40 percent. The increased use of foreign tobacco is partly due to improvements in the quality of this tobacco, its relatively low price, reduced barriers to trade in tobacco, and the increased market penetration of lower-quality generic cigarettes, which include a higher share of imported tobacco.

The decline in the domestic use of tobacco grown in the United States has been offset somewhat by increased exports of domestically grown tobacco. However, unmanufactured exports peaked at 765 million pounds in 1978 and have fallen fairly steadily since; in 1998, total exports were 539 million pounds (Table 6.3). The largest export markets for U.S.-grown tobacco in recent years have been Japan, Germany, the Netherlands, and Turkey (USDA 1998a).

The combination of declining U.S. tobacco exports and increased tobacco production in foreign countries (particularly Argentina, Brazil, Malawi, and Zimbabwe) has reduced the U.S. share in world tobacco exports. In 1960, the United States' share of world tobacco exports was 27 percent. By 1997, this share had fallen to 11 percent. Moreover, in 1993, the United States

Table 6.1. Burley tobacco production and value, 1975–1998

Crop year	Production (million lbs.)	Average price to farmers (cents/lb.)	Real price to farmers* (cents/lb.)	Farm value (million \$)	Real farm value* (million \$)
1975	640	105.5	196.1	675.1	1,254.8
1976	664	114.2	200.7	758.3	1,332.7
1977	613	120.0	198.0	735.6	1,213.9
1978	614	131.2	201.2	805.8	1,235.8
1979	472	145.2	200.0	685.6	944.4
1980	558	165.9	201.3	925.7	1,123.4
1981	726	180.7	198.8	1,311.9	1,443.2
1982	777	181.0	187.6	1,406.4	1,457.4
1983	527	177.3	178.0	934.4	938.1
1984	674	187.6	180.6	1,264.4	1,217.0
1985	542	159.7	148.4	865.6	804.4
1986	420	156.5	142.8	657.3	599.7
1987	428	156.3	137.6	669.0	588.9
1988	468	161.0	136.1	753.5	636.9
1989	498	167.2	134.8	832.7	671.5
1990	592	175.3	134.1	1,037.8	794.0
1991	657	178.8	131.3	1,174.7	862.5
1992	700	181.5	129.4	1,270.5	905.6
1993	627	181.6	125.7	1,138.6	788.0
1994	568	184.1	124.2	1,045.7	705.6
1995	480	185.5	121.7	890.4	584.3
1996	516	192.2	122.5	991.8	632.1
1997	629	188.5	117.4	1,185.7	738.7
1998 ⁺	590	190.3	116.7	1,123.3	688.9

^{*}Real price to farmers and real farm value are obtained by dividing the nominal average price and farm value by the national Consumer Price Index; the average of 1982–1984 is the benchmark.

†Subject to revision.

Sources: U.S. Department of Agriculture 1996, 1999a; U.S. Department of Labor 1999.

lost to Brazil its historically dominant position as the leading exporter of tobacco (Womach 1994b).

These trends for domestically grown, unmanufactured tobacco have not been observed for domestic production of the chief manufactured tobacco product—the cigarette (Table 6.3). Although total annual domestic consumption fell fairly steadily from a 1982 peak of 634 billion cigarettes to an estimated 435 billion in 1999, total

domestic cigarette consumption peaked in 1996. The difference is the result of large increases in the export of domestically produced cigarettes. In 1985, the United States exported 58.9 billion cigarettes. Exports peaked in 1996 at more than 240 billion cigarettes, almost one-third of total domestic production in that year. Since 1996, however, cigarette exports have fallen, to an estimated 150 billion by 1999.

Table 6.2. Flue-cured tobacco production and value, 1975–1998

Crop year	Production (million lbs.)	Average price to farmers (cents/lb.)	Real price to farmers* (cents/lb.)	Farm value (million \$)	Real farm value* (million \$)
1975	1,415	99.8	185.5	1,412.2	2,624.9
1976	1,316	110.4	194.0	1,452.9	2,553.4
1977	1,124	117.6	194.1	1,321.8	2,181.2
1978	1,206	135.0	207.1	1,628.1	2,497.1
1979	974	140.0	192.8	1,363.3	1,877.5
1980	1,086	144.5	175.4	1,569.3	1,904.5
1981	1,144	166.4	183.1	1,903.6	2,094.2
1982	994	178.5	185.0	1,774.3	1,838.6
1983	855	177.9	178.6	1,521.0	1,527.2
1984	850	181.1	174.3	1,539.4	1,481.6
1985	789	171.9	159.8	1,356.3	1,260.5
1986	667	152.7	139.3	1,018.5	929.3
1987	683	158.7	139.7	1,083.9	954.2
1988	796	161.3	136.3	1,283.9	1,085.3
1989	838	167.4	135.0	1,402.8	1,131.3
1990	920	167.3	128.0	1,539.2	1,177.6
1991	882	172.3	126.5	1,519.7	1,115.8
1992	901	172.6	123.0	1,555.1	1,108.4
1993	892	168.1	116.3	1,499.5	1,037.7
1994	807	169.8	114.6	1,370.3	924.6
1995	854	179.4	117.7	1,532.1	1,005.3
1996	897	183.4	116.9	1,645.1	1,048.5
1997	1,014	172.0	107.2	1,744.1	1,086.7
1998 [†]	815	175.5	107.7	1,430.0	877.5

^{*}Real price to farmers and real farm value are obtained by dividing the nominal average price and farm value by the national Consumer Price Index; the average of 1982–1984 is the benchmark.

Sources: U.S. Department of Agriculture 1996, 1999a; U.S. Department of Labor 1999.

Tobacco Price Supports

Despite being such a profitable crop, tobacco, like other U.S. crops, has benefited from agricultural price supports that have been in place for much of the 20th century. In the 1920s, before these supports were in place, tobacco cooperatives had formed in various regions in an attempt to control the supply of tobacco

and consequently raise tobacco prices and the incomes of tobacco farmers. These and other agricultural cooperatives were largely responding to the steep reductions in the prices of tobacco and other agricultural products during the recession of 1921. The cooperatives had little success and were eventually disbanded.

[†]Subject to revision.

Table 6.3. Selected production and trade statistics for U.S.-grown, unmanufactured tobacco and for U.S.-produced cigarettes, 1975–1999

	Pound	ds of toba	cco* (millions	s)	Number of cigarettes [†] (billions		
			Actual use				
Year	Total production	Total	Domestic use	Exports	Total production	Domestic consumption [‡]	Exports
1975	2,182	1,941	1,286	655	651.2	607.2	50.2
1976	2,136	1,907	1,229	678	693.4	613.5	61.4
1977	1,913	1,895	1,202	693	665.9	617.0	66.8
1978	2,054	1,955	1,190	765	695.9	616.0	74.4
1979	1,527	1,869	1,175	694	704.4	621.5	79.7
1980	1,786	1,759	1,109	649	714.1	631.5	82.0
1981	2,064	1,762	1,065	697	736.5	640.0	82.6
1982	1,994	1,662	1,034	628	694.2	634.0	73.6
1983	1,429	1,532	936	596	667.0	600.0	60.7
1984	1,728	1,621	955	666	668.8	600.4	56.5
1985	1,511	1,620	1,000	620	665.3	594.0	58.9
1986	1,163	1,572	981	591	658.0	583.8	63.9
1987	1,191	1,688	1,115	573	689.4	575.0	100.2
1988	1,370	1,565	1,010	555	694.5	562.5	118.5
1989	1,367	1,677	1,096	582	677.2	540.0	141.8
1990	1,625	1,794	1,163	631	709.7	525.0	164.3
1991	1,664	1,616	976	640	694.5	510.0	179.2
1992	1,722	1,590	960	630	718.5	500.0	205.6
1993	1,614	1,436	898	538	661.0	485.0	195.5
1994	1,583	1,604	1,080	523	725.5	486.0	220.2
1995	1,268	1,491	958	533	746.5	487.0	231.1
1996	1,503	1,698	1,068	630	754.5	487.0	243.9
1997	1,714	1,494	962	532	719.6	480.0	217.0
1998	1,489	1,440	901	539	679.7	485.0	201.3
1999§	1,267	Δ	Δ	Δ	635.0	435.0	150.0

^{*}Marketing year, beginning July 1 for flue-cured and cigar wrapper and October 1 for all other types.

Sources: U.S. Department of Agriculture 1997c, 1998a, 1999a.

[†]Calendar year. May contain imported tobacco. [‡]Allows for estimated inventory change.

[§]Preliminary estimate.

[∆]Not available.

The price support system came into existence a decade later. In response to the impact that the 1930s' Great Depression had on farmers, Congress passed the Agricultural Adjustment Act of 1933 (Public Law 73-10) to control the supply of tobacco and other agricultural products whose prices had fallen sharply. The intent of this and subsequent agricultural price support programs was to support the income of farmers and stabilize the quantity and prices of agricultural commodities. These programs also gave tobacco farmers some ability to counteract the economic power of the highly concentrated cigarette producers (Warner 1988).

Minimum Prices, Nonrecourse Loans, and Quotas

The federal program for tobacco price supports involves specific economic interventions and assistance. To stabilize the price and quantity of tobacco produced, the program guarantees minimum market prices and establishes marketing quotas. Minimum (or support) prices are essentially determined by past tobacco prices adjusted for changes in cost indexes. When unable to find a private buyer at a price at or above the support level, a tobacco farmer is eligible for a nonrecourse government loan from a local price stabilization cooperative. This type of loan allows for a commodity, in this case tobacco, to be used as collateral for the loan at the support price. Under annual contracts with the cooperatives, USDA's Commodity Credit Corporation loans funds it has borrowed from the U.S. Treasury (in the past, at less than market rates of interest [Johnson 1984]). Each cooperative processes and stores the tobacco it has received as the farmer's collateral, and the Commodity Credit Corporation collects interest on the loan. The cooperative then attempts to sell the tobacco. If the cooperative can receive a price above the support price, the proceeds are used to repay the loan, and any excess receipts go to the tobacco farmer. This process has created the appearance that tobacco farmers are not being directly subsidized (Johnson 1984).

Marketing quotas, determined by the U.S. Secretary of Agriculture, are intended to be sufficient to meet the domestic and foreign demand for U.S. tobacco at a price above the government support price. Originally, tobacco could be grown only on land that had been assigned a quota, which was based on that farm's proportion of tobacco produced when the program was initiated (with a limited amount of new production allowed each year). Consequently, almost the only way to begin growing tobacco was to buy or rent a farm that had been granted the right to grow tobacco. In 1961, farmers who grew flue-cured tobacco approved

intracounty lease and transfers of allotments; burley tobacco farmers followed suit in 1971. For the first several decades, these quotas were implemented through national acreage allotment systems. The acreage allotments were replaced by poundage quotas in 1965 for flue-cured tobacco and in 1971 for burley tobacco. The switch to poundage quotas increased flexibility for tobacco growers. In any given year, tobacco farmers could sell up to 10 percent more than their quota if yields exceeded expectations (because of favorable weather conditions, for example). In the following year, however, farmers would have to sell proportionately less than that quota. The opposite would apply when yields fell short of expectations. If yields fell short for several years, tobacco farmers could accumulate excess quotas up to an amount equal to their normal quota. This arrangement resulted in a more stable supply of flue-cured and burley tobacco (Johnson 1984).

Every three years, tobacco farmers vote on whether to continue the price support program and whether to approve any substantive changes in the system. If the referendum is approved by a two-thirds majority, tobacco farmers are subject to marketing quotas.

Effects of Price Supports on Market Prices

Despite the numerous factors that affect the supply and demand for tobacco, the quota and price support system keeps market prices at or above the support level. This effect has been evident—and its correction attempted—almost from the outset. As a result of the Agricultural Adjustment Act of 1933, tobacco prices increased almost immediately. These increases resulted from limits on output achieved by voluntary agreement. In 1934, Congress passed the Tobacco Control Act (Public Law 73-483) to deter noncooperative tobacco farmers from overproducing and taking advantage of the relatively high prices resulting from the reduced supplies of participating farmers. This act led to sharp reductions in tobacco production and consequently to a steep rise in tobacco prices. In early 1936, however, the United States Supreme Court found sections of the Agricultural Adjustment Act unconstitutional, which led Congress to repeal the Tobacco Control Act as well.

In 1935, Congress enacted the Tobacco Inspection Act (Public Law 74-314), which required the USDA to provide tobacco grading (or quality evaluation) services at no cost to tobacco growers. In 1936, the Soil Conservation and Domestic Allotment Act (Public Law 74-461) was passed. This act covered tobacco, as well as most other agricultural products covered by the

Agricultural Adjustment Act of 1933, and rewarded farmers for diverting production from soil-depleting crops (including tobacco) to soil-conserving crops. The limited success of the Soil Conservation and Domestic Allotment Act led to the passage in 1938 of the second Agricultural Adjustment Act (Public Law 75-430). The new act included quotas for tobacco and other agricultural products and imposed penalties on farmers who violated their quotas. Even with subsequent amendments, the tobacco price support program established by the Agricultural Adjustment Act of 1938 is essentially the same today.

The Agricultural Adjustment Act of 1938 set the support price at 75 percent of parity (where parity reflects average tobacco prices from 1919 through 1929). At the beginning of World War II and later through the Agricultural Act of 1949 (Public Law 81-439), this proportion was raised to 90 percent of parity, which was based on average prices for the preceding 10 years. In 1960, to slow the rate of growth in tobacco prices, Congress set new support levels based on the 1959 level and a three-year moving average of prices paid by farmers. Similarly, in 1980, the support prices for the eight lowest quality grades of tobacco were lowered directly.

Assessments to Offset Federal Costs of Price Supports

Until new legislation was passed in the 1980s, the costs to the federal government from operating the tobacco support program were substantial. In 1981 alone, the total administrative cost of the program was \$13.1 million. Moreover, the federal government, through the Commodity Credit Corporation, bore all costs if the local cooperatives were unable to sell the tobacco they received as collateral for the nonrecourse loans. By April 1982, losses from unpaid loan principal totaled \$57 million, and interest losses amounted to \$591 million by the end of 1981 (General Accounting Office [GAO] 1982). These losses spurred opposition to the tobacco support program, which was being threatened with dissolution. To reduce some of the costs of operating the program, in 1981 Congress amended the Tobacco Inspection Act, imposing fees on tobacco growers sufficient to cover the cost of the grading services provided by the USDA.

Far more significant changes to the tobacco support program were introduced by the No Net Cost Tobacco Program Act of 1982 (Public Law 97-218), which was mandated by the Agriculture and Food Act of 1981 (Public Law 97-98). The act was intended to reduce the losses of the tobacco support program by

imposing an assessment on every pound of tobacco brought to market under the loan program. The assessments were supposed to generate revenues sufficient to offset all future losses from these loans. Thus, aside from the administrative costs, the tobacco support program was supposed to operate at no net cost to taxpayers. Other changes were introduced through the act. Rather than distributing excess receipts from the sale of loan tobacco to farmers, these profits were retained by the Commodity Credit Corporation. Farmers of flue-cured tobacco could sell their right to grow tobacco to other active tobacco growers in the same county; moreover, institutional owners of these rights were required to sell them by December 1984. Finally, the U.S. Secretary of Agriculture was given the authority to slow the growth in the support price by allowing the price to increase by as little as 65 percent of the increase implied by the parity formula. These changes led four relatively small associations of tobacco growers (growers of cigar tobacco in three areas) to stop participating in the support program (Miller 1994).

Initially, assessments were expected to be relatively low because of the size of past losses. However, as a result of the tobacco support program, U.S. support prices were well above tobacco prices in world markets, which led producers of cigarettes and other tobacco products to increase their use of imported tobacco. At the same time, reductions in quotas were limited by statute. Consequently, the quantity of tobacco produced exceeded the quantity demanded at the support price, and the surplus was used as collateral for nonrecourse loans (Miller 1994). By 1985, with a growing stock of U.S.-grown tobacco under loan, the no-net-cost assessment on flue-cured tobacco was high: 25 cents per pound (Miller 1994). (The assessment on burley tobacco would have been 30 cents per pound but was limited to 4 cents by legislation.)

The high assessments, the growing importance of imported tobacco in the production of cigarettes and other tobacco products, the increasing stocks of tobacco under loan, and the falling quotas of the early to mid-1980s created a crisis for tobacco farmers and the tobacco support program (Northup 1993). Congress responded by making several changes to the support program (Tobacco Program Improvements) contained in the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99-272). The 1985 act lowered the tobacco support price by 26 cents per pound for both flue-cured and burley tobacco. In addition, both buyers and sellers of surplus tobacco were required to bear part of the burden of running the program (growers of other types of tobacco continued to be responsible for the full assessment). These changes were

meant to encourage the use of domestically grown tobacco over imported tobacco in the manufacturing of cigarettes and other tobacco products (Miller 1994).

Also as a result of this legislation, the amount of flue-cured and burley tobacco that could be sold without penalty was reduced from 110 percent of quota to 103 percent. The formulas used to determine the support prices for flue-cured and burley tobacco were also changed. These prices were now based on their levels in the preceding year, and adjustments were to be made from a five-year moving average of prices and changes in the cost of production. Past prices would be given two-thirds weight, and the remainder would be based on production costs (which included general variable expenditures but excluded costs of land, overhead, assessments, and other expenses not directly related to tobacco growing). The legislation also brought the major cigarette manufacturers into the quota-setting process, because they would be annually providing the U.S. Secretary of Agriculture with their intended purchases of tobacco. These manufacturers would be penalized if they did not purchase at least 90 percent of this intended amount.

When these changes took place, U.S. cigarette companies agreed to buy all future surplus stocks of tobacco (for the next eight years for flue-cured tobacco and the next five years for burley tobacco). Some of the existing stocks under loan were sold at sharp discounts; the federal government absorbed the losses. These changes were somewhat successful in reducing surplus tobacco stocks as well as the amount of tobacco brought under loan in any given year. Over the next five years, stocks of tobacco declined by nearly 40 percent, and total loan outlays fell by nearly 90 percent.

To fund deficit reduction of the federal budget, the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) added further marketing assessments on all commodity price support programs between 1991 and 1995; the marketing assessments were subsequently extended through 1998 (USDA 1997c). Tobacco growers and buyers each paid an additional assessment equal to 0.5 percent of the support price level. These additional assessments generated estimated revenues of more than \$28 million in fiscal year 1997 (Womach 1999).

To further curb the use of imported tobacco, the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66) included the requirement that, beginning in 1994, domestically produced cigarettes include a minimum of 75 percent domestically grown tobacco. If this law was violated, the cigarette manufacturer was assessed on the amount of foreign-grown tobacco used in excess of the 25-percent limit. The assessment rate

was determined by the difference between average prices of imported and domestic tobacco. Those producers who used an excess of imported tobacco were further required to make up the shortfall by purchasing tobacco stocks under loan. The act also subjected imported tobacco to the no-net-cost assessments beginning in 1994. Effective September 13, 1995, however, the domestic content requirement was dropped as part of a presidential tariff-rate quota proclamation because of its inconsistency with the General Agreement on Tariffs and Trade (GATT).

In general, the tobacco quotas have fallen in recent years, while support prices, after adjustment for inflation, have fallen sharply (Tables 6.4 and 6.5). As of March 31, 1995, the principal and interest value of tobacco loan inventory was \$1.6 billion (Robert H. Miller, Tobacco loan status report, unpublished data), which was down significantly from the \$2.75 billion held as of June 30, 1986 (Warner 1988).

The no-net-cost assessment for the 2000 crop of flue-cured tobacco is 2.5 cents per pound for the producer and 2.5 cents per pound for the purchaser. Similarly, the no-net-cost assessment for the 2000 crop of burley tobacco is 3 cents per pound for both the grower and the buyer.

In fiscal year 2000, the federal government budgeted approximately \$14 million for administering the tobacco support program (Womach 1999). In total, the directly tobacco-related activities of the USDA generated an estimated \$174 million in net revenues in fiscal year 1999. The positive net revenues are the result of revenues generated by the loan program and various assessments that more than offset the expenditures on the tobacco program and other tobacco-related activities (including subsidized tobacco crop insurance, tobacco inspection and grading, tobacco research, data collection and analysis, and other activities) (Womach 1999).

Discussion

Several conclusions emerge from analyses of the tobacco support program. The program's success in stabilizing tobacco prices is particularly evident when they are compared with the prices of other agricultural commodities (including those covered by their own support programs). One result of the price stability is that output has also been relatively stable. As Johnson (1984) notes, "growing tobacco has been as close to a sure thing as one can find in U.S. agriculture" (p. 55).

The quantity of tobacco grown domestically is artificially low as a result of the supply restrictions created by the tobacco support program. Consequently,

Table 6.4. Characteristics of the tobacco support program: flue-cured tobacco, 1975-2000

	National marketing	National average	Real average support	No-net-cost assessment [†] (cents/lb.)	
Year	quota (million lbs.)	support price (cents/lb.)	price* (cents/lb.)	Producers	Buyers
1975	1,491	93.2	173.2		
1976	1,268	106.0	186.3		
1977	1,116	113.8	187.8		
1978	1,117	121.0	185.6		
1979	1,095	129.3	178.1		
1980	1,094	141.5	171.7		
1981	1,013	158.7	174.6		
1982	1,013	169.9	176.1	3.0	
1983	910	169.9	170.6	7.0	
1984	804	169.9	163.5	7.0	
1985	775	169.9	157.9 [‡]	2.50	
1986	729	143.8	131.2	2.50	1.50
1987	707	143.5	126.3	2.00	2.00
1988	754	144.2	121.9	1.13	1.13
1989	891	146.8	118.4	1.12	1.12
1990	878	148.8	113.8	1.00	1.00
1991	878	152.8	112.2	1.00	1.00
1992	892	156.0	111.2	1.00	1.00
1993	892	157.7	109.1	1.00	3.00
1994	803	158.3	106.8	3.00	5.00
1995	935	159.7	104.8	0.80	1.80
1996	874	160.1	102.0	1.00	1.80
1997	974	162.1	101.0	1.00	1.00
1998	814	162.8	99.9	1.00	1.00
1999	666	163.2	98.0	1.00	1.00
2000	543	164.0	95.6 [§]	2.50	2.50

^{*}Real average support price is obtained by dividing the nominal support price by the national Consumer Price Index; the average of 1982–1984 is the benchmark.

Sources: U.S. Department of Agriculture 1997b, 1999a,b.

[†]No-net-cost assessment includes marketing budget deficit assessments from 1991 through 1998.

 $^{^{\}ddagger}$ The effective support price in 1985 was 165.0 cents/lb. by reduction of certain grades.

[§]Preliminary estimate.

Table 6.5. Characteristics of the tobacco support program: burley tobacco, 1975-2000

	National marketing	National average	Real average support	No-net-cost assessment [‡] (cents/lb.)	
Year	quota (million lbs.)	support price* (cents/lb.)	price† (cents/lb.)	Producers	Buyers
1975	670	96.1	178.6		
1976	635	109.3	192.1		
1977	636	117.3	193.6		
1978	614	124.7	191.3		
1979	614	133.3	183.6		
1980	614	145.9	177.1		
1981	660	163.6	180.0		
1982	680	175.1	181.5	1.0	
1983	647	175.1	175.8	5.0	
1984	582	175.1	168.5	9.0	
1985	524	148.8	138.3	4.0	
1986	493	148.8	135.8	2.75	1.25
1987	464	148.8	131.0	2.00	2.00
1988	473	150.0	126.8	0.80	0.80
1989	587	153.2	123.5	1.00	1.00
1990	601	155.8	119.2	1.00	1.00
1991	724	158.4	116.3	1.00	1.00
1992	668	164.9	117.5	1.00	1.00
1993	602	168.3	116.5	1.00	3.50
1994	536	171.4	115.7	4.50	4.60
1995	546	172.5	113.2	1.00	1.00
1996	631	173.7	110.7	1.00	1.00
1997	704	176.0	109.7	1.00	1.00
1998	635	177.8	109.1	3.00	3.00
1999	451	178.9	107.4	3.00	3.00
2000	247	180.5	105.2 [§]	3.00	3.00

^{*}The support price was reduced from 178.8 cents/lb. and the no-net-cost assessment was reduced from 30 cents/lb. by Public Law 99-157, sec. 6 (1985).

Sources: U.S. Department of Agriculture 1997a; 1998a,b; 1999a, 2000.

[†]Real average support price is obtained by dividing the nominal support price by the national Consumer Price Index; the average of 1982–1984 is the benchmark.

[‡]No-net-cost assessment includes marketing budget deficit assessments from 1991 through 1998.

[§]Preliminary estimate.

prices for domestically grown tobacco are artificially high. Some estimates of the distortions resulting from the support program were provided by Sumner and Alston (1985) in their analysis of the economic consequences of removing the tobacco price support system. Their estimates were based on a detailed simultaneous equations model of the supply and demand for tobacco and tobacco products (cigarettes) that allows for substitution between domestic and foreign tobacco in cigarette production. The authors estimated that domestic tobacco output would rise by 50-100 percent or more if supply restrictions were eliminated. This large increase in the quantity of tobacco supplied would lead to sharp reductions in tobacco prices. As a result of the increase in output, tobacco prices would fall by 20–30 percent, and the variability of tobacco prices would increase. However, overall revenues from tobacco growing would rise by 15–60 percent or more.

Moreover, this analysis predicted that the sharp drop in domestic tobacco prices that would follow the removal of supply restrictions would lead domestic producers of cigarettes and other tobacco products to use less foreign-grown tobacco. These estimates assumed the elimination of the program in 1983 and thus do not take into account the more recent changes in its operation. More recent estimates from Zhang and colleagues (2000) suggest that the conclusions of Sumner and Alston (1985) still apply. For example, they estimated that the price support program raised tobacco leaf prices by 36 cents a pound in 1994. This price is about 21 percent above the estimated price in the absence of the support program.

The removal of the support program would also make domestic tobacco growers more competitive in world markets. In the 1980s, U.S. tobacco prices exceeded world market prices by 40–60 cents per pound (Warner 1988). Although part of the differential can be explained by the higher quality of U.S. tobacco, a significant factor is the U.S. tobacco support program. Sumner and Alston (1985) predicted that U.S. tobacco exports would have grown by about 100 percent if the tobacco support program had been eliminated in 1983. This change would have had an adverse impact on foreign tobacco growers, as producers of foreign cigarettes and other tobacco products increased their use of tobacco grown in the United States.

Although the artificially high prices resulting from the support program tend to increase the income of small tobacco farmers, they likely receive relatively less benefit from the program than the tobacco quota owners. Because most small tobacco farmers rent some or all of their allotments from the quota owners at a significant cost (Watkins 1990), these farmers pay rents

equivalent to the excess value created by the support program. In the absence of the program, reduced income for these farmers would likely be offset by the resulting reduced rent they paid. Quota owners, on the other hand, have been estimated to lose about \$800 million annually were the support program eliminated (Sumner and Alston 1985).

Despite the differing likely effects on quota owners and small tobacco growers, eliminating the tobacco support program would probably not alter existing trends in the concentration of tobacco production into larger farms (Sumner and Alston 1985). Rucker and colleagues (1995) have estimated that eliminating the program's intercounty restrictions on the transfer of tobacco quotas would have little overall impact beyond redistributing wealth from some tobacco growers and quota owners to others. (Consequently, these researchers suggest that the restrictions have remained in effect not because the gains associated with them are large but because the political costs of removing them are.) Moreover, removing supports would cause a movement away from regions where the costs of growing tobacco are relatively high toward those where costs are relatively low. The loss of income to quota owners would lead to reductions in personal income of up to 2–3 percent for counties that are highly dependent on tobacco; larger losses would occur in the relatively high-cost counties. However, total incomes would rise in areas that experienced a great expansion in tobacco growing. In comparison, the effect of altering another government program would be considerable. Increases in cigarette excise taxes are also likely to bring significant losses to quota owners. Sumner and Wohlgenant (1985) estimated that doubling the federal cigarette excise tax in 1983 would lower quota owners' lease income by an average of 13 percent, or about \$44 million.

As a result of the sharp drop in the price of tobacco, cigarette prices could fall. Tobacco costs, however, are a relatively small component of cigarette prices. Grise (1995) estimates that the 40- to 50-cent per pound drop in tobacco prices resulting from the elimination of the support program would reduce cigarette prices by only 1–2 percent. Zhang and colleagues (2000) estimate an even smaller impact, concluding that cigarette prices are 0.52 percent higher than they would be in the absence of the support program. As noted by Sumner and Alston (1985), a reduction in cigarette prices would lead to a rise in U.S. cigarette exports. Moreover, estimates of the price responsiveness of cigarette demand (described in "Effect of Price on Demand for Tobacco Products," later in this chapter) suggest that the reduction would lead to an increase of no more

than 1 percent in cigarette smoking. At least part of the increase would come from increased smoking among young people.

Opponents of the tobacco support program suggest that it can be removed with little impact on the farmers it is intended to benefit. For example, the less than 2-percent reductions in cigarette price that would result from eliminating the support program could be more than offset by an increased excise tax on cigarettes. A portion of the revenues generated from the tax hike could be used to help tobacco farmers diversify into other crops (through low-interest loans, grants, or other programs) or to purchase the farmer's tobacco base to retire it from tobacco growing (Northup 1993). Similarly, some of the funds could be used to develop nonfarm businesses, train farmers for other occupations, provide income support, and offer other economic support for local economies in transition (Womach 1994a).

Critics also point out that the support program creates indirect political consequences: the dependence created by the support program results in a strong political constituency, composed of tobacco farmers and holders of tobacco allotments, that can impede legislation to reduce tobacco use (Taylor 1984; Warner 1988; Zhang and Husten 1998). In the absence of the support program, tobacco growing would likely become much more concentrated (Sumner and Alston 1985). Warner (1988) has observed that the reduction in numbers would lead to reduced political influence. Moreover, he describes the apparent inconsistency present when one arm of the federal government seemingly endorses tobacco production by continuing an economic support program even as another engages in numerous activities to reduce tobacco use (Warner 1988).

Evolution of the U.S. Cigarette Industry

Through much of the 19th century, most of the demand for tobacco products centered on smokeless tobacco and cigars (see Chapter 2). Cigarettes were relatively less popular, although the demand for them increased gradually during the middle of the century (USDHHS 1992). The watershed year for the cigarette, however, was 1881, when James Albert Bonsack announced his development of a machine that replaced hand-rolling as the primary means of making cigarettes. The mechanization of production significantly reduced the costs of manufacturing cigarettes and, consequently, reduced cigarette prices. The steep declines in cigarette prices relative to the prices of other tobacco products, due largely to Bonsack's cigarette

machine, contributed significantly to the rapid rise in the popularity of cigarettes during the late 19th and early 20th centuries (Wagner 1971).

James Buchanan Duke was the first cigarette producer to acquire rights to the new machines, which he installed in 1884. Duke entered into long-term contracts with Bonsack to use the machines at a cost lower than Bonsack would make them available to other producers. Because of the resulting substantial cost advantage in production for his company, Duke successfully waged price wars with other producers while still earning relatively high profits. Over the next decade, the Duke family formed a holding company, which was composed of their firm and several competitors they had acquired. By 1889, as a result of its aggressive pricing and marketing strategies, the holding company effectively monopolized U.S. cigarette markets (controlling more than 90 percent of the market), as well as portions of the markets for other tobacco products. Eventually, in an attempt to avoid antitrust prosecution under the Sherman Act, the Dukes converted the holding company into The American Tobacco Company. By 1901, The American Tobacco Company dominated all of the U.S. tobacco markets except cigars. The company was also a considerable presence in cigarette markets around the world.

In response to allegations that The American Tobacco Company was abusing its market position, the U.S. Department of Justice charged the firm with violating the Sherman Act. In 1911, the Supreme Court dissolved the company, thereby creating several new firms from the conglomerate, including a new American Tobacco Company (which later became American Brands, Inc.), Liggett & Myers Tobacco Company, R.J. Reynolds Tobacco Company, and Lorillard Tobacco Company. The American Tobacco Company was also divested of its foreign holdings (Imperial Tobacco Ltd. and British-American Tobacco Company Ltd. [B.A.T. Company]). Imperial Tobacco Ltd. eventually monopolized cigarette manufacturing in Great Britain, and B.A.T. Company concentrated on manufacturing in British colonies and elsewhere. Both companies ultimately resumed some operations in the United States (Johnson 1984). Although Imperial Tobacco Ltd. eventually dropped out of U.S. markets, B.A.T. Industries PLC, the parent company of B.A.T. Company, owns Brown & Williamson Tobacco Corporation, a large U.S. cigarette manufacturer.

R.J. Reynolds Tobacco Company (which had no cigarette production after the breakup) soon developed a new type of cigarette by using burley tobacco, which was quickly copied by the other producers. By the 1920s, the cigarette producers were competing

aggressively in promoting their main brand—for example, R.J. Reynolds Tobacco Company's Camel, The American Tobacco Company's Lucky Strike, and Liggett & Myers Tobacco Company's Chesterfield. In addition, firms on the competitive fringe attempted to compete through price with their so-called 10-cent brands (Robert 1967). (For a more detailed discussion of the domestic operations of U.S. cigarette firms before World War II, see the Surgeon General's report Smoking and Health in the Americas [USDHHS 1992]).

The U.S. Department of Justice eventually challenged the four producers' coordinated wholesale and retail pricing practices. In 1941, on the basis of conduct starting as early as 1933, these producers were charged with violating the Sherman Act by conspiring to restrain trade in an attempt to monopolize the industry. Their wholesale tobacco-purchasing practices were deemed to be monopsonistic—that is, characteristic of a market situation where one buyer exerts a disproportionate influence—and their retail pricing was thought to reflect collusive behavior. In 1946, basing its decision on the novel legal concept of "conscious parallelism," the Supreme Court upheld a jury decision that found the firms guilty. The uniformity of prices at both the wholesale and the retail level (a result that could occur in any highly competitive market), the near-synchronous increases in prices, and the raising of wholesale prices when labor costs were falling were viewed by the court as evidence of tacit collusion. As a result, the firms were fined up to \$250,000 each, a relatively minor penalty compared with their profits.

Johnson (1984) and others have noted that the Court's decision was not supported by purely economic reasoning. There was little if any evidence that cigarette firms were jointly restricting output to raise cigarette prices and, consequently, profitability. Similarly, there was no evidence that the firms limited their wholesale purchases of tobacco to depress tobacco prices and production costs and, consequently, to increase profits.

The Court's decision had little impact on the subsequent structure of the U.S. cigarette industry. The practical result has been that, from 1946 until today, the combined market shares of the six major firms (five after the merger of Brown & Williamson and American Brands, Inc.) has exceeded 99 percent, although individual market shares have changed significantly (Table 6.6).

More important in changing relative market shares was the release of information during the 1950s and 1960s on the health consequences of cigarette smoking. In the 1950s, Philip Morris Companies Inc., R.J. Reynolds Tobacco Company, and Lorillard Tobacco Company aggressively marketed filtered cigarettes (Marlboro, Winston, and Kent, respectively), which were perceived as less dangerous than standard unfiltered cigarettes; The American Tobacco Company and Liggett & Myers Tobacco Company were not as

Table 6.6. Domestic market shares of U.S. cigarette firms, selected years

	R.J.	Philip	Brown &	American		Liggett &	
Year	Reynolds	Morris	Williamson	Brands	Lorillard	Myers	Total
1913	0.2	NA*	NA	35.3	22.1	34.1	91.7
1925	41.6	0.5	NA	21.2	1.9	26.6	91.8
1940	21.7	9.6	7.8	29.5	5.4	20.6	94.6
1955	25.8	8.5	10.5	32.9	6.1	15.6	99.4
1970	31.8	16.8	16.9	19.3	8.7	6.5	100.0
1975	32.5	23.8	17.0	14.2	7.9	4.4	99.8
1980	32.8	30.8	13.7	10.7	9.8	2.2	100.0
1985	31.7	35.8	11.8	7.4	8.2	5.0	99.9
1991	27.8	43.4	11.1	7.0	7.3	3.4	100.0
1996	24.6	47.8	17.2	NA	8.4	1.9	99.9

^{*}NA = Not available.

Sources: Tennant 1950; Overton 1981; Clarifeld 1983; Standard & Poor's 1989, 1993; Federal Trade Commission 1997.

successful in marketing their competing brands (Johnson 1984). Similarly, after the 1964 release of the U.S. Surgeon General's first report on the health consequences of cigarette smoking, and after the Federal Trade Commission's (FTC) publishing of tar and nicotine content in the late 1960s, Philip Morris Companies Inc. and R.J. Reynolds Tobacco Company introduced and aggressively marketed low-tar and low-nicotine cigarettes (again, products perceived as healthier than existing cigarettes), whereas the other companies were less successful. As a result of the brand loyalty these two firms were able to establish at this time, they came to dominate cigarette markets; in 1996, the two firms had a combined market share of 72.4 percent.

Another notable change in the tobacco industry, beginning in the 1960s, was the diversification of the cigarette-manufacturing companies. Perhaps in part to offset the impact that the campaign to reduce tobacco use had on the industry's profitability, the six major domestic cigarette producers acquired or merged with U.S. firms in a variety of nontobacco markets, including food, alcoholic beverages, and transportation. Both U.S. and international cigarette producers significantly expanded their international activities. Diversification was relatively easy because of the high profitability from cigarettes and the low long-term debt of these firms (Overton 1981). By 1972, no major domestic cigarette company was completely dependent on tobacco for its revenue (Johnson 1984). During the 1980s, diversification strategies and successes among the six firms varied markedly; some firms returned to a focus on cigarettes and other tobacco products, whereas others diversified further. By the late 1980s, a three-tiered classification of world cigarette producers, based on their international activities, had emerged: those involved in most global tobacco markets (Philip Morris Companies Inc., B.A.T. Industries PLC, R.J. Reynolds Tobacco Company, and Rothmans International Tobacco Ltd.); those with some international, but not global, activities (including American Brands, Inc.); and smaller firms concentrating primarily on their domestic markets (including Liggett & Myers Tobacco Company and Lorillard Tobacco Company) (USDHHS 1992).

Economic Implications of Concentrated Tobacco Production

The concentration of production among relatively few firms in the cigarette industry has implications for cigarette pricing, marketing, product development, and other activities. Clearly, the cigarette industry is an oligopoly; no more than six firms have controlled virtually all cigarette output in the United States for the past 80 years (Table 6.6). Economic theory suggests that firms in oligopolistic industries have substantial market power in that their production decisions will have a significant impact on price. Moreover, these firms recognize their interdependence. That is, each firm recognizes that its pricing and marketing strategies have a significant impact on the sales and profitability of its competitors, as well as on its own sales and profitability. Consequently, each firm understands that its competitors are likely to respond to any changes in its own pricing, marketing, or other strategies.

Economic theory provides several possibilities regarding the conduct and performance of firms in an oligopolistic industry. At one extreme, if entry is easy and if sunk (nonrecoverable) costs are low, firms in an oligopolistic industry will behave competitively. That is, firms will have little market power (their output decisions will have little impact on market prices), prices will reflect the costs of production, and firms will not earn excessive profits. At the other extreme, firms could behave collusively, jointly restricting output, raising prices well above costs, and earning very high profits. Most theoretical models of oligopolistic industries suggest behavior between the two extremes: prices and profitability will be above and output will be below what would result from highly competitive behavior, and output will be higher and prices and profitability will be lower than their levels in a monopolized or highly collusive industry.

Casual empiricism suggests that cigarette prices have historically been well above costs, thereby allowing cigarette producers to achieve a rate of return well above that earned in most other industries. Even after the health consequences of cigarette smoking became apparent, the U.S. tobacco industry led all U.S. industries in profitability (Miles 1982). Moreover, in the two major antitrust cases brought against the cigarette industry in the 20th century, firms were found guilty in 1911 of monopolization and in 1946 of a conspiracy to restrain trade (collusion). Most industry analysts suggest that the primary source of market power in the cigarette industry is the entry barriers resulting from marketing efforts, which create significant brand loyalties that are nearly impossible for a new producer to overcome.

High Tobacco Concentration and the Impact of **Prevention Policies**

The high concentration of the cigarette industry and the apparent market power this concentration engenders have implications for the effects of changes in cigarette taxes and other prevention policies on the pricing, marketing, and other strategies of cigarette firms. For example, the historically high profitability of existing cigarette producers provides them with the resources needed to successfully develop and market new products, as was seen in the development and introduction of filtered cigarettes in the 1950s and lowtar and low-nicotine cigarettes in the 1960s in response to the initial reports linking cigarette smoking to lung cancer. More recently, in response to the increased awareness of the harmful effects of environmental tobacco smoke (ETS) on nonsmokers and the widespread restrictions on smoking that have been designed to protect nonsmokers, R.J. Reynolds Tobacco Company introduced its Eclipse brand in several test markets beginning in mid-1996, and Philip Morris Companies Inc. is currently testing its Accord brand in the United States and Japan. Both are ostensibly "smokeless" cigarettes, primarily heating rather than burning tobacco; consequently, both generate less secondhand smoke than conventional cigarettes.

Economic theory can predict some effects of increases in excise taxes on price, output, and profitability. At one extreme, tax increases in a perfectly competitive market with constant costs of production should result in price increases of the same magnitude with no impact on long-run profitability. Reductions in output would depend on the effect that price has on demand. At another extreme, standard models for a monopolized market suggest that producers and consumers would share the burden of the tax increase but consumers would pay a greater share of the tax, because demand is less sensitive than production to price. Output and profitability would fall, with smaller reductions in both—again because demand is less sensitive to price. Recent advances in the theoretical and empirical study both of oligopolistic behavior and of the supply of addictive goods have yielded several interesting predictions. Perhaps most interesting is the possibility that prices will increase by more than the amount of the tax increase when excise taxes are raised.

Several early studies of these relationships produced generally inconsistent conclusions concerning how much cigarette prices would increase after an increase in cigarette taxes (Barzel 1976; Johnson 1978; Sumner 1981; Sumner and Ward 1981; Bulow and Pfleiderer 1983; Bishop and Yoo 1985; Sullivan 1985; Sumner and Wohlgenant 1985; Ashenfelter and Sullivan 1987). One general weakness of these studies was their failure to account for the dynamic interaction of firms in an oligopolistic industry. Instead, the studies generally assumed that rules for the firms' behavior were established, and then, with observed prices and taxes, the studies worked backward to

determine the degree of competition within the industry (Harris 1987).

More recent studies have addressed these weaknesses. Harris (1987) used the estimates obtained from several studies of cigarette demand and supply to evaluate the impact of doubling the federal cigarette excise tax in 1983; moreover, Harris' framework allowed the change in the tax to affect the interaction of firms in the industry. Using data on wholesale and retail cigarette prices as well as the costs of production, Harris concluded that the 8-cent increase in the tax led to a 17-cent increase in the retail price of cigarettes. He further argued that the price increase above the tax hike could not be accounted for by increases in production costs. Instead, this increase was attributed to the recognized interdependence of cigarette firms in an oligopolistic industry; that is, the firms recognize that their profitability would rise if all could successfully restrict output and raise prices. However, because formal agreements on output and prices are illegal, the firms are alert to other bases on which they can coordinate their behavior. Harris suggested that such a base was the announced increase in the federal tax, scheduled for January 1, 1983, which served as a coordinating mechanism for a joint oligopolistic price increase. As Barnett and colleagues (1995) note, Harris' analysis fails to account for existing trends in cigarette prices. Barnett and colleagues argue that Harris attributed too much of the coordinated rise in price to the increase in the federal tax, because the upward trend in prices predates the consideration of the tax hike. The authors suggest that producers used the introduction of discount cigarettes in 1981 to coordinate the earlier price hikes for premium brands, because the lower-priced "generic brands" would keep more price-sensitive smokers in the market. The spirit of this argument is the same as Harris', because both suggested that certain events served as focal points allowing firms to engage in more collusive behavior without appearing to establish a formal agreement.

Keeler and colleagues (Sung et al. 1994; Barnett et al. 1995; Keeler et al. 1996) used national- and state-level data to estimate the effects of cigarette tax increases on price. Their empirical models have been used to examine the interaction of cigarette supply and demand in determining cigarette prices. By using alternative assumptions about firm behavior, these studies formally account for the oligopolistic aspects of the cigarette industry in their empirical models of cigarette supply. At least some of these models also account for the addictive nature of cigarette demand.

In a study using data on all U.S. states from 1960 through 1990, Keeler and colleagues (1996) conclude

that the oligopolistic behavior of the industry results in increases in cigarette prices that exceed increases in state excise taxes. A 1-cent increase in the state tax would raise retail prices in that state by an average of 1.11 cents. Moreover, the researchers conclude that producers selectively lower prices in states with stronger state and local antismoking laws, offsetting the impact of tobacco control policies. Similarly, a study using data on 11 western states for the same period predicts that the state cigarette price would rise by 1.27 cents for every 1-cent increase in the state cigarette tax (Sung et al. 1994).

Another study by Barnett and colleagues (1995) suggests that increases in federal cigarette excise taxes would generate larger increases in cigarette prices than those that would result from state tax hikes. These investigators attribute this phenomenon to the increase in sales across state borders, which can result from a state tax increase and can thereby limit the impact of the tax increase on price. A 1-cent increase in the federal cigarette tax was predicted to raise cigarette prices by just over 1.0 cent, whereas a comparable increase in state cigarette taxes would yield an estimated retail price increase of about 0.9 cents. The investigators conclude that the industry has been less competitive since 1980; they attribute this finding both to the relatively lax enforcement of antitrust laws associated with the deregulatory climate of the 1980s and to the focal points that triggered more collusive behavior.

Basing their analysis on a published economic model of addictive behavior (Becker and Murphy 1988), Becker and colleagues (1994) suggest an alternative explanation for the observation that cigarette prices increase more than cigarette taxes increase: tobacco companies raise prices to obtain maximum profit from current smokers, for whom cost concerns alone will likely motivate reducing but not quitting their addictive behavior; these increased profits are intended to help offset future losses from the reduced demand that will occur among would-be new smokers, who will be put off by any price increase, whether from taxes or other causes. As is discussed later in this chapter (in "Effect of Price on Demand for Tobacco Products"), addiction is to some extent a wild card in estimates of price and demand. Becker and colleagues (1994) express this only-apparent paradox as follows: "If smokers are addicted and if the industry is oligopolistic, an expected rise in future taxes and hence in future prices induces a rise in current prices even though current demand falls when future prices are expected to increase" (p. 413). The same effect would apply to other anticipated changes in policies that would be expected to reduce future cigarette smoking. The authors explain this hypothesis as follows: cigarette firms with market power may set relatively low prices to "hook" consumers on their addictive product, thus raising the future demand for their cigarettes; policies (including tax increases) that reduce future smoking also reduce the firms' profitability of maintaining low prices. Nevertheless, the relatively low prices of these forwardlooking firms (compared with those of more myopic firms) will still exceed the marginal and average costs of production and distribution. A similar hypothesis has been used to explain studies that found that cigarette producers appear to advertise beyond the profitmaximizing level (Showalter 1991). These firms may be engaging in excessive advertising (i.e., more than can be recouped through brand switching among current smokers) to attract new consumers and hoping to later benefit from a higher demand for cigarettes as a result of these newly addicted consumers.

The rapid increases in cigarette prices since the early 1980s, which are only partly explained by increases in taxes and costs, thus reflect profit-maximizing behavior by a highly concentrated cigarette industry that anticipates decreased future demand as additional efforts to reduce tobacco use are implemented (Becker et al. 1994). An empirical application of this model to the supply and demand for cigarettes (Showalter 1991) supports these hypotheses concerning the behavior of firms with market power that are selling an addictive product.

A second group of empirical studies has focused on the relationships between industry concentration, restrictions on cigarette advertising, cigarette prices, and market power. One such analysis supports the conventional wisdom that advertising is an important competitive strategy in developing and maintaining brand loyalty for firms in the cigarette industry (Nguyen 1987). Another analysis, using an empirical model that allows firms in an oligopolistic industry to have some degree of market power, concludes that advertising raises market power and, consequently, profitability in the cigarette industry (Tremblay and Tremblay 1995). A likely explanation of this effect is that by fostering loyalty to existing brands, cigarette advertising raises barriers to other brands that try to enter the market and share in the profits.

Several studies (Porter 1986; Mitchell and Mulherin 1988; Eckard 1991) have concluded that banning cigarette advertising from television and radio made the industry even less competitive, thereby further raising profitability. One such study attributed the increases in cigarette prices after the advertising ban to the reduced competition resulting from the ban (Porter 1986). This conclusion was supported, to some

extent, by the observation by Doron (1979) that cigarette firms apparently favored the 1971 ban on television and radio advertising, although the firms' concerns about counteradvertising may have played a role as well (see "Advertising and Promotion" in Chapter 5).

Discussion

The highly concentrated, oligopolistic structure of the U.S. cigarette industry has important implications for the effects of increases in cigarette excise taxes and of stronger prevention policies on cigarette prices. Much of the recent research on the supply of cigarettes has found that the cigarette industry became less competitive in response to the 1971 ban on cigarette advertising on television and radio. One consequence of this reduced competition was that cigarette prices rose more rapidly than they would have otherwise. Moreover, this research suggested that further reductions have occurred in competition since the early 1980s, partly because of the relaxed regulatory climate for business. Increases in cigarette excise taxes and stronger prevention policies have also contributed to the reduced competition. The net result of the increased market power of cigarette producers is that cigarette prices have risen more rapidly than production costs have increased. In addition, increases in cigarette taxes during this period resulted in greater than a 1:1 increase in cigarette prices.

Two recent activities, however, suggest that price competition in the cigarette industry is increasing at both the wholesale and the retail levels. In 1993, cigarette manufacturers experimented with price reductions on premium brand cigarettes through coupon and promotional activities beginning in April. This experiment was soon followed by a 25-percent drop in wholesale cigarette prices, which resulted in a sharp decline in retail prices (USDA 1994b). Although prices were eventually raised, these activities indicate that there may be greater price competition among cigarette producers in the future. Similarly, the recent growth of low-price stores specializing in the sale of cigarettes, such as the Cigarettes Cheaper! chain in the San Francisco area and Puff 'N' Stuff in northern Illinois, has also reduced the retail price of cigarettes. These stores, which depend on high volume to profit, charge significantly less for cigarettes than supermarkets and other outlets do. For example, in mid-1994, a carton of premium cigarettes that cost \$18-22 in many outlets in California sold for \$14.99 at Cigarettes Cheaper!, and some name brands sold for even less (Schevitz 1994).

In contrast, the proposed June 20, 1997, national tobacco settlement would have reduced competition in the cigarette industry by granting cigarette companies an antitrust exemption to achieve the aims of the agreement. In its analysis of the proposed settlement, the FTC (1997) concluded that, based on past behavior and the structure of the industry, firms were likely to coordinate substantial price increases that would likely exceed the cost of the payments required by the agreement. Given this, the FTC concluded that the proposed settlement might generate substantial profits for cigarette producers.

Trade Policy, Tobacco, and Tobacco Products

Although acreage devoted to tobacco production has fallen worldwide, technological improvements have led to overall increases in tobacco production (Roemer 1993). In 1999, estimated global production of tobacco was more than 6 million metric tons; more than 60 percent of this was accounted for by four countries: China (34.9 percent), India (9.7 percent), the United States (9.4 percent), and Brazil (8.2 percent). In some producing countries (e.g., Zimbabwe), nearly all tobacco production is exported.

Up to 85 percent of global tobacco production is used for cigarettes. In 1996, global cigarette production was nearly 6 trillion cigarettes; more than half of this production was accounted for by three areas: China (30.0 percent), the European Community (13.7 percent), and the United States (13.1 percent) (USDA 1997c). Although cigarette consumption is falling in industrialized countries, global consumption is rising because of significant increases in developing countries. This global increase in demand has created opportunities for U.S. and other global cigarette firms to expand. World trade in cigarettes has grown steadily for at least the past 30 years. U.S. cigarette firms capitalized on this growth, expanding cigarette exports from an average of 24.3 billion per year in the late 1960s to a peak of almost 250 billion in 1996; as a result, domestic cigarette production rose even as domestic sales declined rapidly.

Through the 1990s, nearly 30 percent of all cigarettes produced in the United States were exported. The major U.S. cigarette exporters are Philip Morris Companies Inc., R.J. Reynolds Tobacco Company, and Brown & Williamson Tobacco Corporation; these companies account for more than 99 percent of U.S. cigarette exports (FTC 1997). In 1981, the three firms formed the U.S. Cigarette Export Association to compete more

effectively in foreign markets (this type of association is exempt from antitrust law under the Webb-Pomerene Act).

As Grise (1990) notes, trade in tobacco and tobacco products would be even higher if not for general trade policies and, in particular, widespread agricultural and industrial policies that protect domestic tobacco growers and producers of tobacco products. Numerous countries have policies that support domestic tobacco growing; in the United States, examples are the tobacco support program and the shortlived mandatory minimum content of domestic tobacco in domestic cigarettes. Likewise, both tariff and nontariff barriers to trade in tobacco and tobacco products have been erected around the world. These barriers include quotas, restricted product lists, exchange controls, prior deposits, mixing regulations, licensing requirements, and limits on advertising and other promotional activities (Grise 1990). Moreover, in several countries (including Japan, South Korea, and Thailand), various aspects of the manufacture and distribution of cigarettes have long been controlled by government monopolies that have largely prevented the import of foreign cigarettes (GAO 1992).

When tariff and nontariff barriers to trade are used to protect domestic tobacco and tobacco products, total supply of these products is usually lower than it would be otherwise, whereas domestic supply is higher. In the case of tobacco products, this arrangement has public health benefits resulting from the generally higher prices and reduced consumption of the protected products. Domestic suppliers benefit by supplying more at higher prices. Foreign suppliers, however, are likely to lose in this arrangement, because their access to these markets is limited and costs of supplying the markets are higher. In addition, restrictions on advertising and promotion in given countries are likely to make it difficult for new firms to successfully enter newly opened markets where existing brands are firmly entrenched.

Past Tobacco-Related Trade Policy

In general, tobacco products exported from the United States are specifically exempted from federal laws and regulations concerning the export of potentially harmful products, including the Federal Hazardous Substances Act (Public Law 86-613), the Toxic Substances Control Act (Public Law 94-469), and the Controlled Substances Act (Public Law 91-513) (GAO 1992). Similarly, although federal regulations (1) require that all cigarette packaging and advertising in the United States contain health warning labels and

(2) prohibit television and radio cigarette advertising, there are no federal regulations or laws concerning the packaging or advertising of domestically produced cigarettes that will be exported (GAO 1992).

Various U.S. policies and programs have been used to help domestic tobacco growers and cigarette companies expand into foreign markets (Connolly and Chen 1993). These policies include the USDA's Food for Peace Program, which sent more than \$1 billion in domestically produced tobacco to developing countries in the 1970s and early 1980s, and the 1984 Export Credit Guarantee Program, which exported domestically grown tobacco and helped U.S. cigarette producers enter Mideast markets (including Algeria, Egypt, Iraq, and Turkey) (Taylor 1984). Perhaps the most important, however, is Section 301 of the Trade Act of 1974 (Public Law 93-618) and its subsequent amendments.

Section 301 of the Trade Act of 1974

The Trade Act of 1974 was initiated by the Nixon administration when it sought permission to begin the Tokyo Round of GATT. GATT, an international trade agreement honored by nearly 120 countries, governs various aspects of international trade. (GATT is discussed in greater detail in "Multinational Trade Agreements," later in this chapter.) The first of these agreements was reached among 23 nations shortly after the conclusion of World War II. Since then, seven rounds have occurred, including the Uruguay Round, which concluded in April 1994 after more than seven years of negotiations.

The Trade Act of 1974 included in its final legislation various measures with the stated purpose of promoting free trade. One of these measures was Section 301, which gave the President the authority to investigate cases where trade and other practices of foreign countries were considered unjustifiable, unreasonable, or discriminatory in that they limited the ability of U.S. firms to sell their goods and services in foreign markets.

Section 301 expanded the authority given to the President by the Trade Expansion Act of 1962 (Public Law 87-794). That earlier legislation allowed for investigations of unjustifiable trade sanctions (those that directly violated GATT). Consequently, the act applied only to goods covered by GATT (which at the time excluded agricultural products, including tobacco). Section 301 expanded presidential authority to include trade in all U.S. goods and services and allowed the investigation of practices that were unreasonable but did not necessarily violate GATT. If negotiations were not successful in reducing or eliminating the unjustifiable

or unreasonable limits on trade, Section 301 authorized the President to impose retaliatory trade sanctions. Initially, Section 301 received little attention, although it would later become a widely used tool of U.S. trade policy (Nivola 1993).

Section 301 of the Trade Act of 1974 was strengthened by the Trade and Tariff Act of 1984 (Public Law 98-573) and the Omnibus Trade and Competitiveness Act of 1988 (Public Law 100-418). Now known as "Super 301," the section required the U.S. Trade Representative to annually identify countries and their practices that consistently limited market access to U.S. firms. More important, if negotiations failed to eliminate the unfair trading practices of these countries, mandatory retaliatory measures were to be imposed unless the President deemed these measures harmful to U.S. economic interests.

Four Section 301 cases in the late 1980s dealt with cigarettes: cases against Japan in 1985 and Taiwan in 1986 were initiated by the U.S. Trade Representative at the President's request, and cases against South Korea in 1988 and Thailand in 1989 were the result of the U.S. Cigarette Export Association's petitioning of the U.S. Trade Representative. Threats of retaliatory sanctions under Section 301 led to agreements with each country; as a result, U.S. cigarette firms were permitted access to those markets. The opening of the markets resulted in aggressive tobacco advertising by U.S. firms (Roemer 1993). Each of the four newly "opened" countries has laws, regulations, and ordinances concerning cigarette advertising and promotion. The governments of some of the countries have alleged that U.S. cigarette companies have violated restrictions on advertising and promotion.

A brief review of the four Section 301 cases follows; more details are contained in reports from the GAO (1990, 1992), and an empirical analysis of their impact on cigarette smoking is contained in Chaloupka and Laixuthai (1996).

Japan

The tobacco industry in Japan is largely monopolized by the company Japan Tobacco Inc. In 1979, Japan was the subject of two Section 301 cases, one involving cigars, which was prompted by the Cigar Association of America, and a second related to pipe tobacco, which was initiated at the request of the Associated Tobacco Manufacturers. The two cases were resolved in an agreement with Japan, which reduced market restrictions and lowered import duties (GAO 1990).

Before 1986, the domestic cigarette monopoly was protected from foreign competition through tariffs of 28 percent on all imported cigarettes and through Japanese distribution practices, which discriminated against imported cigarettes. The threat of Section 301 sanctions led to an October 1986 agreement that eliminated Japanese cigarette tariffs and changed excise tax payment procedures and other distribution practices that adversely affected imports of U.S. cigarettes. Existing Japanese policies related to cigarette advertising and other promotional practices were not affected by the agreement.

The agreement resulted in a significant expansion of U.S. cigarette firms in Japan. Japanese imports of U.S. cigarettes more than tripled in 1987 alone and continued to rise in 1988 and 1989, by which time the market share of U.S. firms was more than 15 percent (Grise 1990). This growth appeared to have slowed or stopped in the early 1990s. Total U.S. cigarette exports to Japan ranged from 54.0 billion to 57.7 billion annually during 1991–1993.

A downward trend during the 1970s and 1980s in per capita cigarette consumption in Japan appears to have reversed itself after the Japanese cigarette markets were opened to U.S. firms. Overall per capita consumption appears to have remained steady or increased slightly in recent years. However, among Japanese women, smoking prevalence rose from 8.6 percent in 1986 (before the agreement) to 18.2 percent by 1991. The 1991 rates were even higher among young adult women (27 percent) (Connolly and Chen 1993).

Part of this increase may be the result of advertising and promotional activities by U.S. cigarette firms in Japan. Between 1987 and 1990, total expenditures on cigarette advertising and promotion by U.S. cigarette companies in Japan nearly doubled. Most of these expenditures were on television advertising, which is allowed in Japan (but subject to some restrictions). Before the agreement, the domestic monopoly did not engage in extensive advertising. Afterward, it significantly expanded its advertising and promotional efforts. As a result, cigarette advertising moved from 40th to 2nd place in total television advertising in Japan (Sesser 1993).

Taiwan

Virtually all aspects of the tobacco industry in Taiwan are controlled by a state-run monopoly. In 1986, the U.S. Trade Representative threatened Taiwan with retaliatory trade sanctions over several governmental policies that limited the market access of U.S. cigarette companies. These policies included quotas and tariffs

on imported cigarettes, a ban on the retail sale of imported cigarettes, and a ban on print advertising of imported cigarettes. An agreement was reached in December 1986 that reduced tariffs and eliminated other barriers, thereby allowing U.S. cigarette companies greater access to the Taiwanese cigarette market. The agreement also contained several restrictions relating to cigarette packaging (which was required to have a specified health warning label) as well as advertising and promotional activities (e.g., the distribution of free samples was limited and point-of-purchase promotions were restricted to licensed establishments).

The agreement greatly increased U.S. cigarette companies' access to the Taiwanese cigarette market. In 1987 alone, total U.S. cigarette shipments to Taiwan increased 24-fold, and the market share of U.S. cigarette companies rose from 2 to 17 percent (Grise 1990); by 1997, the market share of imported cigarettes had risen to 30 percent (Hsieh and Yin 1998). Moreover, Taiwan's imports of relatively higher-quality U.S. tobacco rose, as the portion of U.S. tobacco in Taiwanese cigarettes increased from 35 to 55 percent to better compete with imported cigarettes (Grise 1990). However, per capita consumption of cigarettes, after increasing somewhat during the 1970s and early 1980s, fell from 1987 through 1996, due to public and private antismoking policies (Hsieh and Yin 1998). Smoking prevalence among Taiwanese women significantly increased in the late 1980s and has remained stable throughout the 1990s (Hsieh and Yin 1998).

Advertising and promotion of U.S. cigarettes after the agreement are likely to have contributed to the large rise in the market share of U.S. cigarette companies in Taiwan. Before the agreement, the only advertising and promotion permitted by the Taiwan Tobacco & Wine Monopoly Bureau were new product announcements and the use of billboards in the bureau's branch offices and distribution centers (GAO 1992). In 1987, spending on advertising and promotional activities by U.S. cigarette firms in Taiwan rose sharply but fell somewhat in the next three years. Nevertheless, total spending rose by 43.8 percent from 1987 to 1990 (GAO 1992). Given preagreement restrictions on advertising and promotion, almost all of these expenditures would have been for point-of-purchase and magazine advertising. Advertising by the Taiwanese cigarette monopoly, however, was limited even further after the agreement.

Authorities in Taiwan have alleged that point-ofpurchase promotional activities by U.S. cigarette companies have violated the terms of the 1986 agreement (GAO 1992). The agreement limits these activities to licensed wholesale, distribution, and retail establishments, which the Taiwan Tobacco & Wine Monopoly Bureau defines as those with a permit registering them as profit-seeking enterprises. Taiwanese authorities contend that U.S. cigarette firms have distorted this definition to include unlicensed retailers selling cigarettes, resulting in widespread advertising and unauthorized sales of U.S. cigarettes (GAO 1992).

After 1987, the government of Taiwan enacted several strong tobacco control policies, largely in response to the liberalization of cigarette trade resulting from the Section 301 agreement (Hsieh and Yin 1998). Many of these policies were initially rejected by the U.S. Trade Representative as unfair or discriminatory toward the tobacco industry and in violation of the 1986 agreement. One contentious issue pertained to the health warning labels proposed for cigarette advertising and packaging. The Taiwanese government initially proposed a set of strong, rotating health warning labels that would appear on the front of cigarette packaging and on all advertising. In response to the U.S. Trade Representative's opposition, the content of the label was changed to "excessive smoking is dangerous to health," and the label was placed on the side of packaging (Hsieh and Yin 1998). Eventually, in 1992, the labels were changed to include six rotating warnings communicating more specific information about the hazards of smoking.

The dispute over the Smoking-Hazards Prevention Act, introduced in 1991 with the stated aim of protecting the public health by preventing and controlling damage from tobacco products, was even more contentious (GAO 1992). The aim of the act would be accomplished by prohibiting smoking by those under 18 years of age, banning vending machine sales of tobacco products, limiting the tar and nicotine content of all cigarettes, requiring that the packaging of all tobacco products include not only health warning labels but also tar and nicotine content in Chinese, and banning all tobacco advertising and certain other promotional activities. The act was immediately challenged by the U.S. Trade Representative as a unilateral violation of the 1986 agreement that allowed U.S. cigarette companies to advertise in Taiwan (GAO 1992). Sesser (1993) reports that a confidential position paper drafted by the U.S. Trade Representative in January 1992 stated that the proposal was an attempt to protect the Taiwanese cigarette monopoly from foreign competition and that the various measures proposed would have little impact on smoking. In July 1993, the Clinton administration's U.S. Trade Representative, Michael Kantor, stated that his office would not challenge the act if it was enacted (Sesser 1993). Six years after its introduction, the Smoking-Hazards Prevention Act was finally enacted with compromise clauses that permit cigarette advertising in magazines (Hsieh and Yin 1998).

South Korea

South Korea's Tobacco & Ginseng Corporation controls all aspects of that country's tobacco growing and production, which had traditionally been protected by high tariffs imposed on foreign cigarettes. In 1982, South Korea enacted and aggressively enforced legislation making it a criminal offense to sell, buy, or possess foreign cigarettes (Eddy and Walden 1993). Beginning in 1987, almost all cigarette advertising and other promotional activities were banned by the Tobacco Monopoly Act. After petitioning by the U.S. Cigarette Export Association in January 1988, the U.S. Trade Representative investigated these practices. In response to the threat of retaliatory sanctions on South Korean textile exports to the United States, a Record of Understanding was signed by the two countries in May 1988. This agreement opened South Korean cigarette markets to U.S. firms by eliminating the ban on the sale of foreign cigarettes, reducing the tariff on imported cigarettes, allowing the distribution of free samples, and allowing some print advertising of cigarettes and the sponsorship of sporting events. The agreement also prohibited advertising that targeted women and young people (smoking is prohibited in South Korea for persons under 20 years of age). Finally, all cigarette packaging and magazine advertising were required to include a health warning label.

Although cigarette smoking had been increasing steadily in South Korea during the 1980s, the rate of growth in smoking more than tripled when cigarette markets were opened to foreign competition (Roemer 1993). Much of the increase appeared to have been the result of dramatic increases in smoking prevalence among young people. From 1988 to 1989 alone, smoking prevalence among male teenagers rose from 18 to 30 percent, and smoking prevalence among female teenagers increased from 2 to 9 percent (Sesser 1993). Much of the increase in consumption was accounted for by the increased use of imported cigarettes. Import share in the market rose from 0.06 percent before the agreement to nearly 8.5 percent in 1994 and continued to increase steadily (U.S. Department of Commerce, Tobacco Export Task Force Analysis, unpublished data, November 13, 1995). Part of the increase may be attributable to an increase in advertising by U.S. cigarette companies in South Korea after the liberalization of cigarette trade. In late 1988, South Korea passed the Tobacco Business Act (effective January 1, 1989), which limited advertising and promotional efforts to point-of-purchase advertising, magazine advertising, and sponsorship of public events (GAO 1992). In 1991, the Korea Tobacco Association (comprising the U.S. Cigarette Export Association firms and the Korean tobacco monopoly) outlined a self-regulating voluntary marketing agreement to comply with the Record of Understanding and the Tobacco Business Act.

Nevertheless, the South Korean government indicates that some promotional activities of U.S. cigarette companies violate the spirit of the Tobacco Business Act. These allegations concern distribution of free cigarettes, advertising placement for televised events sponsored by U.S. tobacco firms, the distribution of nontobacco "gifts" bearing company trademarks, and the targeting of youth. Although no formal actions related to these violations were initiated, the Koreans did begin renegotiating the Record of Understanding with the United States in 1995. In August 1995, the United States government agreed to modify the market access agreement with the Koreans to allow them greater flexibility to impose nondiscriminatory, health-based measures that restrict the use of tobacco products, including limitations on tobacco product advertising.

Thailand

Perhaps the most publicized and contentious Section 301 dispute was initiated by the U.S. Trade Representative in response to petitioning by the U.S. Cigarette Export Association in April 1989 over Thailand's virtual ban on the import of cigarettes and complete ban on cigarette advertising and other promotional activities in that country. The complaint cited various restrictions on the importation and sale of cigarettes and referred to discriminatory duties and taxes on cigarette imports (GAO 1992). All aspects of the domestic tobacco markets in Thailand are controlled by a government-run monopoly, which stopped its own cigarette advertising and promotion in April 1988. However, foreign companies continued their activities, which prompted a total government ban on cigarette advertising in Thailand in February 1989. The formal investigation began in May. After no agreement could be reached, the U.S. Trade Representative consented to submit the complaint to the GATT dispute resolution process.

The panel created by GATT investigated the U.S. complaint that the import barriers and advertising restrictions were a violation of the international agreement's principles. In October 1990, the GATT Council sustained the panel's recommendations and ruled that the ban on imports was a violation of the

GATT treaty. However, the council upheld the high Thai cigarette excise taxes (applied to both domestic and foreign cigarettes) and the right of the government to restrict the overall supply of cigarettes. Regarding the Thai advertising ban, the council noted that GATT allows member nations to use various policies to protect public health if the policies are applied to both domestic and foreign products. A cigarette advertising ban that made it difficult for new foreign firms to compete with existing domestic firms was ruled justifiable under the treaty, because allowing advertising could stimulate the demand for cigarettes, particularly among youth (Contracting Parties to the General Agreement on Tariffs and Trade 1991; Roemer 1993). This decision was based on Article XX of GATT, which states that:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting parties of measures . . . necessary to protect human . . . health [or] necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement.

The GATT ruling led to an agreement in November 1990 between the United States and Thailand that allowed the importation of U.S. cigarettes into Thailand. Imported cigarettes were then subject to the same laws and regulations as those marketed by the Thai Tobacco Monopoly (GAO 1992). Thus, U.S. cigarettes would be taxed the same and subjected to the same supply restrictions, and the advertising and promotion of these cigarettes (including the use of cigarette company logos, trademarks, and other symbols on nontobacco products) would be prohibited. The Thai government, however, has indicated that U.S. cigarette companies have tried to circumvent the ban on promotional activities by tactics such as sponsoring sporting events and placing cigarette logos or symbols in televised programming. No formal complaints have been filed.

After its success in upholding the ban on advertising and promotion, the Thai government in 1992 enacted two laws restricting smoking: the Non Smokers Health Protection Act and the Tobacco Products Control Act. The first act restricted smoking in designated public places. The second was a comprehensive act that required that all tobacco products disclose

their ingredients, allowed the Ministry of Public Health to determine all aspects of labeling, including health warnings, and banned the following: smoking by those under 18 years of age (imposing fines on violators); vending machine sales; distributing free samples, exchanges, and gifts of cigarettes; tobacco advertising (including, under the Thai definition of advertising, the use of cigarette logos and other symbols on nontobacco products) except in international magazines and live telecasts originating outside Thailand; advertising products with the same name as tobacco products; producing, importing, advertising, and selling products imitating tobacco products; and selling cigarettes not complying with the labeling provisions (Roemer 1993).

The cigarette trade agreement that opened the Thai cigarette market to U.S. firms has led to a rise in imports from less than 1 percent of the market before the agreement to about 4 percent in 1993. Because of current trends, this change is likely to increase substantially in the future (e.g., U.S. cigarette exports to Thailand rose by more than 56 percent from 1992 to 1993). Part of the increase may be the result of increased smoking prevalence among women and young people in Thailand (USDA 1994a).

Multinational Trade Agreements

The North American Free Trade Agreement

In 1993, the United States approved the North American Free Trade Agreement (NAFTA), a comprehensive agreement that eliminated most of the barriers to trade between the United States, Canada, and Mexico; implementation began January 1, 1994. This agreement further reduced already low trade barriers between the United States and Canada resulting from an earlier free trade agreement. More important, the new agreement substantially reduced existing trade barriers between the United States and Mexico by eliminating all nontariff barriers to trade and by phasing out most tariffs. Mexican tariffs on U.S. tobacco and tobacco products were initially set at 50 percent; the 1998 rate was 25 percent. Supporters of the agreement argued that it would lower prices, lead to a net increase in jobs (particularly in export industries), and spur economic growth in all three countries. Opponents countered that U.S. firms would have an incentive to shift production to Mexico to reduce labor and other operating costs, thereby leading to a net reduction in U.S. employment.

Before the agreement, some trends in tobacco production in the United States, Canada, and Mexico were similar. Total tobacco production and acreage devoted to tobacco growing in 1990 were well below their 1981 levels in all three countries, but downward trends in the United States had reversed by 1987. Similarly, in recent years, tobacco production in Mexico has been expanding (USDA 1997d). During the 1980s and early 1990s, cigarette consumption fell sharply in both the United States and Canada but rose in Mexico. At least part of the increase in the Mexican demand for cigarettes resulted from increases in income, which contributed to a shift to the consumption of higherquality cigarettes among Mexican smokers (USDA 1992). Since 1994, however, cigarette imports into Mexico have fallen as consumer purchasing power declined; no imports were expected in 1997 (USDA 1997d).

Trade in tobacco among the three countries was relatively limited before the agreement. Mexican exports of tobacco to the United States were about 5 percent of total exports, or less than 2 percent of total U.S. tobacco imports. Similarly, less than 4 percent of U.S. tobacco imports came from Canada, and about 7 percent of U.S. tobacco exports went to Canada. Finally, almost no tobacco was exported from the United States to Mexico (USDA 1992).

Trade in tobacco products (mainly cigarettes) was even more limited before the agreement. In 1990, just over 0.1 percent of total U.S. cigarette exports went to Mexico, and only 0.07 percent went to Canada. Similarly, there was no trade in cigarettes between Canada and Mexico. The only exception was for exports of cigarettes from Canada to the United States, which were almost 64 percent of total Canadian cigarette exports and almost 20 percent of total Canadian production (USDA 1992). However, as is discussed later in this chapter (see "International Tobacco Taxes"), most of these cigarettes were reintroduced into a Canadian black market to evade the significantly higher Canadian cigarette taxes (Sweanor and Martial 1994).

Because of the earlier free trade agreement between the United States and Canada, NAFTA does not appear to have had a significant impact on trade in tobacco and tobacco products between the two countries. If anything, the reduction in Canadian cigarette taxes in 1994 has led to a substantial reduction in Canadian cigarette exports to the United States, as the smaller differential in cigarette prices reduced the incentive to export cigarettes to the United States for bootlegging back into Canada.

The agreement's elimination of Mexican import licenses on tobacco and cigarettes, and gradual reduction in Mexican tariffs on tobacco and tobacco products, however, were expected to increase Mexican imports of both flue-cured and burley tobacco as well as cigarettes from the United States (USDA 1992). The elimination of U.S. tariffs on Mexican tobacco and the improved quality of this tobacco were also expected to result in increased Mexican tobacco exports to the United States. Privatization of the unmanufactured tobacco industry in Mexico, however, has changed the nature of the industry and has led to an improvement in the quality of Mexican leaf tobacco (USDA 1997d). The slow elimination of tariffs and the improved quality of domestically grown tobacco, coupled with the decline in the value of the peso, appear to have limited the impact of NAFTA on trade between the United States and Mexico in tobacco and tobacco products. This may change, however, as tariffs are further reduced and, eventually, eliminated and if the peso continues its recent strengthening against the dollar.

Uruguay Round of GATT

This latest GATT agreement, which concluded in April 1994, involved 117 countries, and many other nonmembers have agreed to abide by its provisions. Formal approval of the agreement by the U.S. Congress came at the end of 1994.

Several basic principles are outlined in GATT: a commitment to achieving free trade by limiting and eventually eliminating tariff and nontariff barriers to trade, the nondiscriminatory application of any restrictions on trade to all member countries, the compensation of trading partners for any damages resulting from changes in trade barriers, and the negotiated settlement of any trade disputes through an orderly process rather than through retaliation. However, GATT has had no enforcement power.

Since the conclusion of its first round in 1947, GATT has led to sharp reductions in tariffs and other impediments to trade in manufactured goods. Before the most recent round, GATT had not been applied to trade in agricultural commodities or services. The 1994 Uruguay Round, however, significantly expanded GATT's coverage to include trade in agricultural products, services, and more. Moreover, the new agreement created the World Trade Organization, a permanent forum for GATT members to address traderelated issues among member countries. This forum strengthened GATT's ability to resolve trade disputes.

Supporters of the GATT treaty have argued that it will lead to a substantial increase in world trade to the economic benefit of all countries involved. For example, President Bill Clinton stated in the introduction to the

Uruguay Round Agreements Act that the treaty, when fully implemented, would add \$100-200 billion to the U.S. economy annually and would create hundreds of thousands of new jobs. He went on to note that because the United States is the world's largest trading nation, it would be the biggest beneficiary of the treaty (U.S. Congress 1994).

The Uruguay Round of GATT was expected to benefit the U.S. tobacco industry by reducing the historically high tariffs on tobacco and tobacco products imposed in numerous countries and by reducing other widely used nontariff barriers to trade. For example, the European Community would reduce tariffs on cigars by 50 percent, tariffs on cigarettes and other manufactured tobacco products by 36 percent, and tariffs on unmanufactured tobacco by 20 percent, and the Philippines would reduce tariffs on leaf tobacco, cigars, and cigarettes by 10 percent (USDA 1994b). Similarly, foreign access to U.S. markets would rise, as U.S. tariffs on cigar wrappers would be eliminated. At the same time, U.S. tariffs on cigar filler and binder tobacco, cigars, and most cigarettes would be reduced by 55 percent; tobacco stems and refuse by 20 percent; and other unmanufactured tobacco and smoking tobacco by 15 percent (USDA 1994b).

More important, Section 422 of the Uruguay Round Agreements Act allowed the President of the United States to waive Section 1106(a) of the Omnibus Budget Reconciliation Act of 1993 if he determined that this action was necessary or appropriate to comply with international trade agreements that include the United States. As noted previously, the 1993 legislation requiring that cigarettes manufactured in the United States include a minimum of 75 percent domestically grown tobacco or face penalties was waived by President Clinton's tariff rate-quota proclamation in September 1994.

The reductions in tobacco-related trade barriers achieved in the Uruguay Round appear to have had a dramatic impact on global trade in tobacco and tobacco products (Chaloupka and Corbett 1998). From 1994 to 1997, for example, there was a 12.5-percent increase in unmanufactured tobacco exports globally, following a decade of almost no growth; similarly, global cigarette exports rose by 42 percent from 1993 to 1996, while global cigarette consumption rose by 5 percent (Chaloupka and Corbett 1998). As discussed previously, however, the GATT Council's resolution of the tobacco-related dispute between Thailand and the United States clearly indicates that the adoption and implementation of strong tobacco control policies aimed at improving public health is consistent with the liberalization of trade.

Discussion and Recent Developments

The threat of retaliatory trade sanctions under Section 301 of the Trade Act of 1974 has successfully opened some foreign markets to U.S. cigarette manufacturers, thereby significantly expanding trade in tobacco products between the United States and these countries. Chaloupka and Laixuthai (1996), in their empirical examination of these agreements, concluded that the market share of U.S. cigarette companies in the affected countries was 600 percent higher, on average, in 1991 than it would have been in the absence of these agreements. More important, they concluded that overall cigarette smoking rose as a result of the Section 301 agreements. Chaloupka and Laixuthai (1996) estimated that per capita cigarette consumption in 1991 was 10 percent higher, on average, in the four countries than it would have been had the markets remained closed to U.S. cigarettes. They attributed the increase in smoking to greater competition in the cigarette markets, resulting in lower cigarette prices and increased cigarette advertising. In addition, they predicted that similar actions in other historically closed countries would lead to similar increases in cigarette smoking.

Similarly, the implementation of multinational agreements liberalizing trade, including trade in tobacco and tobacco products, is likely to further increase U.S. exports of tobacco and tobacco products to countries around the world. A probable consequence of this increase is that the prices of cigarettes and other tobacco products will fall as trade barriers are reduced or eliminated and competition is enhanced. As is discussed in detail later in this chapter (see "Effect of Price on Demand for Tobacco Products"), reductions in price will stimulate the use of cigarettes, particularly among adolescents and young adults. Because of the substantial health consequences associated with cigarette smoking, one likely result of the increased liberalization of trade in tobacco and tobacco products, then, is a global increase in morbidity and mortality related to cigarette smoking and other tobacco use. Recent estimates confirm the relationship between trade liberalization and tobacco use. Taylor and colleagues (in press) conclude that reductions in trade barriers globally have led to increased tobacco use, with the largest impact in low- and middle-income countries.

The apparent conflict between some U.S. policies that promote free trade and help U.S. firms enter foreign tobacco markets and other U.S. policies that both discourage smoking domestically and support international efforts to reduce tobacco use has been described in two GAO reports. The reports were completed at

the request of congressional members concerned about U.S. efforts to open foreign cigarette markets. In the second report, the GAO (1992) presented the U.S. Trade Representative's position "that as long as cigarettes remain a legal commodity in the United States and abroad, there is no legal basis to deny cigarette manufacturers assistance in gaining market access. Thus, when [the U.S. Trade Representative] determines that unfair foreign trade barriers, such as import restrictions and discriminatory practices, hinder the import and marketing of U.S. cigarettes abroad, it negotiates for their removal" (p. 23). Similarly, the U.S. Trade Representative maintained that the USDHHS's "jurisdiction does not extend to trade policy—it does not have a foreign affairs mandate. Its clear responsibility lies in the domestic realm, not the international one" (p. 24).

In the first report on this predicament, the GAO (1990) had offered three alternatives for reconciling those apparent conflicts in U.S. policy.

- If Congress believes that trade concerns should dominate, it may choose to do nothing to alter efforts aiding U.S. cigarette exporters even while it continues to promote awareness (domestically and internationally) of the health consequences of smoking and to encourage efforts to reduce smoking.
- If Congress believes that health considerations should have primacy, it may grant the USDHHS the responsibility to decide whether to pursue trade initiatives involving products with substantial health consequences (including cigarettes and other tobacco products).
- Rather than having one policy dominate, Congress could require that health matters be included in the trade policy process through the participation of the USDHHS so that these issues could be considered case by case.

Several factors indicate that the apparent dichotomy between trade and health policy is changing in favor of the third approach suggested by the GAO. For example, in 1989 a bill was introduced in Congress to (1) require U.S. cigarette firms in foreign markets to operate under the same guidelines as they do in domestic markets, (2) mandate health warning labels on all exported tobacco products, and (3) strongly discourage the executive branch from assisting U.S. tobacco company efforts to open foreign tobacco markets (Roemer 1993). Later that year, as a result of the U.S. Trade Representative's investigation of Thailand's trade practices, a public hearing on the case was held.

Numerous congressmen, public health officials, and others (including former U.S. Surgeon General C. Everett Koop) testified against tobacco-related U.S. trade policies (Eddy and Walden 1993). Although neither effort was successful (the bill did not pass, and the hearing produced no change in trade policy), both linked the issue of the health consequences of tobacco use to U.S. trade policy. The 1990 GAO report, for example, was the direct result of the failed 1989 bill.

More recently, interagency discussions between the office of the U.S. Trade Representative and officials from the USDHHS have pursued the harmonization of trade and health policy while representatives from the USDHHS have participated in recent negotiations with Taiwan, South Korea, and others concerning cigarette trade issues (Holzman 1997). Moreover, the U.S. Trade Representative has shown greater sensitivity to public health concerns and has not opposed nondiscriminatory tobacco control legislation in other countries (Bloom 1998; National Cancer Policy Board 1998). This position has been formalized as part of the Doggett Amendment to the Department of Commerce and Related Agencies Appropriations Act, 1998, that allows for the use of Section 301 in very limited circumstances. Specifically, the Doggett Amendment, sponsored by Lloyd Doggett (D-TX), states that:

None of the funds provided by this Act shall be available to promote the sale or export of tobacco or tobacco products, or to seek the reduction or removal by any foreign country of restrictions on the marketing of tobacco or tobacco products, except for restrictions which are not applied equally to all tobacco or tobacco products of the same type (Public Law 105-119, Section 618).

Similar guidelines were distributed by the Clinton administration to all diplomatic posts in February 1998. These guidelines state that:

In light of the serious health consequences of tobacco use, the U.S. Government will not promote the sale or export of tobacco or tobacco products or seek the reduction or removal by any foreign country of nondiscriminatory restrictions on the marketing of tobacco or tobacco products. At the same time, the U.S. Government will continue to seek elimination of discriminatory trade practices and will strive to ensure that U.S. firms are accorded the same treatment in foreign countries as that country's own firms and firms from other countries (The National Economic Council and The National Security Council of the White House, Final Guidelines on Health, Trade, and Commercial Issues, facsimile transmission to all diplomatic and consular posts, February 16, 1998).

Moreover, as part of the guidelines, U.S. diplomatic "posts are encouraged to assist and promote tobacco-control efforts in host countries."

Several important issues remain unresolved. Perhaps most important is the opening of Chinese cigarette markets to U.S. and other multinational tobacco companies as part of China's World Trade Organization accession. With more than 300 million cigarette smokers (67 percent of men but only 7 percent of women), China is a particularly attractive market for international cigarette producers. In recent years, U.S. and other multinational tobacco companies have entered the Chinese tobacco markets through joint ventures with the Chinese government's tobacco monopoly, the China National Tobacco Corporation (Holzman 1997).

Economic Impact of the U.S. Tobacco Industry

Tobacco growing played a key role in the development and growth of the U.S. economy. Throughout much of the 20th century, however, the importance of tobacco to the overall economy has diminished significantly, although its regional and local importance in some areas remains high. Several recent studies provide more detailed evidence concerning the economic importance of tobacco to the U.S. economy.

A recent study by American Economics Group, Inc. ([AEG] 1996), which was funded by the tobacco industry, provides some information concerning the impact of tobacco on the U.S. economy in 1994. The report updates similar previous reports by other firms, including that by Price Waterhouse (1992). AEG divided the macroeconomic effects of tobacco into those affecting the core sector, which includes tobacco production and distribution, and those affecting the supplier sector, which consists of industries producing and distributing intermediate goods for the core sector (including the goods and services used in cigarette production). The analysis also separately considered expenditure-induced impacts, which depend on the multiplier effects associated with spending by those in the core and supplier sectors, and tobacco-related tax revenues, including those raised by tobacco taxes, general sales taxes on tobacco products, and income and other taxes on tobacco industry employees and firms. The study estimated that in 1994, more than 1.8 million persons were employed, earning \$54.3 billion in wages and benefits, as a result of the tobacco business in the United States. Total estimated tax revenues from tobacco were almost \$36 billion in 1994. The report concluded that tobacco made a significant contribution in every state and the District of Columbia.

Several recent studies, however, have indicated that these estimates significantly overstated the economic impact of tobacco on the U.S. economy. At the request of the Coalition on Smoking OR Health (CSH), Arthur Andersen Economic Consulting (1993) reviewed the Price Waterhouse estimates for 1990. They concluded that, as a result of several methodological flaws, the Price Waterhouse "employment and job loss figures are grossly inflated" (p. 1). For example, of the 681,351 jobs Price Waterhouse attributed to tobacco in its core and supplier sectors, only 259,616 were directly related to tobacco growing, manufacturing, warehousing, and wholesaling. Of the difference, 166,791 were retail jobs and 254,944 were supplier jobs, most of which were not devoted full-time to tobacco. Thus, stating that these jobs depended on tobacco was inaccurate.

Other studies questioned the Price Waterhouse assumption that every one job that is dependent on tobacco creates, through the multiplier effect, an additional 2.35 jobs throughout the economy. This assumed effect would result because those who purchase tobacco products would generate income for those who produce and those who distribute tobacco, who in turn would spend this income on other goods and services—thereby generating income for others, as this effect spread even further. Warner (1994) and Arthur Andersen Economic Consulting (1993) noted that this multiplier effect is likely to significantly overstate the impact of tobacco, because it implicitly makes the incorrect assumption that money spent on tobacco would not be spent elsewhere in the absence of tobacco. Instead, those funds not spent on tobacco would be spent on other goods and services, creating jobs and generating income that would also be spent.

Warner and Fulton (1994) addressed these issues by using a macroeconomic model to consider the net impact of tobacco on the economy of one state, Michigan. The Price Waterhouse study had estimated that direct tobacco-related employment in Michigan was 7,724 in 1990 and that all tobacco-related employment in Michigan totaled 69,575. Warner and Fulton (1994) estimated that in 1992 in Michigan, 7,843 jobs directly depended on tobacco but that only an additional 11,284 jobs were either indirectly related to tobacco or induced by spending from those whose jobs were dependent on tobacco. (This estimate for indirect tobacco-related jobs did not consider [as the Price Waterhouse estimate

did] the impact of income derived from tobacco production and distribution in the rest of the nation and spent on products produced in Michigan.) These researchers further estimated that, in the absence of tobacco, total employment in Michigan would have risen by about 5,600 because of a redistribution of spending away from tobacco products to other goods and services, including those more integral to the Michigan economy. As a result of the changes in employment, total incomes in Michigan would have been \$226 million higher in 1992 in the absence of tobacco. This amount resulted not only from incomes associated with new jobs but also from higher incomes for those with existing jobs (in part because of a change in job mix from lower-income to higher-income jobs in the absence of tobacco).

Warner and colleagues (1996) extended this analysis to examine the impact of tobacco on the regional economies of the United States. The researchers examined the effects of reducing or eliminating domestic expenditures on tobacco on nine regional economies (the eight regions defined by the U.S. Department of Commerce, Bureau of Economic Analysis, subdividing the Southeast into two parts based on tobacco growing and producing). They estimated that the elimination of spending on tobacco products in 1993 would have led to 303,000 fewer jobs in the Southeast tobacco region, while increasing jobs in all other regions by about the same amount. By the year 2000, they estimated that, under this scenario, the loss in jobs in the tobacco region would fall to about 222,000 as the regional economy adjusts, while the net impact nationally would be an increase in jobs of 133,000. A more realistic scenario—one that doubles the recent rate of decline in tobacco use—is estimated to have smaller effects on employment. Warner and colleagues (1996) estimated a loss of 36,600 jobs in the tobacco region by the year 2000, an amount equal to 0.2 percent of total regional employment. They concluded that the industry's claims concerning job losses resulting from reduced tobacco use are significantly overstated and that the impact of tobacco on employment should not be a primary concern, given the magnitude of the toll it takes on health.

The AEG and Price Waterhouse reports were limited also because they presented static estimates of the economic impact of tobacco (Arthur Andersen Economic Consulting 1993). That is, the reports ignored underlying trends in the domestic demand for cigarettes, trends in the import and export of tobacco and tobacco products, and changes in agricultural and manufacturing technologies that themselves are reducing employment in tobacco growing and manufacturing. Warner and

Fulton (1994) considered these factors by predicting the net impact that eliminating tobacco-related revenues would have on the Michigan economy if existing downward trends in tobacco sales continued: by 2005, the loss of revenue from tobacco in Michigan would yield a net gain of 1,500 jobs in the state.

A similar issue was considered in two recent reports of the USDA (1993, 1997c). The reports noted that the large declines in tobacco production throughout the 1980s had a relatively minor impact on the macroeconomics of major tobacco-growing regions. Indeed, total personal income, adjusted for inflation, grew by 14–57 percent from 1979 through 1989 in the nine major regions analyzed; the average growth in all U.S. tobacco-growing counties was 28 percent (USDA 1993). This phenomenon was attributed to the relatively small share of tobacco in these diverse regional economies (on average, less than 1 percent of total income was accounted for by tobacco in tobaccogrowing counties). Even though acreage devoted to tobacco growing has declined over time, rising prices have helped to keep gross income from tobacco growing relatively stable, while clearly reducing the share of tobacco in local economies (USDA 1997c).

Critics of higher cigarette excise taxes and other policies to reduce tobacco use have argued that the macroeconomic consequences of these policies would be significant, particularly for some state and local economies. For example, economist Dwight R. Lee predicted that the 75-cent increase in the federal cigarette excise tax included in the proposed 1993 Health Security Act would lead to a loss of about 82,000 jobs and \$1.9 billion in incomes in the tobacco sector, which would cause an additional loss of 192,000 jobs and an attendant loss of income throughout the economy (U.S. House of Representatives 1994). He further noted that southern states would be particularly hard hit by this tax increase.

Similar arguments, based on the AEG and Price Waterhouse analyses, were made in the recent debate over proposed national tobacco legislation. For reasons noted previously, predictions based on these estimates are almost certain to substantially overstate the effects of higher tobacco taxes and stronger prevention policies on the U.S. macroeconomy. As discussed previously, Warner and colleagues' (1996) regional analysis of the economic role of tobacco concluded that tobacco has a negative net economic impact in all but the most tobacco-dependent region. Thus, it appears inappropriate to raise concerns about adverse economic impact in opposing policy measures that would discourage tobacco use.

Moreover, many supporters of legislation calling for increases in the cigarette excise tax have urged that measures be included to mitigate the possible adverse economic impact of the higher taxes for tobaccoproducing regions. For example, Richard J. Durbin (D-IL) suggested that part of the revenues from higher cigarette excise taxes could be earmarked for efforts to help tobacco farmers switch to other crops, thereby easing the transition for tobacco-producing regions. Likewise, the CSH (1994) recommended that a portion of new tobacco tax revenues be earmarked for buying out tobacco allotments, constructing infrastructure and modernizing equipment for agricultural diversification, and stimulating economic development in areas relatively dependent on tobacco. Similarly, President Clinton called for assistance for tobacco farmers and their communities to be included in any tobacco legislation sent to him (USDA 1998a).

A final objection to the AEG and Price Water-house estimates is that they failed to consider the health and other consequences of cigarette smoking (Arthur Andersen Economic Consulting 1993). In one sense, they underestimated the economic contribution of cigarette smoking. As Schelling (1986) and Warner (1994) note with some irony, the employment figures in these and other industry-funded studies do not

include the income that tobacco generates for health care personnel, undertakers, and a variety of other persons whose jobs are related to the negative health consequences of tobacco use; nor do these industry estimates include the considerable income derived from specifically smoking-related services, such as air filtration systems. The total amount spent in the United States to treat smoking-related illnesses has been estimated to exceed the total amount spent on tobacco products (Centers for Disease Control and Prevention [CDC] 1994; Warner 1994). Similarly, as described in greater detail later in this chapter (in "Estimates of the Costs of Smoking"), the Price Waterhouse study did not include other economic costs associated with cigarette smoking, such as lost productivity due to smoking-related morbidity and mortality. Finally, as Northup (1993) states, the Price Waterhouse estimates of employment dependent on tobacco invite a disturbing comparison, for they imply that "one person must die each year to sustain two jobs. Put another way, at least twenty-two people must die to support the forty-four year career of a [tobacco industry] employee. Surely, no one would argue that this is an acceptable trade-off. It is absurd for the tobacco industry to use lost jobs as a rationale for not saving lives" (p. 86).

Effect of Price on Demand for Tobacco Products

One of the fundamental laws of economics is that of the downward-sloping demand curve: as the price of a product rises, the quantity demanded of that product falls. In the terminology of economists, this inverse relationship arises from the process known as the consumer's constrained utility maximization. That is, when facing a given set of prices, consumers will try to maximize the benefits or satisfaction they receive from consuming, but these efforts are constrained by the consumers' available resources, including income and time.

The demand for tobacco products is different from the demands for most other consumer goods because of the addictive drug (nicotine) found in these products. The key implication that addiction has for demand is that past consumption decisions will be an important determinant of current choices. For example, to an addicted smoker, one of the benefits of continued cigarette smoking is avoiding nicotine

withdrawal. In the past, many researchers viewed addictive consumption as an irrational behavior not conducive to standard economic analysis (e.g., Elster 1979; Winston 1980; Schelling 1984). This view implied that the demand for addictive products, including tobacco, did not follow the basic laws of economics, including that of the downward-sloping demand function that ordinarily applies when constraints (such as cost) are raised against use. However, as will be described later in this section, numerous studies of cigarette smoking and other tobacco use, including several recent studies that explicitly account for tobacco's addictive nature, find a strong inverse relationship between price and consumption.

To economists, price includes not only the money price of purchasing a product but also the time and other costs associated with buying and using that product. Measures that limit minors' access to tobacco, for

example, may discourage underaged smoking by raising the time and potential legal costs associated with obtaining these products. Similarly, sufficiently stringent restrictions on smoking in public places will raise the costs of smoking, whether by forcing people outdoors if they want to smoke (thereby increasing time and perhaps comfort costs) or by imposing fines for smoking in restricted areas (thereby increasing money costs).

The health consequences associated with cigarette smoking are another important component of the price of cigarettes. As consumers perceive greater health risks from cigarette smoking, their demand for cigarettes tends to fall. This effect is clearly seen in the reductions in smoking prevalence and average cigarette consumption that occurred soon after the release of the 1964 Surgeon General's report on smoking and health, which for the first time drew widespread public attention to the health problems caused by cigarette smoking (U.S. Department of Health, Education, and Welfare 1964). Thus, when economists and others study the demand for tobacco products, efforts are made to include not only money prices but also measures that reflect the other costs of consuming these products.

In addition to price, several other factors affect the demand for any product. Disposable income, for example, is an important determinant of demand. In general, as income rises, so does consumption of most goods. Economists define these goods as normal goods. Inferior goods, on the other hand, are those for which demand falls as income rises. An individual's tastes or preferences will also affect demand. Because these tastes are difficult to observe and measure, certain sociodemographic characteristics are usually included as proxies in studies of the demand for tobacco. These characteristics include sex, ethnicity, education, religious beliefs, marital status, and employment status.

Finally, because the addictive nature of tobacco use has been clearly documented, many recent studies of demand have tried to account for the effects of past consumption on current consumption. Many of these studies were based on a model that applies the standard rational, utility-maximizing paradigm of economics to the consumption of addictive substances (Becker and Murphy 1988). This model explicitly recognizes the intertemporal links in consumption by making current consumption decisions dependent on past choices. The model thus incorporates the elements of tolerance, reinforcement, and withdrawal, which distinguish the consumption of addictive from non-addictive substances (USDHHS 1988).

Although many of the factors described in this introduction have an important impact on demand, the studies subsequently reviewed in this section emphasize the effects of money prices on cigarette smoking and other tobacco use. In reviewing empirical studies of the demand for cigarettes and other tobacco products, this section focuses primarily on estimates of the price elasticity of demand, which is defined as the percentage change in consumption that results from a 1-percent increase in price. (An overall reduction in cigarette consumption comprises both a reduction in the number of cigarettes consumed by current, persisting smokers and a reduction in the prevalence of smoking itself—which itself comprises both an increase in smoking cessation and a decrease in smoking initiation.)

Numerous studies have estimated the price elasticity of demand for cigarettes. These studies used diverse econometric and other statistical methods on different types of data from many countries. Relatively few studies have examined the demand for other tobacco products, and none have examined the effects on brand choice of the price differentials between premium brands and the lower-price discount and generic cigarettes.

Studies Using Aggregate Data

Several studies of the demand for cigarettes in the United States have used aggregate data (Table 6.7). Some of these were time series studies for the nation as a whole or for geographic units (notably California). Others employed pooled cross-sectional time series data consisting of annual observations for some or all states over time. Price elasticity (the percentage change in the quantity demanded resulting from a 1-percent increase in price) estimates obtained from recent studies using aggregate data fall in the overall wide range of -0.14 to -1.12, but most of these estimates are between -0.3 and -0.5. Differences in the estimates resulted from differences in theoretical and empirical modeling, in the data employed, and in the econometric and statistical methods used to analyze these data.

All but two of these studies were econometric studies that tried to control for other factors that could affect the demand for cigarettes, including income, socioeconomic and demographic factors, and existing policies for reducing tobacco use. The other two studies (Baltagi and Goel 1987; Peterson et al. 1992) used alternative quasi-experimental methods that compared changes in cigarette consumption in states with tax increases with those in states with no tax increases; both studies obtained estimates of the price

Table 6.7. Recent estimates of the price elasticity of cigarette demand from aggregate data

Study	Estimated price elasticity	Comments
Advisory Commission on Intergovernmental Relations 1985	-0.45	Time series of state cross-sections, 1981–1983; ordinary least squares methods; detailed effort to account for short-distance smuggling of cigarettes.
Bishop and Yoo 1985	-0.45	Time series for United States, 1954–1980; three-stage least squares methods; simultaneous model of supply and demand.
Baltagi and Levin 1986	-0.14	Time series of 46 state cross-sections, 1963–1980; instrumental variables methods; partial adjustment model used to account for habitual consumption.
Porter 1986	-0.27	Time series for United States, 1947–1982; two-stage least squares methods; simultaneous model of supply and demand.
Baltagi and Goel 1987	-0.56 (1956-1964) -0.17 (1972-1983)	Time series of state cross-sections, 1956–1983; quasi-experimental methods.
Seldon and Doroodian 1989	-0.40	Time series for United States, 1952–1984; three-stage least squares methods; simultaneous model of demand and advertising.
Seldon and Boyd 1991	-0.22 (short run) -0.37 (long run)	Times series for United States, 1953–1984; varying parameter methods.
Showalter 1991	–0.56 to –0.71	Time series of annual state cross-sections, 1956–1988; simultaneous modeling of supply and demand with addiction; detailed modeling of short- and long-distance smuggling.
Simonich 1991	-0.37	Quarterly time series for United States, 1960–1983; two-stage least squares methods.
Tegene 1991	-0.66 (1956) -0.15 (1985)	Time series for United States, 1956–1985; Kalman filter methods; allows change in elasticity over time.
Chaloupka and Saffer 1992	-0.28	Time series of state cross-sections, 1975–1985; two-step endogenous law model; detailed modeling of shortand long-distance smuggling.
Flewelling et al. 1992	-0.25 to -0.35	Quarterly time series for California, 1980–1990; ordinary least squares and ridge regression methods.
Peterson et al. 1992	-0.49	Time series of state cross-sections, 1955–1988; epidemiologic approach.

Table 6.7. Continued

Study	Estimated price elasticity	Comments
Keeler et al. 1993	-0.3 to -0.5 (short run) -0.5 to -0.6 (long run)	Monthly time series for California, January 1980– December 1990; detailed modeling of addiction; full information maximum likelihood with instrumental variables and correction for autocorrelation.
Becker et al. 1994	-0.36 to -0.44 (short run) -0.73 to -0.79 (long run)	Time series of annual state cross-sections, 1956–1985; instrumental variables methods; detailed modeling o short- and long-distance smuggling and addiction.
Harris 1994	-0.47 (1993)	Annual time series for United States, 1964–1993; separate modeling of smoking participation and average consumption; controls for changes in average nicotine delivery per cigarette.
Hu et al. 1994	-0.39 (long run)	Monthly time series for California, January 1984– December 1991; intervention analysis.
Sung et al. 1994	–0.40 (short run) –0.48 (long run)	Time series of annual state cross-sections for 11 western states, 1967–1990; recursive model of supply and demand with addiction; generalized least square methods correcting for heteroscedasticity and autocorrelation.
Barnett et al. 1995	−0.76 to −1.12	Annual time series for United States, 1955–1989; simultaneous modeling of supply and demand.
Goel and Morey 1995	-0.28 to -0.37	Time series of annual state cross-sections, 1959–1982; joint demands for cigarettes and alcohol; accounts for addiction.
Hu et al. 1995b	-0.30 (state tax elasticity)	Quarterly time series for California, 1980–1992; autoregressive moving-average time-series methods.
Moore 1995	Not applicable	Time series of annual state cross-sections, 1954–1988; reduced form estimates of impact of cigarette taxes or various smoking-related mortality rates.
Tremblay and Tremblay 1995	-0.41	Annual time series for United States, 1955–1990; simultaneous modeling of supply and demand.
Yurekli and Zhang 2000	-0.48 to -0.62	Time series of annual state cross-sections, 1970–1995; detailed modeling of smuggling and clean indoor air laws.

elasticity of demand comparable to those obtained in the econometric studies.

Several difficulties can be encountered when analysts use time series data to estimate the demand for cigarettes. In a time series model, estimated price and income elasticities of demand are sensitive to the inclusion of variables controlling for the effects of other determinants of smoking, including advertising, changes in existing policies for reducing tobacco use, and increased awareness of the health consequences of smoking. A serious problem can also result from the high correlations that are likely to exist among many of the variables reflecting key determinants of smoking. These correlations can lead to unstable estimates for the parameters of interest. However, excluding potentially important but highly correlated determinants of demand could produce biased estimates of the impact of the included variables on demand. Time series estimates are also more likely to estimate the short-run responses of demand to changes in independent variables rather than the long-run responses that are of greater interest to policymakers. However, recent studies using state-of-the-art econometric methods for time series data have appropriately addressed many of these difficulties (Seldon and Boyd 1991; Simonich 1991; Flewelling et al. 1992; Barnett et al. 1995; Hu et al. 1995b; Meier and Licari 1997). Almost all of the estimates obtained from time series methods based on alternative economic theories and applied to various data produced estimates of the price elasticity of demand in a relatively narrow range, which was centered on -0.4.

The use of state cross-sectional data over time can also create various estimation problems. In general, such studies considered in this section employed data on state taxes paid for cigarette sales; these data may not accurately reflect average cigarette smoking within the states, because cigarettes may have been smuggled from low-tax states into high-tax states. (This problem is discussed in detail in "Theoretically Optimal Cigarette Taxes," later in this chapter.) In particular, these sales data are likely to overstate consumption in low-tax states and understate consumption in high-tax states. If this smuggling is not controlled for, estimates of the price elasticity of demand from these data are likely to overstate the impact of price on cigarette smoking. However, many of the most recent studies of cigarette demand that employed pooled time series cross-sectional data for states made careful efforts to control for both casual and organized smuggling of cigarettes (Advisory Commission on Intergovernmental Relations [ACIR] 1985; Baltagi and Levin 1986; Showalter 1991; Chaloupka and Saffer 1992; Becker et al. 1994; Yurekli and Zhang 2000). Although imperfect, these efforts should have significantly reduced the biases associated with the use of the pooled state data. When analyses controlled for the possible smuggling of cigarettes from low-tax to high-tax states, estimated price elasticities of demand that were based on state tax-paid sales data were generally in the range of -0.3 to -0.5.

A further problem in the analysis of aggregate data arises because cigarette prices are determined by the interaction of supply and demand. Failing to account for simultaneity would lead to biased estimates of the price elasticity of demand. Several recent studies that employed both pure time series data and pooled state-level data have theoretically and empirically modeled the supply and demand for cigarettes (Bishop and Yoo 1985; Porter 1986; Showalter 1991; Sung et al. 1994; Barnett et al. 1995; Tremblay and Tremblay 1995). Most studies that controlled for the potential simultaneity biases in their aggregate data produced estimates of the price elasticity of demand that were in the narrow range found in other studies. An alternative approach to the simultaneity problem is to use natural experiments, such as the large increase in the California cigarette excise tax, to look at the impact of price on demand. Several recent studies have used this approach (Sung et al. 1994; Hu et al. 1995b). Estimates of the price elasticities of demand based on this natural experiment are consistent with those in other studies.

Many of the most recent studies of cigarette demand that used aggregate data empirically modeled the addictive aspects of cigarette consumption in the context of Becker and Murphy's (1988) economic model of addictive behavior (Showalter 1991; Becker et al. 1994; Sung et al. 1994). One of the most interesting implications of the economic models of demand for addictive goods, including cigarettes, concerns short-run versus long-run effects. Economists generally define the short run as a period during which at least some factors have not fully responded to the change being examined. In contrast, the long run is when all changes have occurred; the Congressional Research Service (CRS) defined the long run for cigarette demand as 69 years, a time period that would allow the current 12- to 80-year-old population (which includes almost all smokers) to adjust to a change in cigarette taxes (Gravelle and Zimmerman 1994). For addictive goods, the long-run impact of price on demand will exceed the short-run impact because the latter largely entails current consumption, which represents an established addiction that tends to be slow to decrease even in the face of a price increase. In the studies that used such a model, the estimated longrun impact of price elasticities of demand indeed exceeded—by up to twice as much—the estimates for the short-run impact, presumably because the longrun impact reflected would-be newly addicted consumers who were put off by price increases. (These short- and long-run effects are further discussed in "Tobacco Taxation and Revenues," later in this chapter.)

Finally, studies employing aggregate data are generally limited because they estimate the effects of prices and other factors on aggregate or per capita estimates of cigarette consumption. Such studies thus cannot provide information on the effects of prices and other policies on smoking prevalence, initiation, cessation, or quantity and type of cigarette smoked. Similarly, these studies cannot explore differences that sex, age, and socioeconomic status may have on responsiveness to price and other policies. Furthermore, aggregate studies are of only limited use in considering the health effects of changes in existing policies for reducing tobacco use. A few recent studies have addressed some of these limitations. Harris (1994) used annual time series data on both smoking prevalence and average cigarette consumption among smokers during 1964–1993. The study estimated that the price elasticity of smoking prevalence in 1993 was -0.238 and that the elasticity for average consumption among smokers was comparable; the 1993 total price elasticity of demand of -0.47 was comparable to that obtained in other studies. Townsend and colleagues (1994) used aggregate data on smoking prevalence and average consumption constructed from the biennial data gathered in the British General Household Surveys from 1972 through 1990. The study found that men and women in lower socioeconomic groups were most responsive to changes in cigarette prices, that women were more responsive to price than men, and that smokers in the youngest age groups (16–19 years and 20–24 years) were least affected by price. In another study, Moore (1995) used state data from 1954 through 1988 to analyze the effects of cigarette taxes on smoking-related death rates. The study estimated that a 10-percent increase in cigarette taxes would prevent an estimated 5,200 smoking-related deaths each year.

Studies Using Individual-Level Data

Relatively few studies of cigarette demand have been based on individual-level data. Table 6.8 summarizes the findings of these studies for samples of adults, and Table 6.9 presents the results of studies focusing on adolescents and young adults.

In general, the estimated price elasticities of demand obtained from these studies were comparable to those found in the aggregate studies. By using selfreported measures of smoking prevalence and average cigarette consumption, these studies avoided some of the problems associated with aggregate data on state taxes paid for cigarette sales. Each of these studies also carefully considered the effect that casual smuggling could have on their estimates of the price elasticity of demand. Moreover, because an individual smoker's purchase decisions are too small to affect the market price of cigarettes, the use of individual-level data in these studies avoided the potential simultaneity biases inherent in the use of aggregate data. However, the use of individual-level data may be subject to a substantial ecological bias, to the extent that omitted variables affecting tobacco use may be correlated with the included determinants of demand. Excluding these variables will, consequently, produce biased estimates for the included variables (see the later discussion of Wasserman et al. 1991). Furthermore, the use of individual-level data is subject to potential reporting biases. Studies using individual-level data have implicitly assumed that underreporting is proportional to true consumption (i.e., heavy, moderate, and light smokers underreport by the same proportion). With this assumption, elasticity estimates will not be systematically biased.

The use of individual-level data allows researchers to explore issues difficult to address adequately with aggregate data. In particular, researchers can use a two-part method to distinguish between the effects of cigarette price on two decisions: whether to smoke (smoking prevalence) and how many cigarettes to smoke (cigarette consumption). Likewise, the effects of cigarette prices on smoking cessation can be investigated. Individual-level data also allow researchers to explore the differential responses of various socioeconomic and demographic groups to changes in cigarette prices and existing prevention policies. However, the potential underreporting of cigarette consumption can be problematic in interpreting these data (Warner 1978).

Lewit and colleagues (Lewit et al. 1981; Lewit and Coate 1982; Grossman et al. 1983) were the first to use individual-level data to examine the effects of prices and smoking prevention policies. Lewit and Coate (1982) used data on 19,288 persons aged 20–74 years who had participated in the 1976 National Health Interview Survey. The investigators first estimated the effects of cigarette price on smoking prevalence and then looked at the effects of price on cigarette consumption. These equations were estimated not only for

Table 6.8. Estimates of the price elasticity of cigarette demand for adults from individual-level data

Study	Estimated price elasticities	Comments
Lewit and Coate 1982	-0.42	1976 National Health Interview Survey; ordinary least squares methods; elasticities by age and sex.
Mullahy 1985	-0.47	1979 National Health Interview Survey; instrumental variables and probit methods; detailed modeling of addiction; elasticities by sex.
Chaloupka 1990	-0.60 (men) not statistically different from zero (women)	Second National Health and Nutrition Examination Survey, 1976–1980; instrumental variables methods; detailed modeling of addiction; elasticities by sex.
Chaloupka 1991 and 1992	−0.27 to −0.48	Second National Health and Nutrition Examination Survey, 1976–1980; instrumental variables methods; detailed modeling of addiction; elasticities by age and educational attainment.
Wasserman et al. 1991	0.069 (1970) -0.23 (1988)	1970, 1974, 1976, 1979, 1980, 1983, and 1985 National Health Interview Surveys; generalized least squares and two-part methods; allow changes in elasticity over time.
Hu et al. 1995a	-0.46	California Behavioural Risk Factor Surveys, 1985–1991; two-part methods; controls for interdependence of other behavioral risk factors and smoking.
Ohsfeldt et al. 1997	–0.05 (tax elasticity, males)	1985 Current Population Survey, males aged 16 years and older; treats taxes and control policies as endogenous; elasticity estimates for prevalence only.
Centers for Disease Control and Prevention 1998	-0.25 (full sample) -0.14 (whites) -0.32 (blacks) -1.89 (Hispanics) -0.29 (at or below median income) -0.17 (above median income) -0.26 (men) -0.19 (women)	1976–1980, 1982, 1985, 1987–1992 National Health Interview Surveys; two-part methods.
Evans and Ringel 1999	-0.25 to -0.56	Natality Detail data, 1989–1992, pregnant women; two-part models.
Ohsfeldt et al. 1999	–0.15 (tax elasticity, males)	1992/93 Current Population Survey, males aged 16 years and older; treats taxes and control policies as endogenous; elasticity estimates for prevalence only.

the full sample but also for subsamples based on age (20–25 years, 26–35 years, and 36–74 years) and sex. Price had a greater impact on whether a respondent smoked at all than on how many cigarettes a respondent smoked. The estimated elasticity of demand for smoking prevalence was –0.26 for the full sample, and the total price elasticity of demand was –0.42. The effects of price were larger for younger persons: the total estimated price elasticity for persons 20–25 years old was approximately double that for persons 26–74 years old. The study also found that men, particularly those aged 20–35 years, were quite responsive to changes in cigarette prices, whereas women were almost unaffected by price.

These findings regarding age are substantiated as well by Lewit and colleagues (1981), who used data from Cycle III of the Health Examination Survey (1966– 1970) to examine the impact that prices and the antismoking advertisements broadcast under the Fairness Doctrine had on cigarette smoking among 6,768 adolescents (12–17 years old). Using the same basic methods employed in the study by Lewit and Coate (1982), this analysis estimated that the impact of price on adolescent smoking (measured at a total price elasticity of -1.44) was about three times that for adult smoking (Lewit and Coate 1982). The study by Lewit and colleagues (1981) also confirmed that price had a greater impact on the decision to smoke (elasticity of -1.20) than on the average quantity of cigarettes consumed by smokers (elasticity of –0.25). These findings were generally supported by another analysis of data from the 1974, 1976, 1977, and 1979 National Household Surveys on Drug Abuse (Grossman et al. 1983).

Mullahy (1985) was the first to estimate cigarette demand on the basis of a theoretical and empirical model treating cigarette smoking as an addictive behavior. This model implied that a person's smoking decisions at any point in time are dependent on that person's smoking history. However, unlike most of the more recent econometric applications of addictive behavior, this analysis assumed that individuals behave myopically—that is, they ignore the future consequences of their cigarette addiction when making current smoking decisions. Using data on 13,794 persons who participated in the 1979 National Health Interview Survey, Mullahy (1985) estimated smoking prevalence and average cigarette consumption separately for men and women (aged 17 years and older). In finding that a person's past cigarette smoking had a significant impact on current smoking decisions, the analysis supports the hypothesis that cigarette smoking is an addictive behavior. The study also found that both smoking prevalence and average cigarette consumption were inversely related to cigarette prices. Finally, Mullahy estimated that men were somewhat more responsive to price than women (total price elasticities of demand were –0.56 and –0.39, respectively).

Wasserman and colleagues (1991) used data from several of the National Health Interview Surveys from the 1970s and 1980s to consider how the price sensitivity of cigarette demand changed over time. Using a generalized linear model, the investigators concluded that cigarette demand has become more responsive to price over time. In the earlier years of their sample, they found that increased cigarette prices did not reduce cigarette smoking. However, they estimated that, beginning in 1985, when the overall price elasticity of cigarette demand was -0.23, increases in cigarette prices would reduce smoking. As part of the same study, these investigators used data on 1,891 youth aged 12-17 years who had participated in the Second National Health and Nutrition Examination Survey (1976–1980). Unlike Lewit and colleagues (1981), Wasserman and colleagues (1991) found that the estimated price elasticity for youth was not statistically different from that for adults. Indeed, the estimated effects of price on youth smoking were not statistically different from zero in any of the models. The investigators attributed their relatively low estimates of the price elasticity of demand to their including in their demand equations an index that controlled for smoking restrictions. This index, which was highly correlated with price, had a negative significant effect on smoking (particularly on young people's decision to smoke). Wasserman and colleagues argued that because of the high correlation between the index and cigarette prices, excluding this index would lead to biased estimates of the effect of prices on demand. Indeed, when they excluded the index from their estimated equations, their estimated price elasticities were comparable to those from other studies.

Chaloupka (1990, 1991, 1992) used data from the Second National Health and Nutrition Examination Survey (1976–1980) in applying the Becker and Murphy (1988) model of rational addiction to cigarette smoking. The assumption of rational (or nonmyopic) addictive behavior implies that individuals consider, to some degree, the future consequences of their current smoking decisions (which depend on past choices). Chaloupka's estimates supported the hypotheses that smoking is an addictive behavior and that the future consequences of this addiction are an important determinant of current cigarette smoking. Moreover, the estimated long-run price elasticity of demand (in the range of –0.27 to –0.48) was well above that obtained when the addictive aspects of cigarette

Table 6.9. Estimates of the price elasticity of cigarette demand for youth and young adults from individual-level data

	Esti	mated price (elasticitie	es	
Study	Prevalence	Quantity	Total		Comments
Lewit et al. 1981	-1.20	-0.25	-1.44		Health Examination Survey, Cycle III, 1966–1970; ordinary least squares methods for consumption and smoking participation; aged 12–17 years.
Lewit and Coate 1982	-0.74	-0.20	-0.89		1976 National Health Interview Survey; ordinary least squares methods; elasticities by age and sex; aged 20–25 years.
Grossman et al. 1983	0.88 -0.62 -0.93 -0.89	-1.55 0.11 0.91 0.73	-0.67 -0.51 -0.02 -0.16	(1974) (1976) (1977) (1979)	National Household Surveys on Drug Abuse, 1974, 1976, 1977, and 1979; least squares methods; aged 12–17 years.
Chaloupka 1991		istically diffe rom zero	rent		Second National Health and Nutrition Examination Survey, 1976–1980; instrumental variables methods; detailed modeling of addiction; aged 17–24 years.
Wasserman et al. 1991	from adults modeling); no	stically diffe (generalized t statistically (two-part m	l linear different	:	Second National Health and Nutrition Examination Survey, 1976–1980; generalized (iterative weighted) least squares and two-part methods; aged 12–17 years.
Douglas and Hariharan 1994	No significa smoking i	nt effect of p nitiation dec			1988 and 1989 National Health Interview Surveys; hazard models of smoking initiation; detailed modeling of addiction.
Chaloupka and Grossman 1996	-0.675	-0.638	-1.313		1992, 1993, and 1994 Monitoring the Future surveys of 8th, 10th, and 12th graders; two-part methods; mostly aged 12–18 years.
Chaloupka and Wechsler 1997	-0.53	-0.58	-1.11		1993 Harvard College Alcohol Study; two-part methods; college students mostly aged 18–22 years.
Chaloupka et al. 1997	-0.43	-0.16	-0.59		1992, 1993, and 1994 Monitoring the Future surveys of 8th, 10th, and 12th graders; smokeless tobacco use by young males; two-part methods; mostly aged 12–18 years.

Table 6.9. Continued

	Estin	nated price	elasticities	
Study	Prevalence	Quantity	Total	Comments
Lewit et al. 1997	–0.87 (prev –0.95 (inter			1990 and 1992 data from COMMIT* sites; 9th graders.
Centers for Disease Control and Prevention 1998	-0.37	-0.21	-0.58	1976–1980, 1982, 1985, 1987–1992 National Health Interview Surveys; two-part methods; aged 18–24 years.
Douglas 1998	No significa smoking initia of approxima	tion decision	s; elasticity	1987 National Health Interview Survey; hazard models of smoking initiation and cessation; detailed modeling of addiction.
DeCicca et al., unpublished data, April 1998	-1.32 (8th § -0.95 (10th -0.71 (12th -0.03 (smo	grade) grade)	oth to 12th grade)	1988 National Education Longitudinal Survey; treats each wave independently for prevalence; longitudinal data used to estimate effect of price on smoking onset.
DeCicca et al., unpublished data, August 1998	-1.994 to -0.746 (8th grade) -1.230 to -0.660 (10th grade) -0.982 to -0.274 (12th grade) -0.505 to -0.025 (smoking onset, 8th to 12th grade)		rade) rade) ng onset,	1998 National Education Longitudinal Survey; treats each wave independently for prevalence; longitudinal data used to estimate effect of price on smoking onset.
Dee and Evans, unpublished data, 1998	-2.19 to -2.01 (8th grade) -1.15 to -0.94 (12th grade) -0.79 to -0.63 (smoking onset, 8th to 12th grade)		le) onset,	Re-analysis of DeCicca et al. April 1998 data with same methods; differences in sample construction and variable definitions.
Evans and Huang, unpublished data, 1998	-0.20 (1977 -0.50 (1985			1977–1992 Monitoring the Future surveys; high school seniors; stateaggregated prevalence rates; allow for state effects and state-specific time trends.
Chaloupka and Pacula 1999	-0.928 (me -0.595 (wo -0.639 (wh -1.108 (Afr	men)	ans)	1992, 1993, and 1994 Monitoring the Future surveys of 8th, 10th, and 12th graders; prevalence only; mostly aged 12–18 years.

^{*}COMMIT = Community Intervention Trial for Smoking Cessation.

Table 6.9. Continued

	Estimated price elasticities	
Study	Prevalence Quantity Total	Comments
Harris and Chan 1999	-0.831	1992–1993 Current Population Survey; two-part methods; also considered differential effects of premium and discount brand prices.
Tauras 1999	0.269 to 0.466 price elasticity of cessation	Monitoring the Future survey longitudinal data; young adults; multiple failure duration analysis; parametric and semi-parametric models.
Tauras and Chaloupka 1999b	-0.121 -0.67 -0.791	Monitoring the Future longitudinal data formed from high school senior surveys for 1976–1993; mostly aged 18–32 years.
Gruber 2000	-0.666 -0.059 (older teens, Monitoring the Future surveys) -0.210 -0.003 (younger teens, Monitoring the Future surveys) -0.311 -0.029 (all teens, Monitoring the Future surveys) -1.534 -1.576 (older teens, Youth Risk Behavior Survey) 0.419 -0.227 (younger teens, Youth Risk Behavior Survey) -0.126 -0.526 (all teens, Youth Risk Behavior Survey) -0.376 -0.145 (older teens, Natality Detail files) -0.240 -0.058 (younger teens, Natality Detail files) -0.353 -0.124 (all teens, Natality Detail files)	1991–1997 Monitoring the Future surveys of 8th, 10th, and 12th graders; 1991, 1993, 1995, and 1997 Youth Risk Behavior Surveys; 1991–1997 Vital Statistics Natality Detail files for teens giving birth before age 19; two-part models; state and year fixed effects.

smoking were ignored. Furthermore, these estimates of the price responsiveness of demand were not sensitive to the inclusion of variables reflecting smoking restrictions. Chaloupka (1990, 1991, 1992) found that young adults were not responsive to changes in cigarette prices (in contrast to the findings of Lewit and Coate [1982]) and that men and less-educated persons were much more responsive to changes in cigarette prices than were women and more-educated persons.

Douglas and Hariharan (1994) applied ideas from Becker and Murphy's (1988) economic model of addiction to look at smoking initiation decisions. Using data from the 1978 and 1979 smoking supplements to the National Health Interview Survey, Douglas and Hariharan estimated a parametric duration model that accounted for observed patterns of smoking initiation: the "hazard" of smoking initiation rises sharply from ages 12 through 20 and then declines dramatically, with initiation being unlikely after age 25. On the basis of this model, the analysis found that increases in cigarette prices had no impact on teenagers' decisions to begin smoking. Douglas (1998) extended this work by estimating a model of the hazards of smoking initiation and cessation using data from the cancer risk factor supplement to the 1987 National Health Interview Survey. Douglas also finds little empirical evidence that higher cigarette prices would reduce smoking initiation. However, the investigators noted that their estimated price effects were likely to be biased downward because of problems with the measurement of the price variables they employed. Douglas did find, however, that increases in cigarette prices significantly increase the likelihood of smoking cessation, concluding that a 10-percent increase in price would reduce the duration of smoking by approximately 10 percent.

More recent work by Tauras confirms the findings that higher cigarette prices induce smoking cessation (Tauras 1999; Tauras and Chaloupka 1999a). Using the longitudinal data on young adults from the Monitoring the Future project, Tauras (1999) estimated parametric and semi-parametric duration models that allow for multiple cessation attempts by young adult smokers. His estimates indicate that the likelihood of an initial cessation attempt and the probabilities of subsequent attempts rise as cigarette prices rise, with an average price elasticity of cessation of 0.343. In a somewhat less sophisticated analysis using the same data that examined the potential for gender differences in the effects of price on cessation, Tauras and Chaloupka (1999b) concluded that the likelihood of smoking cessation among both young adult men and young adult women rises significantly as cigarette prices rise.

Hu and colleagues (1995a) used data from the 1985–1991 California Behavior Risk Factor Surveys to estimate smoking prevalence and average cigarette consumption through equations that accounted for the interdependence of smoking and other behavioral risk factors. Using two-part methods, Hu and colleagues found that their estimates of the price elasticity of smoking prevalence were significantly lower when allowing for the interdependence of smoking and other behavioral risk factors (such as drinking and obesity), whereas their estimates of the effect of price on average cigarette consumption by smokers were unaffected. The analysis estimated that the price elasticity of demand was –0.46 overall, –0.24 for smoking prevalence, and –0.22 for cigarette consumption.

More recently, data from the 1976–1980, 1983, 1985, and 1987–1992 National Health Interview Surveys have been used to study the effects of prices on smoking among adults (CDC 1998). Researchers found that both the probability of smoking and the average cigarette consumption among smokers were inversely related to cigarette prices, with an overall estimated price elasticity of demand of -0.25. In addition, they found significant differences in price responsiveness for various subpopulations, including those defined by race/ethnicity, age, family income, and gender. They found that blacks are twice as responsive as whites to changes in cigarette prices and that Hispanics are even more price sensitive. Similarly, the researchers' estimated price elasticity of -0.58 for young adults (aged 18-24 years) is well above that estimated for the full sample, whereas individuals with family incomes at or below the sample median were about 70 percent more responsive to price than those with higher family incomes. Finally, they found that men are much more price responsive than women.

To determine whether smokers engage in any form of compensating behavior in response to higher cigarette taxes, Evans and Farrelly (1998) focused on the data from the 1979 Smoking and 1987 Cancer Control Supplements to the National Health Interview Survey. These supplements were unique in that they collected information on the brand of cigarettes smoked. This information was converted into detailed data on tar and nicotine content, length of cigarette, and type of filter. The investigators found that continuing smokers engage in compensating behavior in response to higher cigarette taxes. That is, they found that smokers in high-tax states were more likely than smokers in low-tax states to smoke higher-tar and higher-nicotine cigarettes as well as longer cigarettes. This compensating behavior by continuing smokers left their average daily tar and nicotine intake unchanged. Moreover,

younger smokers were much more likely to engage in this compensating behavior, so much so that the higher taxes led to an increase in average daily tar and nicotine intake among continuing young adult smokers.

Recent research by Chaloupka and colleagues focused on the price responsiveness of cigarette smoking among adolescents and young adults. Chaloupka and Wechsler (1997) used 1993 data from 16,277 students in 140 U.S. colleges and universities to estimate the price elasticity of cigarette smoking among young adults. Using two-part methods, the investigators separately estimated the effects of prices on smoking prevalence and on average consumption among smokers after controlling for restrictions on cigarette smoking and limits on youth access to tobacco. College students, who were mostly aged 18-22 years, were very responsive to changes in cigarette prices. The estimated price elasticity of smoking prevalence in this population was -0.53, and the elasticity for average cigarette consumption was −0.58, for an overall price elasticity of demand of −1.11.

Chaloupka and Grossman (1996) employed similar methods to examine cigarette smoking among more than 110,000 young people participating in the 1992, 1993, and 1994 Monitoring the Future surveys of 8th-, 10th-, and 12th-grade students. Like several other researchers, Chaloupka and Grossman found that smoking by younger persons is very responsive to changes in cigarette prices. Their estimated elasticity of smoking prevalence for this sample of mostly 12- through 18-year-olds was –0.675, with an overall estimated price elasticity of demand centered on -1.313. Chaloupka and Pacula (1999) used these data to look at the differential response by gender and race, concluding that young men and young African Americans are more responsive to price than young women and young whites.

Most recently, Tauras and Chaloupka (John A. Tauras and Frank J. Chaloupka. Price, clean indoor air laws, and cigarette smoking: evidence from longitudinal data for young adults, unpublished data, July 1, 1998) used data from the longitudinal component of the Monitoring the Future surveys to estimate the effects of price on young adult smoking. Using 35 panels formed from the 1976 through 1993 high school senior surveys, they estimated models controlling for unobserved state and individual factors affecting cigarette demand. For their sample of young adults, mostly aged 18-32, Tauras and Chaloupka estimated an overall price elasticity of demand centered on -0.79. Taken together, these estimates imply that increases in cigarette prices would lead to relatively large reductions in smoking among adolescents and young adults.

This conclusion is supported by recent studies by Lewit and colleagues (1997) and Evans and Huang (William N. Evans and Lynn X. Huang, Cigarette taxes and teen smoking: new evidence from panels of repeated cross-sections, unpublished data, April 15, 1998; Harris and Chan 1999; Gruber 2000). Lewit and colleagues used data for ninth-grade students in 1990 and 1992 collected in the 22 North American communities from the Community Intervention Trial for Smoking Cessation (COMMIT). They found that both youth smoking prevalence and youth intentions to smoke are inversely related to cigarette prices, with estimated price elasticities of -0.87 and -0.95, respectively. Evans and Huang estimated a somewhat smaller effect of -0.20 for high school seniors by using annual, statelevel measures of smoking prevalence aggregated from the 1977 through 1992 Monitoring the Future surveys. However, they concluded that this had increased over time, estimating an elasticity of -0.50 for the period from 1985 through 1992. Harris and Chan (1999), using data from the 1992–1993 Tobacco Use Supplement to the Current Population Survey, provide consistent evidence that price responsiveness falls with age. Their estimated elasticities range from -0.996 for 15- to 17year-olds to -0.329 for 27- to 29-year-olds. Gruber (2000) reaches a somewhat different conclusion using data from the 1991 through 1997 Monitoring the Future surveys, the 1991, 1993, 1995, and 1997 Youth Risk Behavior Surveys, and the 1991 through 1997 Vital Statistics Natality Detail files for teens giving birth before their 19th birthday. His estimates indicate that older teens are relatively more responsive to price than younger teens (approximately 17 to 18 years of age compared with approximately 13 to 16 years of age). His estimated price elasticity of smoking prevalence for older teens centers on -0.67, while he finds that younger teens, on average, are not sensitive to price. In addition, he concludes that price sensitivity among older teens is greatest for more socioeconomically disadvantaged groups, such as young blacks or those with less educated parents.

In contrast, DeCicca and colleagues (Philip DeCicca, Donald Kenkel, and Alan Mathios, Putting out the fires: will higher taxes reduce youth smoking?, unpublished data, April 1998) concluded that higher cigarette taxes have a very small impact on smoking initiation among youth. Using data from the 1988, 1990, and 1992 waves of the National Education Longitudinal Study (NELS) of 1988, and treating each wave separately, the investigators estimated price elasticities for youth smoking prevalence comparable to those discussed above. However, when they used the longitudinal data to examine the onset of daily smoking between 8th and 12th grade among youth not smoking in 8th grade, DeCicca and colleagues found little effect of price. In a separate analysis of the same data, Dee and Evans (Thomas S. Dee and William N. Evans, A comment on DeCicca, Kenkel, and Mathios, unpublished data, May 10, 1998) come to the opposite conclusion. Dee and Evans made two adjustments to the construction of the sample used by DeCicca and colleagues—including respondents with missing data on some covariates (about 20 percent of the sample) and redefining several variables based on the categorical data. After making these changes, Dee and Evans estimated a price elasticity for the onset of smoking of –0.63, consistent with several of the other recent studies of youth smoking based on cross-sectional data.

In response to Dee and Evans, DeCicca and colleagues (Philip DeCicca, Donald Kenkel, and Alan Mathios, Putting out the fires: will higher taxes reduce youth smoking?, unpublished data, August 1998) conducted a reanalysis of NELS data by using an alternative approach to dealing with the problem of missing data. Their reanalysis produced somewhat more significant estimates for the effect of cigarette taxes on the onset of daily smoking between 8th and 12th grade; the implied price elasticities from alternative specifications ranged from -0.025 to -0.505. However, smaller, less significant effects are found for models that employ cigarette prices. After obtaining separate estimates based on race and ethnicity, DeCicca and colleagues concluded that higher cigarette taxes have little impact on smoking onset by black and white youth but significantly reduce onset among Hispanic youth and youth of other races. The use of longitudinal data to research the impact of cigarette tax and price changes on smoking initiation is clearly an important and appropriate step. The differing conclusions from earlier studies of the same data suggest, however, that these discordant results should be weighed cautiously against the prevailing findings of recent studies.

Finally, two recent studies by Ohsfeldt and colleagues (1997, 1999) examined the impact of cigarette and other tobacco taxes on the probabilities of cigarette and smokeless tobacco use by males 16 years of age and older using data from the 1985 and 1992/1993 Current Population Surveys. To account for the potential reverse causality between demand and tobacco control policies (including taxes), the researchers estimate a simultaneous equations model. They find consistent evidence that higher cigarette taxes reduce the probability of smoking.

Behavioral Economics Studies of Cigarette Demand

Behavioral economics is the relatively new application of the principles of consumer demand theory to experimental psychology (Hursh and Bauman 1987). In a laboratory setting, behavioral economists studying addiction-related behaviors focus on the impact of unit price on drug dependence, including nicotine dependence. Price, in this literature, is defined as the response required to receive one dose of the drug (Bickel et al. 1993; Bickel and Madden 1999). As in standard economic theory, a key prediction of this branch of behavioral economics is that drug consumption is inversely related to price. One advantage of this experimental approach in the analysis of cigarette demand is that it allows researchers to study the effects of differences in cigarette prices that are many times larger than the price differences observed in cross-sectional data, time series data, or both. One limitation, however, is that these methods are generally applicable only to dependent individuals. Thus, for example, they do not pertain to initiation.

In a series of papers, Bickel, DeGrandpre, and their colleagues reported the results of research on cigarette smoking in their behavioral economics laboratory (Bickel et al. 1991, 1992; DeGrandpre et al. 1992, 1994; Bickel and DeGrandpre 1996). In the experiments, nicotine-dependent smokers were rewarded with two puffs on a cigarette after the completion of a specified number of responses. The total number of puffs received is the measure of consumption, and the number of responses required is the measure of price. The number of responses required to receive two puffs varied from 100 to 3,200, thereby allowing the researchers to study the impact of price on demand over a large range of prices. As in the econometric and other studies described previously, this experimental approach found an inverse relationship between cigarette smoking and price. More interesting, however, is the nature of the relationship between price and consumption. The investigators found that the price elasticity of demand rose as price rose. That is, the percentage reduction in consumption for a given percentage rise in price was larger at higher prices.

Studies of Smokeless Tobacco Use and **Price**

Although numerous studies have examined the impact of cigarette prices and smoking prevention policies on cigarette smoking, relatively few studies

have examined the corresponding issues for smokeless tobacco use, and virtually none consider such use in diverse culture groups. Similarly, few analyses have examined the possible substitution of smokeless tobacco products or cigarettes in response to changes in their relative prices.

Ohsfeldt and colleagues begin to address these gaps in the literature in two studies of smokeless tobacco use (Ohsfeldt and Boyle 1994; Ohsfeldt et al. 1997, 1999). Using state-level data for males aged 16 years and older who had participated in the September 1985 Current Population Survey, Ohsfeldt and Boyle examined the impact of various tobacco taxes on the prevalence of smokeless tobacco use. Their analysis, which controlled for other determinants of demand, found that higher taxes on smokeless tobacco were associated with lower use of smokeless tobacco. The prevalence of smokeless tobacco use, however, was positively related to cigarette excise taxes. The investigators suggested that these findings might partly explain the growth in smokeless tobacco use among young males during the 1980s. During this period, when cigarette excise taxes were rising more rapidly than smokeless tobacco taxes, comparatively larger increases occurred in cigarette prices. As the research previously described indicates, increases in cigarette prices significantly reduce cigarette smoking. Ohsfeldt and Boyle's analysis, however, suggested that tobacco use overall might not be significantly reduced, because some smokers might turn to using the comparatively less expensive smokeless tobacco products. These findings were generally confirmed by the analysis by Ohsfeldt and colleagues (1997) of the individual-level data from the September 1985 Current Population Survey and their subsequent analysis of data from the September 1992, January 1993, and May 1993 surveys (Ohsfeldt et al. 1999). The authors concluded that higher smokeless tobacco taxes reduce the probability of smokeless tobacco use but that higher cigarette taxes, while reducing the probability of smoking, increase the likelihood of smokeless tobacco use.

Similarly, using data on young males from the 1992, 1993, and 1994 Monitoring the Future surveys of 8th-, 10th-, and 12th-grade students, Chaloupka and colleagues (1997) concluded that both the prevalence and the frequency of smokeless tobacco use are inversely related to its price. They estimated an overall price elasticity of smokeless tobacco demand by young males of -0.59, with more than two-thirds of the effect on the prevalence of smokeless tobacco use.

Cigarette Prices and Other Substance Use

Little is known about the relationships between cigarette prices and other substance use, whereas much is known about the impact of cigarette price on smoking. Economists define two goods as complements if an increase in the price of one good reduces the consumption of not only that good but also the consumption of the other. Conversely, substitutes are goods for which an increase in the price of one results in an increase in the consumption of the other. A few very recent econometric studies have examined the relationship between cigarette prices and other substance use (Pacula 1998a,b; Chaloupka et al. 1999; Farrelly et al. 1999; Pacula et al. 2000).

Research on patterns of substance use among youth generally concludes that youth begin with tobacco, or alcohol, or both and that some youth progress to marijuana and other illicit drug use (Kandel 1975; Kandel and Yamaguchi 1993; USDHHS 1994). Other research concludes that cigarette smoking is a significant predictor of both the probability and the frequency of other drug use (USDHHS 1988; Henningfield et al. 1990). This research suggests that cigarettes and other substances are complements for one another and that higher cigarette prices, by discouraging smoking among youth, could significantly reduce youth and adult drinking and illicit drug use.

Pacula (1998a), in the first econometric examination of this "gateway hypothesis," used data from the National Longitudinal Survey of Youth to examine the impact of cigarette prices in earlier years on current marijuana use by young adults. Her estimates are consistent with the gateway hypothesis; that is, higher past cigarette prices (which are expected to reduce past cigarette smoking) reduce the likelihood that a young adult currently uses marijuana. However, she finds no relationship between contemporaneous cigarette prices and marijuana use (Pacula 1998b). Chaloupka and colleagues (1999) used data from the 1992 through 1994 Monitoring the Future surveys of 8th-, 10th-, and 12thgrade students to examine the relationship between current cigarette prices and current cigarette smoking and marijuana use. They found that higher cigarette prices, in addition to reducing current cigarette smoking, also reduce current marijuana use. Farrelly and colleagues (1999) found similar evidence for adults using several of the recent National Household Surveys on Drug Abuse. In addition, they found that higher cigarette prices reduced alcohol use. More recently, using a longer time series of data from the Monitoring the Future surveys of 12th-grade students, Pacula and colleagues (2000) found little impact of cigarette taxes on youth marijuana use. The growing evidence suggests that cigarettes and marijuana are not substitutes for one another, implying that higher cigarette prices will not lead to increased marijuana use, with several studies implying the opposite—that higher cigarette prices will reduce both cigarette and marijuana smoking. Much more research is needed, however, to firmly establish these relationships.

Discussion

A few general conclusions can be drawn from these studies of the effects of cigarette prices on smoking. First, increases in cigarette prices lead to significant reductions in cigarette smoking; most studies, using a wide variety of data and methods with various strengths and weaknesses, predict that a 10-percent increase in price will reduce overall cigarette consumption by 3–5 percent. Second, the effects of increases in

cigarette prices are not limited to reductions in average cigarette consumption among smokers but include significant reductions in smoking prevalence. These effects on smoking prevalence constitute both an increase in smoking cessation among smokers and a reduction in smoking initiation among potential young smokers. Third, although evidence concerning the effects of prices on adolescent smoking is mixed, the majority of the evidence from recent studies indicates that adolescents and young adults are significantly more responsive than adults to changes in cigarette prices. Most recent studies found that adolescents and young adults were two to three times more sensitive than adults to price. Ongoing research, particularly that based on longitudinal data, will help clarify this issue. Finally, the limited number of studies of smokeless tobacco use suggest that increases in smokeless tobacco prices would reduce the prevalence of smokeless tobacco use.

Taxation of Tobacco Products

As the preceding section indicates, numerous studies of the demand for cigarettes confirm a fundamental principle of economics: increased tobacco prices will reduce tobacco use. In general, several factors will determine the retail prices of cigarettes and other tobacco products. For example, factors that reduce the supply of tobacco will raise the prices of tobacco products. As described previously, these factors include tobacco price support programs, market power and collusive behavior among firms in the markets for tobacco products, and restrictions on trade in tobacco and tobacco products. The most important policy-related determinants of prices, however, are taxes on tobacco products.

In the United States, tobacco is taxed in various ways by the federal, state, and local governments. The most important of these are the excise, or per unit, taxes imposed on cigarettes and the general sales tax (an ad valorem tax) applied to cigarettes and other tobacco products in most states. Ad valorem taxes are a fixed percentage of the price and thereby increase or decrease as price changes. Excise taxes, on the other hand, do not change over time with prices.

Tobacco taxes have relatively low administrative costs and can generate substantial revenues. In recent years, increased taxation of tobacco products has been used as a strategy to reduce tobacco consumption and thereby to improve public health. For example, the health benefits of tax-induced reductions in smoking were often cited by supporters of the federal cigarette excise tax proposed as part of the Clinton administration's proposed Health Security Act of 1993, which included an increase of 75 cents per pack. (The act did not pass.) Similarly, anticipated large reductions in youth smoking were, in part, the rationale for tax increases of up to \$2.00 per pack proposed as part of most proposals for national tobacco legislation and the average \$2.00 state and federal tax set as a goal for 2010 by the Healthy People 2010 initiative. The health benefits of higher taxes were also the focus of the large voter-initiated tax increases in Arizona, California, Massachusetts, Michigan, and Oregon, as well as the large legislated tax increases in Alaska, Maine, and elsewhere.

Rationales for Tobacco Taxation

Alternative approaches have been used to determine the appropriate level of cigarette and other tobacco taxes. One such approach is the historical or comparative standard, which looks at the relative value of these taxes over time or cross-sectionally. A second approach is to use an efficiency standard based on the external costs of smoking; this approach implies that tobacco taxes can be thought of as "user fees" sufficient to cover the external costs of tobacco use. This approach, however, raises questions concerning the fairness of such taxes. A further argument has been made for substantial increases in tobacco taxes, because these tax hikes would lead to substantial reductions in the morbidity and mortality associated with cigarette smoking. Finally, because taxes on cigarettes and other tobacco products are a relatively simple way to generate revenues, it has been suggested that these taxes can be set at levels that maximize their returns. Each of these alternatives will be discussed.

Historical or Comparative Standard

Federal Tobacco Taxes

Tobacco has been taxed in North America since the British government first imposed taxes during colonial times. Beginning in 1794, the U.S. government imposed tobacco taxes that periodically rose with revenue needs and subsequently fell because of consumer opposition. Since 1864, when cigarette and other tobacco taxes were included in a package to finance the Civil War, taxes on tobacco in one form or another have remained a part of the federal tax system. Taxes continued to rise and fall over the next 87 years, generally increasing with revenue needs during the Spanish-American War, World Wars I and II, and the Korean War (Table 6.10). The final war-related increase in the federal excise tax per pack of cigarettes was from 7.0 cents to 8.0 cents per pack on November 1, 1951, where it remained for the next three decades.

The most recent federal tax increases were motivated by a need to raise revenues for a different purpose—to reduce the increasing federal budget deficit. The first of these hikes in the federal cigarette excise tax came as part of the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248), which temporarily doubled the per pack tax to 16.0 cents, effective January 1, 1983. The tax was to revert to 8 cents on October 1, 1985, but after several extensions, the 16-cent tax was made permanent in 1986. As the result of two 4-cent increases included in the Omnibus Budget Reconciliation Act of 1990, the tax per pack

was increased to 20.0 cents on January 1, 1991, and then to 24.0 cents on January 1, 1993. Finally, as a result of the 1998 budget agreement, federal cigarette excise taxes are scheduled to rise by 10 cents per pack in 2000 and by an additional 5 cents per pack in 2002.

Also as part of the Consolidated Omnibus Budget Reconciliation Act of 1985, taxes of 8.0, 24.0, and 45.0 cents per pound were imposed on chewing tobacco, snuff, and pipe tobacco, respectively. These were the first new federal taxes on chewing tobacco and snuff since 1965, when the taxation was set at 10 cents per pound. These taxes are currently 12.0, 36.0, and 67.5 cents per pound (Table 6.11). This assessment amounts to approximately 2.7 cents per 1.2-ounce can of snuff, 2.3 cents per 3-ounce pouch of chewing tobacco, and 6.3 cents per 1.5-ounce pouch of pipe tobacco. Tobacco for roll-your-own cigarettes is not taxed at the federal level.

State and Local Tobacco Taxes

All 50 states and the District of Columbia currently impose excise taxes on cigarettes. The first of these was a tax levied by Iowa in 1921. It was followed in 1923 by taxes in Georgia, South Carolina, South Dakota, and Utah. On October 1, 1969, North Carolina became the last state to impose a tax on cigarettes. As of May 1, 2000, these taxes ranged from 2.5 cents per pack in Virginia to \$1.11 per pack in New York (Table 6.12). Forty-four states currently impose taxes on tobacco products other than cigarettes (Table 6.13); only 17 states imposed such taxes in 1964. In general, these other taxes are ad valorem taxes. The general sales tax in most states applies to cigarettes and other tobacco products, with the tax base in most states including the excise tax. As of November 1, 1999, these sales taxes added 8-25 cents per pack to the price of cigarettes (Table 6.12). In eight states, 450 cities and counties impose additional taxes on the sale of cigarettes, and 85 of these also tax other tobacco products. The largest of the local cigarette taxes are those imposed in Chicago (combined county and city taxes of 34 cents per pack) and New York City (8 cents per pack).

At least until the 1950s, state taxes on cigarettes were enacted and raised to generate revenues rather than to discourage consumption. The average year such taxes were initiated in the six major tobaccoproducing states (1939) slightly predates the average year for the other states (1940) (Warner 1981). Before the widespread publicity on the health consequences of smoking, the average tax rate in the six tobacco states was only slightly lower than that in the other states

(2.5 vs. 2.9 cents per pack). Since the release in the mid-1950s of the first reports describing the adverse health effects of cigarette smoking, and even more so since the 1964 release of the initial Surgeon General's report on smoking and health, state governments have actively used cigarette taxes as a principal tool in their

Table 6.10. Federal cigarette excise taxes, selected dates, 1864–2002

Effective date	Tax per pack of 20 cigarettes (cents)
June 30, 1864*	0.8, 2.4
April 1, 1865 [†]	2.4, 4.0
August 1, 1866 [‡]	4.0, 8.0, 8.0+20%
March 2, 1867	10.0
July 20, 1868	3.0
March 3, 1875	3.5
March 3, 1883	1.0
August 15, 1897	2.0
June 14, 1898	3.0
July 1, 1901§	1.08, 2.16
July 1, 1910	2.5
October 4, 1917	4.1
February 25, 1919	6.0
July 1, 1940	6.5
November 1, 1942	7.0
November 1, 1951	8.0
January 1, 1983	16.0
January 1, 1991	20.0
January 1, 1993	24.0
January 1, 2000	34.0
January 1, 2002^{Δ}	39.0

^{*}Lower rate applied to cigarettes valued at \$6 or less per 100 packs of 25 each.

Source: Orzechowski and Walker 2000.

campaigns to reduce tobacco use. For example, the number of tax increases has risen from an average of less than three per year in the early 1950s to an average of more than eight per year in the late 1950s, and a record 22 states increased their cigarette taxes in 1965 (Table 6.14). Similar activity occurred during 1967-1970, when antismoking ads were broadcast under the Fairness Doctrine and after cigarette advertising on television and radio was banned in 1971. The oncenegligible difference in cigarette excise tax rates between the tobacco-producing states and other states grew substantially over this period. By May 1, 2000, the simple average of cigarette taxes in the six largest tobacco-growing states was 7.1 cents compared with 46.5 cents in the remaining states and the District of Columbia.

The use of increased cigarette and other tobacco taxes to discourage all tobacco use was even more obvious in the late 1980s and early 1990s. In November 1988, California voters approved the Tobacco Tax and Health Protection Act (Proposition 99), the thenlargest single increase (25 cents per pack) in any state excise tax on cigarettes. New taxes were also imposed on other forms of tobacco. The novel feature of this tax hike was that 20 percent of the new revenues generated by the tax increase was earmarked for tobaccorelated education activities and 5 percent was allocated to tobacco-related research.

The success of Proposition 99 in California led to a similar voter-approved measure in Massachusetts. In November 1992, voters passed Question 1, which raised the state cigarette tax from 26 cents to 51 cents per pack and increased the state tax on chewing

Table 6.11. Federal excise tax rates (cents/pound) on chewing tobacco, snuff, and pipe tobacco, selected years, 1986–2002

Year	Chewing tobacco	Snuff	Pipe tobacco
1986	8.0	24.0	45.0
1991	10.0	30.0	56.25
1993	12.0	36.0	67.5
2000	17.0	51.0	95.67
2002*	19.5	58.5	109.69

^{*}Scheduled.

Sources: Advisory Commission on Intergovernmental Relations 1991; Bureau of Alcohol, Tobacco and Firearms 2000.

[†]Lower rate applied to cigarettes valued at \$5 or less per 100 packs of 25 each.

[‡]Lower rate applied to cigarettes valued at \$8 or less per 1,000. Higher rate applied to cigarettes valued at more than \$12 per 1,000.

[§]Lower rate applied to cigarettes valued at \$2 or less per 1,000.

[∆]Scheduled.

Table 6.12. State cigarette excise taxes and sales taxes (cents/pack) applied to cigarettes

State	Excise tax rate May 1, 2000	Sales tax November 1, 1999	State	Excise tax rate May 1, 2000	Sales tax November 1, 1999
Alabama	16.5	11.0	Montana	18.0	0
Alaska	100.0	0	Nebraska	34.0	13.0
Arizona	58.0	16.0	Nevada	35.0	20.0
Arkansas	31.5*	13.0	New Hampshire	52.0	0
California	87.0	25.0	New Jersey	80.0	17.0
Colorado	20.0	0	New Mexico	21.0	14.0
Connecticut	50.0	19.0	New York	111.0	13.0
Delaware	24.0	0	North Carolina	5.0	10.0
District of Columbia	65.0	19.0	North Dakota	44.0	18.0
Florida	33.9	17.0	Ohio	24.0	13.0
Georgia	12.0	8.0	Oklahoma	23.0	12.0
Hawaii	100.0	15.0	Oregon	68.0	0
Idaho	28.0	14.0	Pennsylvania	31.0	17.0
Illinois	58.0	20.0	Rhode Island	71.0	23.0
Indiana	15.5	13.0	South Carolina	7.0	13.0
Iowa	36.0	14.0	South Dakota	33.0	11.0
Kansas	24.0	13.0	Tennessee	13.0	21.0
Kentucky	3.0	15.0	Texas	41.0	18.0
Louisiana	20.0	11.0	Utah	51.5	15.0
Maine	74.0	18.0	Vermont	44.0	15.0
Maryland	66.0	16.0	Virginia	2.5	11.0
Massachusetts	76.0	18.0	Washington	82.5	23.0
Michigan	75.0	20.0	West Virginia	17.0	15.0
Minnesota	48.0	19.0	Wisconsin	59.0	16.0
Mississippi	18.0	19.0	Wyoming	12.0	11.0
Missouri	17.0	11.0			

^{*}Arkansas tax can rise to 34 cents if the state does not appropriate adequate funds for breast cancer research and control.

Sources: Orzechowski and Walker 2000; Centers for Disease Control and Prevention, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data.

tobacco by 25 percent. Although Massachusetts law prevents funds raised by the tax from being earmarked for tobacco-related education and prevention efforts, the funds are placed into a Health Protection Fund, and the wording of the approved measure strongly

recommended that at least part of the funds be allocated to activities related to reducing tobacco use.

More recently, Michigan voters in 1994 enacted Proposal A, which changed the financing for Michigan public schools. Part of this plan included raising the general state sales tax (which is applied to cigarettes and other tobacco products) from 4 to 6 percent and tripling the state excise tax on cigarettes to 75 cents per pack, representing the largest single increase in cigarette taxes ever implemented in the United States. New taxes were also imposed on various other tobacco products. Six percent of the new revenues were earmarked for health improvement activities, including tobacco-related education and prevention efforts.

In November 1994, Arizona voters approved the Tobacco Tax and Health Care Act, which included a 40-cent increase in the state cigarette tax with earmarking provisions similar to those in California, Massachusetts, and Michigan. At the same time, however, voters in Colorado rejected a tax hike of 50 cents per pack with similar features. In November 1996, Oregon voters approved Measure 44, which increased cigarette taxes by 30 cents per pack, raised the tax on other tobacco products from 35 to 65 percent of wholesale price, and dedicated a portion of the increased revenue to tobacco use prevention and education. Similar large cigarette-tax increases, including some that dedicate significant funds to tobacco control activities, have been recently legislated in a number of states, including Alaska, Maine, New Jersey, and New York. In addition, in 1998, voters in California approved an additional 50-cent per pack increase in the state cigarette tax.

The relative ease with which cigarettes and other tobacco products can be transported and the potential profits from illegal activity of this kind have limited state and local governments' ability to further raise tobacco taxes. The large disparities in price resulting from differences in tobacco taxation create incentives to (1) smuggle on a casual level (involving small quantities for personal use) or on an organized level (involving large quantities, generally for resale); (2) purchase cigarettes through tax-free outlets, including military stores and American Indian reservations; and (3) illegally divert cigarettes within the usual distribution system by forging tax stamps, which results in underreporting. Altogether, this "butt legging" (ACIR 1977) can result in a net loss of revenues when tobacco taxes are increased.

Although casual smuggling has always been a problem, states reported that organized smuggling activities rose significantly after the cigarette tax hikes of the late 1960s. In response to state pressure, the Trafficking in Contraband Cigarettes Act of 1978 (Public Law 95-575) was enacted. This act, which dealt only with the organized smuggling of cigarettes, prohibited the single-transaction transport, receipt, shipment, possession, distribution, or purchase of more than

60,000 cigarettes not bearing the tax indicia of the state in which the cigarettes were initially sold. The ACIR (1985) suggests that the law was even more effective than its proponents predicted. Casual smuggling, however, may become a more significant problem as the differences between cigarette taxes in neighboring states increase as the result of some of the recent large tax hikes in some states.

Several econometric analyses of cigarette demand have carefully considered the effects of price differentials on organized and casual cigarette smuggling on state cigarette sales (Baltagi and Levin 1986, 1992; Chaloupka and Saffer 1992; Becker et al. 1994; Saba et al. 1995; Jackson and Saba 1997; Yurekli and Zhang 2000). In general, these studies concluded that smuggling has a significant, but small, impact on cigarette demand, implying that a state cigarette tax increase will lead to some smuggling. Yurekli and Zhang (2000), for example, estimate that, on average, 6 percent of state cigarette tax revenues were lost due to smuggling activities in 1995. However, given the magnitude of these estimates, Merriman (1994) and Baltagi and Levin (1992) estimated that state cigarette taxes are below their revenue-maximizing levels. Thus, states can raise cigarette taxes and generate increased revenues, even as cigarette sales decline and interstate smuggling increases.

Cigarette Taxes and Cigarette Prices

Increases in cigarette and other tobacco taxes result in higher prices for these products. Most cigarette taxes, however, are excise taxes; unless they are increased regularly over time, the value of the tax will fall in real terms (after analysis accounts for the effects that inflation, as measured by the Consumer Price Index, has on the tax). Because taxes are an important component of price, one of the consequences of an excise tax system with relatively infrequent increases is that, at least during the period between excise tax increases, the real price of cigarettes will fall over time as the prices of other goods and services increase more rapidly.

When trends are examined in real cigarette prices over the past four decades, three clear periods are observed (Table 6.15). The first is 1955–1971, when states were increasing taxes not only to raise revenues but also to discourage smoking. The real value of state taxes during this period approximately doubled from 13.1 cents (1982–1984 dollars) to 26.4 cents per pack. This increase was more than sufficient to offset the reductions in the real federal tax (from 29.9 cents to 19.8

Table 6.13. State tax rates on tobacco products other than cigarettes as of January 1, 2000

State	Taxes on other tobacco products
Alabama	Cigars retailing for: a) ≤3.5 cents each or less, \$150 per thousand; b) >3.5 and ≤5 cents each, \$3.00 per thousand; c) >5 and ≤8 cents each, \$4.50 per thousand; d) >8 and ≤10 cents each, \$7.50 per thousand; e) >10 and ≤20 cents each, \$15 per thousand; f) >20 cents each, \$20.25 per thousand. Little cigars: 2 cents for each 10 or fraction thereof. Smoking tobacco: a) ≤1.125 ounces, 2 cents; b) >0.125 ounces and ≤2 ounces, 5 cents; c) >2 ounces and ≤3 ounces, 8 cents; d) >3 ounces and ≤4 ounces, 11 cents; e) 3 cents additional tax for each ounce or fraction part thereof over
	4 ounces. Chewing tobacco: 0.75 cents of each ounce or fraction thereof. Snuff: a) ≤0.625 ounces, 0.5 cents; b) >0.625 ounces, and ≤1.625 ounces, 1 cent; c) >1.625 ounces and ≤2.5 ounces, 2 cents; d) >2.5 ounces and ≤3 ounces, 2.5 cents; e) >3 ounces and ≤5 ounces (cans, packages, gullets), 3 cents; f) >3 ounces and ≤5 ounces (glasses, tumblers, bottles), 3.5 cents; g) >5 ounces and ≤6 ounces, 4 cents; h) 1 cent additional tax for each ounce or fraction thereof over 6 ounces.
Alaska	75% of wholesale price.
Arizona	Cigars retailing for: a) ≤5 cents, 6.4 cents for each 3 cigars; b) >5 cents, 6.4 cents each. Little cigars: 12.9 cents for each 20 or fraction thereof. Smoking and chewing tobacco and snuff: 6.5 cents per ounce or major fraction thereof. Plug tobacco: 1.6 cents per ounce or fraction thereof.
Arkansas	23% of manufacturers' invoice price.
California*	61.56% of wholesale price.†
Colorado	20% of manufacturers' price.
Connecticut*	20% of manufacturers' price.
Delaware	15% of wholesale price.
District of Columbia	None.

^{*}Little cigars taxed at the same rate as cigarettes.

Sources: Orzechowski and Walker 2000; Centers for Disease Control and Prevention, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data.

[†]California rate reset at beginning of each fiscal year; New Hampshire rate reset semiannually.

[‡]Maryland tax becomes effective July 1, 2000.

Table 6.13. Continued

State	Taxes on other tobacco products
Florida	Smoking tobacco, chewing tobacco, and snuff: 25% of wholesale price.
Georgia	Little cigars: weighing ≤3 pounds per 1,000, 2 mills each. All other cigars: 13% of wholesale price.
Hawaii	40% of wholesale price.
Idaho	40% of wholesale sales price.
Illinois	18% of wholesale price.
Indiana	15% of wholesale price.
Iowa*	22% of wholesale price.
Kansas	10% of original invoice price from the manufacturer to the wholesaler.
Kentucky	None.
Louisiana	Cigars:
	a) a list price of \$120 per thousand or less, tax is 8% of net invoice price;b) a list price of over \$120 per thousand, tax is 20% of net invoice price.Smoking tobacco: 33% of net invoice price.
Maine*	Chewing tobacco and snuff: 62% of wholesale sales price. Cigars and smoking tobacco: 16% of wholesale sales price.
Maryland [‡]	All other products 15% of wholesale price.
Massachusetts	75% of wholesale price for smokeless tobacco products. 15% of wholesale price for cigars and pipe tobacco.
Michigan	16% of wholesale price.
Minnesota	35% of wholesale price.
Mississippi	15% of manufacturers' list price.
Missouri	10% of manufacturers' price.
Montana	12.5% of wholesale price.
Nebraska	15% of wholesale price.
Nevada	30% of wholesale price.
New Hampshire [†]	Chewing tobacco and snuff: 17.9% of wholesale price invoiced to retailer.
New Jersey	48% of wholesale price.
New Mexico	25% of product value.
New York	20% of wholesale price.
North Carolina	2% of wholesale price.
North Dakota	28% of wholesale price.
Ohio	17% of wholesale price.
Oklahoma	Cigars, cheroots, stogies, etc., weighing >3 pounds per thousand retailing for: a) ≤4 cents each, \$10 per thousand; b) >4 cents each, \$30 per thousand. Little cigars: 9 mills each. Smoking tobacco: 40% of factory list price.
	Little cigars: 9 mills each.

Table 6.13. Continued

State	Taxes on other tobacco products
Oregon*	65% of wholesale sales price.
Pennsylvania	None.
Rhode Island	20% of wholesale price.
South Carolina	Cigars, cheroots, stogies, etc., retailing for: a) ≤5 cents each, \$11 per thousand; b) >5 cents each, \$20 per thousand. Little cigars: 2 cents for each 8 or fraction thereof. Smoking tobacco: 36% of manufacturers' price. Chewing tobacco and snuff: 5% of manufacturers' price.
South Dakota	10% of wholesale price.
Tennessee*	6% of wholesale price.
Texas	 Cigars: Tax on cigars and tobacco is based on weight per 1,000 and retail selling price. a) ≥3 pounds per 1,000, 1 cent for each 10 cigars; b) >3 pounds per 1,000 and retailing for ≤3.3 cents each, \$7.50 per 1,000; c) >3 pounds per 1,000, retailing for >3.3 cents each and containing a substantial amount of nontobacco ingredients, \$11 per thousand; d) >3 pounds per 1,000, retailing for >3.3 cents each and containing a substantial amount of nontobacco ingredients, \$15 per thousand; e) Chewing, pipe, or smoking tobacco, and snuff: 35.213% of the manufacturers' list price exclusive of any trade discount, special discount, or deal.
Utah	35% of manufacturers' selling price delivered into state.
Vermont	41% of distributors' price.
Virginia	None.
Washington	74.9% of wholesale price.
West Virginia	None.
Wisconsin	20% of wholesale price.
Wyoming	All other products 20% of wholesale price.

cents per pack); as a result, cigarette taxes continued to account for about 50 percent of cigarette prices.

During the 1970s, however, the real price of cigarettes dropped significantly because of the stability of cigarette excise taxes and the relatively rapid increases in the prices of other goods and services. During this period, the real value of the federal cigarette tax (which was unchanged in nominal terms) fell by more than 50 percent, and the real value of state taxes dropped by nearly as much. The net result was a decline of 38.5 percent in the real price of cigarettes. Moreover,

during this period, taxes as a share of cigarette prices fell from 46.8 to 33.1 percent, because the nontax component of real price was relatively stable.

Since 1981, however, the real price of cigarettes has increased sharply, from 69.3 cents to 127.1 cents per pack in November 1992, and further in early 1993. Important factors behind this increase were the federal tax increases in 1983, 1991, and 1993, which tripled the nominal value of the cigarette excise tax. Also important was the steady rise in the real value of average state excise taxes on cigarettes, from a low of

Table 6.14. Number of increases and decreases in state excise taxes on cigarettes,
July 1, 1950–May 1, 2000

Year	Increases (Decreases)	Year	Increases (Decreases)
1950	2	1976	1
1951	7 (1)	1977	4
1952	0	1978	1 (1)
1953	2	1979	4
1954	3	1980	2
1955	11	1981	6 (1)
1956	5 (1)	1982	10
1957	8	1983	13
1958	4	1984	4
1959	15	1985	11
1960	4 (2)	1986	6
1961	17 (1)	1987	13
1962	2	1988	3
1963	15	1989	14 (1)
1964	5	1990	8
1965	22	1991	13 (1)
1966	4 (1)	1992	7
1967	12	1993	15 (2)
1968	8	1994	8
1969	20	1995	5
1970	7	1996	2
1971	16	1997	9
1972	5	1998	2
1973	2	1999	3
1974	2	2000	1
1975	5		

Sources: Orzechowski and Walker 2000; Centers for Disease Control and Prevention, Office on Smoking and Health, State Tobacco Activities Tracking and Evaluation System, unpublished data.

14.0 cents per pack in 1982 to 19.4 cents per pack in 1993. However, even with the increases in the real values of the federal and state taxes on cigarettes, taxes as a share of price fell substantially from 1981 to 1993

(from 33.1 to 24.9 percent). The most important factor behind the rise in real cigarette prices, then, was the sharp rise in nontax (i.e., manufacturer-added) price components. In 1981, the real value of the nontax portion of average cigarette prices was 46 cents. By 1993, this amount was 79.5 cents, which is an increase of more than 70 percent. As described earlier in this chapter, in "High Tobacco Concentration and the Impact of Prevention Policies," much of this increase was attributable to the less than perfectly competitive supply side of the cigarette market. The result of the increases in both the tax and the nontax components of cigarette prices was an increase of almost 85 percent in the real price of cigarettes from 1981 to 1993.

Real cigarette prices declined sharply as a result of "Marlboro Friday" in April 1993, when wholesale cigarette prices, first for Marlboro then soon after for other premium brands, were cut by 25 percent. More recently, however, real cigarette prices have risen significantly. These increases are partly the result of increases in state and federal cigarette excise taxes over the past few years. More important, however, are the significant increases in wholesale cigarette prices beginning in 1997. These prices increased by more than 12 percent between March 1997 and April 1998, returning to their 1992 nominal level (USDA 1998a), in part the result of increased costs associated with tobacco industry settlements with Mississippi, Florida, Texas, and Minnesota. Wholesale prices increased an additional 45 cents per pack in November 1998, on the day the Master Settlement Agreement was announced. This increase, the largest in history, was followed nine months later by an additional 18-cent per pack increase (USDA 2000).

International Tobacco Taxes

Among industrialized countries around the world, the United States has one of the lowest average prices and taxes on cigarettes (Table 6.16). As of December 31, 1996, the average tax in the United States was 66.0 cents per pack, well below the taxes imposed in almost every other industrialized country. At that time, taxes in various other countries, in U.S. dollars, ranged from \$5.23 per pack in Norway to 47 cents per pack in South Africa. Most developed countries have at least double the average tax in the United States. Some interesting features of these taxes include earmarking for tobacco-related education and other health-related activities (in Denmark, Finland, Iceland, Peru, and elsewhere), the creation of state-based Health Promotion Foundations in Australia and the Health Sponsorship Council in New Zealand to fund sporting and artistic

Table 6.15. Cigarette taxes and cigarette prices, 1955–2000 (cents/pack)

Year	Weighted average state tax*†	Average federal tax [†]	Average cigarette price [‡]	Taxes as a percentage of average price [§]	Real average state tax ^{†∆}	Real average federal tax ^{†∆}	Real average cigarette price $^{\Delta}$
1955	3.5	8.0	22.7	48.7	13.1	29.9	84.7
1956	3.8	8.0	23.2	47.4	14.0	29.4	85.3
1957	3.9	8.0	23.8	48.8	13.9	28.5	84.7
1958	4.0	8.0	25.0	48.0	13.8	27.7	86.5
1959	4.2	8.0	25.6	46.6	14.4	27.5	88.0
1960	4.7	8.0	26.1	48.9	15.9	27.0	88.2
1961	4.7	8.0	26.1	48.6	15.7	26.8	87.3
1962	5.1	8.0	26.9	48.3	16.9	26.5	89.1
1963	5.2	8.0	26.8	49.4	17.0	26.1	87.6
1964	5.6	8.0	27.9	49.3	18.1	25.8	90.0
1965	5.9	8.0	28.2	49.8	18.7	25.4	89.5
1966	6.9	8.0	30.0	51.4	21.3	24.7	92.6
1967	7.1	8.0	30.5	50.8	21.3	24.0	91.3
1968	8.4	8.0	32.3	49.2	24.1	23.0	92.8
1969	9.1	8.0	32.8	48.9	24.8	21.8	89.4
1970	10.2	8.0	37.1	47.7	26.3	20.6	95.6
1971	10.7	8.0	38.9	46.8	26.4	19.8	96.0
1972	11.6	8.0	40.0	47.7	27.8	19.1	95.7
1973	12.1	8.0	40.3	48.4	27.3	18.0	90.8
1974	12.1	8.0	41.8	47.6	24.5	16.2	84.8

^{*}State taxes are an average of taxes in all taxing states (42 in 1955; 50 in 1970 and thereafter) and the District of Columbia, weighted by tax-paid cigarette sales in those states.

Source: Orzechowski and Walker 2000.

events previously backed by the tobacco industry, and the differential taxes on cigarettes with high-tar and high-nicotine content used in previous years in the United Kingdom (Roemer 1993). One consequence of the differences in cigarette taxes and prices across countries is the potential for casual and organized cigarette smuggling and other forms of tax evasion. The cigarette industry, for example, frequently argues that cigarette tax increases

[†]Nominal and real average state and federal tax data are for the fiscal year ending June 30.

[‡]Price reflects the median retail price for cigarettes (including generic brands) in all taxing states, generally as of November 1 of the state fiscal year.

[§]Percentages cannot be calculated directly from the tax and price information, because taxes are weighted average taxes for the entire fiscal year, whereas prices and percentages are generally as of November 1.

^ΔReal cigarette taxes and prices are obtained by dividing the nominal taxes and prices by the national Consumer Price Index; the average of 1982–1984 is the benchmark.

¹Preliminary estimate.

Table 6.15. Continued

Year	Weighted average state tax*†	Average federal tax [†]	Average cigarette price [‡]	Taxes as a percentage of average price [§]	Real average state tax ^{†∆}	Real average federal tax ^{†∆}	Real average cigarette price $^{\Delta}$
1975	12.2	8.0	44.5	44.5	22.7	14.9	82.7
1976	12.4	8.0	47.9	41.4	21.8	14.1	84.2
1977	12.5	8.0	49.2	40.5	20.6	13.2	81.2
1978	12.9	8.0	54.3	37.1	19.8	12.3	83.3
1979	12.9	8.0	56.8	35.5	17.8	11.0	78.2
1980	13.1	8.0	60.0	34.5	15.9	9.7	72.8
1981	13.2	8.0	63.0	33.1	14.5	8.8	69.3
1982	13.5	8.0	69.7	29.9	14.0	8.3	72.2
1983	14.7	12.0	81.9	26.8	14.8	12.0	82.2
1984	15.3	16.0	94.7	33.2	14.7	15.4	91.1
1985	15.9	16.0	97.8	32.3	14.8	14.9	90.9
1986	16.2	16.0	104.5	30.8	14.8	14.6	95.3
1987	16.9	16.0	110.0	29.9	14.9	14.1	96.8
1988	18.2	16.0	122.2	28.1	15.4	13.5	103.3
1989	21.8	16.0	127.5	26.5	17.6	12.9	102.8
1990	24.7	16.0	144.1	26.4	18.9	12.2`	110.3
1991	25.9	16.0	153.3	25.6	19.0	11.7	112.6
1992	26.5	20.0	173.5	25.6	18.9	14.3	123.7
1993	28.0	22.0	183.7	24.9	19.4	15.2	127.1
1994	31.5	24.0	169.3	31.4	21.3	16.2	114.2
1995	31.2	24.0	175.8	31.0	20.5	15.7	115.4
1996	31.7	24.0	179.6	31.6	20.2	15.3	114.5
1997	31.8	24.0	185.4	30.5	19.8	15.0	115.5
1998	34.1	24.0	195.0	31.5	20.9	14.7	119.6
1999	36.4	24.0	217.5	28.2	21.8	14.4	130.6
2000	39.8 [¶]	29.0 [¶]	292.6	22.1	23.2 [¶]	16.9 [¶]	170.5 [¶]

will actually lead to reductions in tax revenues due to smuggling and other tax evasion (British-American Tobacco Company Limited 1994). The smuggling problem is exacerbated by the relative ease with which tobacco products can be transported, the potential profits from this illegal activity, the presence of corruption and organized crime, the widespread street selling, the availability of tax-free and duty-free cigarettes, and the

nonexistent or relatively weak policies concerning cigarette smuggling and their lack of enforcement (ACIR 1977, 1985; Joossens and Raw 1995; Joossens et al., in press). Joossens and Raw (1995, 1998) argued that many of these other factors can be as important as price differences in spawning cigarette smuggling. For example, they noted that there is little evidence of smuggling in some of the highest priced European

Table 6.16. Average retail cigarette price and total taxes per pack (U.S. dollars/pack), selected countries, December 31, 1996

Country	Average retail price	Total taxes	Tax as a percentage of retail price*
Norway	7.05	5.23	74
United Kingdom	5.27	4.30	82
Ireland	4.94	4.16	84
Denmark	4.75	4.02	85
Finland	4.54	3.48	77
Australia	4.50	2.92	65
Sweden	4.47	3.13	70
New Zealand	4.17	2.79	66
Canada (highest provincial taxes)	4.09	2.97	73
Singapore	3.72	1.87	50
Hong Kong	3.62	1.76	49
France	3.47	2.61	75
Belgium	3.23	2.39	74
Germany	3.18	2.28	72
Canada (average provincial taxes)	3.00	1.97	66
Austria	2.84	2.11	74
Netherlands	2.66	1.94	73
United States (highest state taxes)	2.65	1.24	47
Italy	2.17	1.59	73
Canada (lowest provincial taxes)	2.02	1.12	55
United States (average state taxes)	1.90	0.66	35
Greece	1.82	1.33	73
Portugal	1.77	1.43	81
United States (lowest state taxes)	1.60	0.34	21
Thailand	1.58	0.89	56
Taiwan	1.45	0.62	43
Brazil	1.43	1.06	74
Spain	1.08	0.81	75
South Africa	1.04	0.47	45

Notes: (a) Figures given are for a package of 20 of the most popular price category; (b) exchange rates are from the Bank of Canada Official Exchange Rates as of December 31, 1996.

Source: Smoking and Health Action Foundation (Canada), unpublished data, April 30, 1997.

^{*}The tax as a percentage of retail price refers to the portion of the average retail selling price that composes all applicable taxes and other fees imposed on the product.

countries, including France, Norway, Sweden, and the United Kingdom, whereas there is extensive evidence of smuggling in countries with relatively low prices, such as Spain and Italy. Merriman and colleagues (in press) provide empirical evidence that the perceived level of corruption explains more of the variance in experts' estimates of the magnitude of cigarette smuggling than do cigarette prices. Moreover, Joossens and colleagues (Joossens and Raw 1998; Joossens et al., in press) concluded that much of the smuggling that does occur in Europe and elsewhere is encouraged by multinational tobacco companies. Thursby and Thursby (1994) provided empirical support for this argument, based on their analysis of data from the United States from which they concluded that increases in federal cigarette excise taxes lead to increased commercial cigarette smuggling.

Perhaps the most interesting international comparison is between cigarette tax policy in the United States and Canada. In 1970, average taxes (including sales taxes) on cigarettes were 30 cents per pack in Canada and 20 cents per pack in the United States. By 1980, the average Canadian tax, 46 cents per pack, was double the U.S. tax. Real prices in both countries had fallen sharply throughout the 1970s, but after 1980, the gap between the two countries widened rapidly. One main reason for this change was the adoption of an ad valorem tax by the federal and provincial governments in Canada. As a result, cigarette taxes in Canada doubled between 1980 and 1984, leading to a 25percent increase in real cigarette prices. In response to pressure from the cigarette industry, however, the ad valorem tax structure was replaced with an excise tax system in 1984.

The growth in Canadian taxes slowed over the next few years. Most taxing took place at the provincial rather than the federal level. In 1988, however, the Canadian federal government committed to an aggressive campaign to reduce tobacco use; highlighting the campaign was a ban enacted that year on tobacco advertising. In 1989, the federal tax was raised by 2 cents per cigarette, and another hike of 3 cents per cigarette occurred in 1991. At the same time, provincial taxes were increasing rapidly. By early 1994, the average tax per pack of cigarettes was \$2.96 (in U.S. dollars), which is more than five times the average U.S. tax.

The large disparities in Canadian and U.S. cigarette prices led to substantial smuggling, which was enabled by the long stretches of unmonitored border between Canada and the United States, the relatively weak border controls, and the high concentration of the Canadian population near U.S. borders (Sweanor

and Martial 1994). Much of the black market trade that resulted was in Canadian-produced cigarettes that had been exported to the United States (exports were not subject to the Canadian taxes) and then smuggled back into Canada. Relatively little black market trade involved cigarettes produced in the United States; U.S. cigarettes use a blend of tobacco different from Canadian cigarettes and are less desired by Canadian smokers (Sweanor and Martial 1994). In a short-lived effort to reduce the smuggling problem, a tax of 80 cents per pack was applied to Canadian cigarette exports in mid-February 1992. This tax was repealed six weeks later, although preliminary evidence indicated that it had been successful in reducing smuggling (Sweanor and Martial 1994). After the repeal of the export tax, Canadian cigarette exports to the United States rose dramatically, and smuggling increased again.

In response to an aggressive industry-sponsored campaign, the federal tax on cigarettes in Canada was reduced by \$5.00 per carton on February 9, 1994. Moreover, the federal government agreed to match provincial reductions in taxes up to an additional \$10.00 per carton. Quebec immediately lowered its provincial tax by \$11.00 per carton for a total tax cut of \$26.00 per carton, leading to a 50-percent drop in price. By August 1994, four other provinces had reduced cigarette taxes substantially. These cuts reduced the average Canadian tax per pack from \$2.96 before the federal tax cut to \$1.97 as of December 31, 1996 (in U.S. dollars), which was an amount still well above the average U.S. cigarette tax of 66 cents per pack at that time.

The Canadian experience was cited by the tobacco industry during the recent debates over the proposed national tobacco settlement as evidence that a black market in cigarettes would develop in the United States in response to large cigarette tax increases. However, there is little evidence to support this contention. Given that Canadian cigarette taxes were reduced because of smuggling from the United States, it is likely that these taxes would be increased if the United States were to adopt large tax increases, making it unlikely that widespread smuggling of cigarettes from Canada into the United States would occur. Cigarette prices in Mexico, however, are well below those in the United States, and large increases in U.S. prices could make smuggling cigarettes from Mexico a highly profitable venture. To date, however, no empirical evidence supports the contention of significant smuggling of cigarettes from Mexico into the United States. Furthermore, unlike the U.S.-Canadian border, the border between the United States and Mexico is relatively short and heavily guarded, making it much more difficult to smuggle large quantities of a bulky product like cigarettes.

Finally, several relatively easy options exist for limiting cigarette smuggling (Joossens and van der Merwe 1997; Joossens et al., in press). These include prominent tax-paid markings on all tobacco products and sizable increases in the penalties for cigarette smuggling. The ACIR (1985), for example, concluded that the Trafficking in Contraband Cigarettes Act (Public Law 95-575), which prohibited the transportation, receipt, shipment, possession, distribution, or purchase of large quantities of cigarettes that did not bear the tax indicia of the state in which the cigarettes are found, led to a significant reduction in interstate cigarette smuggling resulting from interstate price differentials.

Discussion

If one applies Cook and Moore's (1993) discussion of alcohol taxes to cigarette taxes, a provocative question arises when one compares previous cigarette excise taxes with current ones: why is the current tax rate deemed appropriate when it is just over one-half the level that was deemed appropriate in 1951? Unless it is in the public interest to tax cigarettes at a much lower rate now than then (an odd notion, given that in 1951 much less evidence was available on the health hazards of smoking), a case can be made for restoring taxes to their earlier levels. Similar arguments can be made at the state level, particularly in those states where taxes have not changed or have been increased modestly and infrequently over time.

Other, comparative standards for appropriate taxes could be used. For example, as shown in Table 6.12, state excise taxes on cigarettes differ substantially; these differences reflect several factors, including the importance of tobacco for the local economy. At another level of comparison, large differences between cigarette taxes in Canada and the United States gave rise to a significant black market trade, which in turn resulted in reductions in Canadian taxes. At the global level, cigarette and other tobacco taxes in the United States are among the lowest in industrialized countries around the world. Such comparisons suggest that relatively high taxes may be appropriate in some areas and low taxes appropriate in others. On the other hand, one could argue that the taxes on all tobacco products should be equivalent. This last issue is discussed in greater detail in the next section, "Fairness Standard and Optimal Cigarette Taxes."

Taxes on smokeless tobacco products are much lower than taxes on cigarettes, particularly at the federal level. The limited research suggests that increases in cigarette excise taxes may have reduced cigarette smoking but also may have contributed to an increased

use of smokeless tobacco products (Ohsfeldt and Boyle 1994; Ohsfeldt et al. 1997, 1999). Some public health advocates and others have therefore called for the equalization of taxes on tobacco (CSH 1994; U.S. House of Representatives 1994).

Fairness Standard and Optimal Cigarette Taxes

Fair tax policy is an issue that is often debated but difficult to apply when "optimal" taxes of potentially hazardous substances are discussed (Cook and Moore 1993). For taxes on cigarettes and other tobacco products, part of the debate revolves around the perceived health benefits and reductions in social costs associated with higher taxes.

In their analysis of economic interventions to reduce alcohol abuse, Cook and Moore (1993) noted that several criteria can be included to judge fairness by those on both sides of the debate. These criteria include a horizontal equity criterion, which suggests that equals should be treated equally; a vertical equity criterion, which suggests that those with the greatest ability to pay should be taxed more heavily; and a benefit criterion, which suggests that those who receive the greatest benefit from government activities should be taxed more heavily. If the basic notion is accepted that people who are otherwise similar should be taxed differently because one uses more tobacco products than the other (a notion that violates the horizontal equity criterion), then other questions about fairness arise. These include questions concerning the alleged regressivity of the taxes and the external costs of smoking and other tobacco use (Cook and Moore 1993).

Equity, Incidence, and Distribution of the Tobacco Tax Burden

As has been discussed previously, increases in cigarette excise taxes are passed on to consumers through higher cigarette prices. Primarily because of the less than perfectly competitive nature of the cigarette industry, prices have increased by more than recent increases in cigarette taxes. Because consumers will pay at least the full amount of a tax increase in higher cigarette prices, some questions of fairness revolve around the distributional effects of the tax hike. To understand these effects, it is useful to look at the relationship between tobacco use and income (or expenditures). (As Cook and Moore [1993] note, income or expenditures are not the only scale on which fairness can be judged, but they are the most commonly used.)

A 1990 report by the Congressional Budget Office (CBO), which used data from the 1984–1985 Consumer Expenditure Survey, made several observations. For example, expenditures on tobacco products increased with income except for people in the highest income quintile. As a percentage of posttax income, however, spending on tobacco was highest in the lowest income quintile (4.0 percent of posttax income) and fell almost proportionately with increased income. Also, if expenditures on tobacco are considered as a percentage of expenditures on all goods and services, however, the share of tobacco expenditures fell gradually over the first four income quintiles (from 1.6 to 1.1 percent) and dropped sharply only in the top quintile (to 0.7 percent). Thus, the CBO notes, if annual family expenditures are more reflective of lifetime income than annual family income, then expenditures on tobacco are only slightly regressive over income classes. Finally, the CBO noted that younger families spent a higher percentage of income on tobacco products and that their share of spending on tobacco products as a percentage of total expenditures was higher as well.

To examine the distributional impact of cigarette excise tax increases on consumers, the CBO simulated what the effects on expenditures would be were the 1990 federal excise tax on cigarettes (16 cents per pack) doubled. At first glance, the simulated increase appeared to fall most heavily on the lowest income categories, thereby implying that cigarette taxes are regressive. However, when income tax brackets and transfer payments (discussed in the next section, "Estimates of the Costs of Smoking") were indexed to account for the price increases associated with excise tax hikes, lowering individual income taxes and raising transfer payments, the apparent regressivity of the tax was reduced. When looking at the tax increase relative to expenditures rather than income, the CBO concluded that cigarette taxes were approximately proportional rather than regressive. Finally, the CBO noted that the largest share of the simulated tax increase was paid for by families in the third and fourth income quintiles and that the smallest share was paid by families in the lowest income (first and second) quintiles.

All of the CBO estimates were based on measures of current income. Lyon and Schwab (1995) used an alternative approach that used measures of permanent or lifetime income to examine the distributional effects of cigarette and other "sin" taxes. This approach could account for the intertemporal nature of cigarette consumption decisions. The investigators concluded that cigarette excise taxes are as regressive as was implied by studies based on current income.

Although cigarette taxes fall most heavily on lower income groups, two recent studies suggest that increases in cigarette taxes may reduce the perceived regressivity of these taxes. A study using data from the British General Household Survey concluded that people in the lowest income groups were the most responsive to price increases (Townsend et al. 1994). Similar findings have been obtained in the United States using data from 13 of the National Health Interview Surveys conducted from 1976 through 1993 (CDC 1998). The price elasticity of cigarette demand by those at or below the median income was estimated to be approximately 70 percent higher than that for persons above the median. Another study found that less educated persons were more responsive than more educated persons to cigarette price changes (Chaloupka 1991). Given the high correlation between income and education, the three studies implied that increased cigarette taxes would reduce observed differences in smoking among socioeconomic groups (i.e., that smoking prevalence is higher in the lower socioeconomic groups) and would thereby counter the perception that cigarette taxes are regressive. Recent research from developing countries supports the hypothesis that lower income populations are relatively more sensitive to price (Jha and Chaloupka 1999; see Chaloupka et al., in press, for a thorough review). Indeed, while cigarette taxes may fall more heavily on lower income groups, an increase in the cigarette tax, because of the greater price sensitivity of lower income smokers, may actually be progressive. Moreover, given the estimates from these studies, the health benefits resulting from reductions in smoking stimulated by increased cigarette taxes would be disproportionately larger in the lowest income populations.

Finally, as the CBO report pointed out, although the potential regressivity of cigarette taxes is of some concern, the U.S. tax system is a mix of many different taxes. Increased progressivity of other taxes and transfer programs could be used to compensate low income families for the tax increase. The CBO considered three alternative changes—a 5-percent increase in food stamp payments, a 10-percent increase in the earned income tax credit, and a combination of the two—to offset the potential regressivity of an increase in the cigarette excise tax. In each case, the CBO concluded that these changes would spend about 15 percent of the net revenues resulting from the tax increase. A similar idea was implicit in the proposed Health Security Act of 1993, which proposed a federal tax increase of 75 cents per pack to partially finance the provision of health insurance and the expansion of benefits to the uninsured and underinsured, most of whom are

in lower socioeconomic groups. Likewise, several recent proposals for national tobacco legislation contain provisions that would offset the potential regressivity of large increases in cigarette taxes.

Estimates of the Costs of Smoking

An alternative approach to the question of fairness deals with the notion that smokers and other to-bacco users impose costs on nonusers. One of these costs is the health consequences for nonsmokers of exposure to ETS. A second is the financial external effect caused by collectively financed programs (e.g., Medicaid and Medicare) where payments in and out are not tied to changes in costs and life expectancy caused by smoking. Thus it can be argued that it would be fair for smokers and other tobacco users to pay for the consequences of their use. Cigarette and other tobacco taxes are one relatively efficient approach for attaining this result. However, to set taxes at a level sufficient to cover the costs of cigarette smoking and other tobacco use requires an estimate of these costs.

All studies of the economic costs of tobacco use have focused on the costs of cigarette smoking. The Office of Technology Assessment (U.S. House of Representatives 1994) has noted that although measuring these costs is an inexact science, three general components are included:

- The direct costs of providing health care services to those persons with smoking-related diseases.
 Such costs include expenditures for preventing, detecting, diagnosing, and treating smokingrelated diseases and medical conditions.
- The indirect morbidity costs associated with lost earnings from work because of smoking-related illness.
- The indirect mortality costs related to the loss of future earnings from premature death from smoking-related causes.

Researchers have tried to estimate the economic costs of cigarette smoking by using data from the United States (Rice et al. 1986; Manning et al. 1989, 1991; Hodgson 1992; CDC 1994; U.S. House of Representatives 1994; Miller et al. 1998, 1999) and elsewhere (see Lightwood et al., in press, for a comprehensive review). In addition, as part of the research resulting from Proposition 99, several recent studies have estimated these costs for California (California Department of Health Services 1992; Rice and Max 1992; Max and Rice 1995).

Most of the estimates of the economic costs of smoking have been prevalence based. That is, they are based on the estimated prevalence of smoking-related illnesses in a given year and on the costs associated with those illnesses. Because of the long lags between smoking initiation and the onset of most smoking-related illnesses, these estimates reflect historical trends in smoking and thus cannot be used to predict the impact of changes in smoking prevention policies except over long periods. However, this approach has been widely used because of its relatively simple methodology and the availability of reliable data (Rice et al. 1986).

Several of the recent estimates of the costs of smoking have been incidence based (Oster et al. 1984; Manning et al. 1989, 1991; Hay 1991; Hodgson 1992). That is, these studies attempt to estimate the average additional costs of smoking over the smoker's lifetime. Cost estimates would differ by the person's age, sex, and level of smoking (i.e., a heavy smoker would have higher lifetime costs than a relatively light smoker with the same characteristics). These estimates of the costs of smoking can be useful for policymakers, who can estimate the change in the costs of smoking associated with a change in smoking behavior resulting from a change in policies to reduce smoking. However, these estimates are sensitive to assumptions about future costs and about issues such as technological change and its diffusion (Hodgson 1988).

Many of the studies of the economic costs of smoking have included notably different direct costs in their computations. For example, most include the costs of hospital and nursing home care, physicians' fees, and medications used to treat smoking-related illnesses. One such study estimated that these costs in 1993 were \$50 billion and that 43.3 percent of them were paid through public sources (CDC 1994). However, some studies of direct costs have been limited to the costs associated with lung cancer only, whereas others examined a more comprehensive list of smoking-related illnesses, including cardiovascular disease and chronic obstructive pulmonary disease.

Other more recent studies have sought a broader measure of the direct costs of smoking by comparing the differences between total health care spending by smokers and nonsmokers. The most sophisticated of these recent studies control for other risk factors likely to be correlated with smoking in an effort to isolate the impact of smoking on medical expenditures (Miller et al. 1998, 1999). These recent studies estimated smoking-attributable medical care costs of between \$53 billion and \$73 billion for 1993, or between 6.5 percent and 11.8 percent of all U.S. health care expenditures.

It is likely, however, that these studies have underestimated the direct costs of smoking for a variety of reasons (Warner et al. 1999). For example, they ignore other significant economic costs, including the costs of transportation associated with obtaining medical care and the costs of nonmedical care associated with accommodating a person with a smokingrelated chronic illness. These estimates also generally fail to account for other medical care costs related to cigarette smoking, such as burn care from injuries in smoking-related fires and perinatal care for low-birthweight infants of mothers who smoke. Few studies have attempted to include the direct costs for nonsmokers of diseases related to exposure to ETS, and none of these studies has tried to estimate the intangible costs of smoking-related illnesses (i.e., the pain and suffering associated with the illness and the grief experienced by family and friends).

A human capital approach is generally used to estimate the indirect morbidity and mortality costs associated with cigarette smoking. This approach views an individual as producing a stream of output or earnings computed at market value or as the imputed value of housekeeping services. Thus, the value of a person is reflected by his or her earnings, and the lifetime value for that person is equal to the discounted stream of future earnings (Max and Rice 1995). This approach places a relatively high value on morbidity and mortality among young adults, men, and the more educated because of the relatively higher earnings that would be lost by these smokers (Markandya and Pearce 1989); moreover, lost earnings may not be an accurate reflection of the value people place on their health or on their lives. Furthermore, the human capital approach is in contrast to the "willingness-to-pay" approach, which tries to estimate the value a person assigns to reducing his or her risk of premature death.

A more controversial component in the computation of the lifetime costs of smoking concerns the treatment of transfer payments. These transfer payments include the reduction in income taxes and insurance premiums paid by smokers because of reduced earnings associated with smoking-related illnesses, the value of Social Security and private pensions foregone because of smoking-related premature deaths, higher health care costs associated with smoking-related illnesses and paid by public and private insurance plans, and increased sick pay and disability benefits paid during smoking-related illnesses. Particularly objectionable to many people is the idea that foregone Social Security and private pension benefits from smokers who die prematurely from smoking-related illnesses should be considered "benefits" to nonsmokers. As Harris (U.S. House of Representatives 1994) and others have noted, premature deaths are not considered a benefit when policymakers determine what levels of funded research are appropriate for reducing premature deaths from other risk exposures (CSH 1994; Warner et al. 1995, 1999). Nevertheless, several recent estimates of the costs of smoking have considered these foregone benefits in their computations of the economic costs of cigarette smoking (Manning et al. 1989, 1991; Shoven et al. 1989). These studies aim to provide a complete accounting of the costs of smoking to answer the question of whether payments by those who have ever smoked into collectively financed systems such as Medicare and Social Security equal receipts by those who have ever smoked.

Theoretically Optimal Cigarette Taxes

As was just discussed, several estimates of the optimal or fair tax on cigarettes are based on the various studies of the costs of smoking. In the context of the preceding discussion, an optimal tax is one that equates the total revenues from these taxes to the net external costs of cigarette smoking. These estimates have ranged from those implying that current taxes more than cover the external costs of smoking (Manning et al. 1989) to those that have suggested that current taxes are far too low. For example, one such study that included the costs of the long-term intellectual and physical consequences resulting from smoking-related low birth weight among infants born to mothers who smoke indicated that \$4.80 was an appropriate tax on a pack of cigarettes (Hay 1991).

Another study (Pigou 1962) advanced a similar notion in providing a theoretical justification for taxes on goods with market prices not fully reflecting the social costs associated with their production and consumption. From that perspective, these taxes could be viewed as improving economic efficiency by raising a smoker's marginal cost of smoking to a level nearer the social marginal cost. For some goods, taxes could generate revenues that exceed total external costs because the taxes would be based on marginal rather than average external costs (Cook and Moore 1993).

Estimates of optimal taxes on cigarettes imply that smokers are fully informed about the risks associated with cigarette smoking (Cordes et al. 1990). If smokers underestimate these risks, then even higher taxes could be appropriate to discourage people from smoking. This issue may be particularly relevant for an addictive product such as cigarettes if, when people take up smoking, they do not fully understand the addictive properties of consumption and the implications of

addiction for future choices. Gruber and Koszegi (2000), for example, concluded that if these "internalities" are taken into account, they suggest sizable additional taxes of one dollar or more per pack of cigarettes.

Among the most widely cited recent estimates of the optimal tax are the studies of the economic costs of cigarette smoking by Manning and colleagues (1989, 1991). These incidence-based estimates used data from the RAND Corporation's Health Insurance Experiment and the 1983 National Health Interview Survey. To calculate the optimal tax on cigarettes, the analyses estimated both the lifetime external costs associated with cigarette smoking and the perceived "savings" that result from smokers' dying earlier and not realizing their pension and Social Security benefits.

Using their midrange estimates, Manning and colleagues (1989, 1991) concluded that for a new smoker, the total external cost of smoking was 43 cents per pack of cigarettes in 1986. This estimate comprised 1 cent in extra costs for sick leave, 2 cents in costs for smokingrelated fires, 5 cents in added costs for group life insurance, 9 cents in lost tax revenues (to finance retirement and health benefits), and 26 cents in spending on additional medical care. These costs would be offset, however, by an estimated 27 cents per pack in external savings resulting from smoking-related premature deaths. Converting these figures to 1995 dollars (based on the medical service price index and the gross national product deflator), the CRS estimated a net external cost of 33 cents per pack for cigarettes, which is approximately two-thirds of the average federal, state, and local taxes on cigarettes of 50 cents per pack in late 1993 (Gravelle and Zimmerman 1994). The CRS thus concluded that smokers were more than paying their way.

Critics of the studies of Manning and colleagues (1989, 1991) contend that many of the assumptions made in obtaining the estimates are inappropriate. If the analyses had not included the effects of unrealized pension and Social Security benefits of smokers who die prematurely, the resulting external costs of smoking would have amounted to approximately 89 cents per pack in 1995 dollars.

Moreover, the studies of Manning and colleagues (1989, 1991) made a debatable distinction between internal costs (those borne by the smoker) and external costs (those that smokers impose on nonsmokers). For example, the lost productivity costs described in those analyses were treated as internal costs, whereas only the higher, collectively financed, group premiums for health, life, and other insurance that nonsmokers paid to cover smoking-related costs not reflected in the premiums paid by smokers were considered external costs.

More controversial, however, was these analyses' assumption that the cost of ETS was an internal cost. This assumption was based on the argument that the family is the economic unit involved in making smoking and other decisions and that the health consequences of ETS are largely confined to the nonsmoking spouses of smokers. As Manning and colleagues (1991) note, when this assumption is modified to treat the consequences of passive smoking as external costs, the estimated external costs of smoking rise significantly. For example, under the assumptions of Gravelle and Zimmerman (1994) concerning prices, the estimates of Manning and colleagues (1991) imply that including the relatively conservative estimate of 2,400 lung cancer deaths from ETS would add approximately 31 cents per pack (in 1995 dollars) to the external costs of smoking. Similarly, updating the researchers' estimates of the costs of neonatal care for smoking-related low birth weight would add more than 4 cents per pack. Doing the same for deaths from smoking-related fires would add 20 cents per pack and for smoking-related fetal deaths would add 31 cents per pack.

These estimates probably understate the true costs of ETS. After reviewing the literature on the links between ETS and heart disease, Glantz and Parmley (1995) concluded that 30,000–60,000 persons die prematurely from heart disease related to ETS. Including these numbers in estimates by using the same assumptions used in the CRS report would add at least another 70 cents to the estimate of the optimal tax. Moreover, the CRS report ignored the 150,000–300,000 cases of ETS-linked lower respiratory tract infections in children up to 18 months old and the ETS-linked worsening of asthma in 200,000 to 1 million children (Environmental Protection Agency [EPA] 1992). Including these costs would lead to an even larger optimal tax. Finally, the estimates excluded the long-term developmental consequences suffered by infants with smoking-related low birth weight (Hay 1991); were these costs included, the optimal cigarette tax would be nearly \$5 per pack.

Using the human capital approach, Manning and colleagues (1989, 1991) estimated that the life of a nonsmoker who died prematurely from ETS exposure was worth \$1.66 million. In a recent cost-benefit evaluation of the proposed Smoke-Free Environment Act of 1993 (introduced in the 103rd Congress but not passed), the EPA (Mudarri 1994) used the willingness-to-pay approach and obtained a \$4.8 million baseline estimate of the value of a life. The EPA also used this approach to include the effects of ETS on heart disease and children's health when calculating the value of benefits from reduced ETS exposure.

By using the willingness-to-pay approach and making some relatively conservative assumptions, the EPA estimated that the total benefits from the reduced ETS exposure that would result from a ban on smoking in all worksites was \$39–71 billion per year. This estimate assumed that the ban would reduce the number of current smokers by 3–6 percent, the number of future smokers by 5–10 percent, and consumption among continuing smokers by 10–15 percent; the resulting total long-run reduction in consumption would be 14–22 percent. The combined effect of these reductions in smoking and of the creation of designated smoking areas was predicted to reduce out-of-home exposures to ETS by 90 percent and in-home exposures by a midrange estimate of 6 percent. Estimates from the 1992 EPA report on ETS and lung cancer suggested that 73 percent of exposures to ETS occur outside the home and that 27 percent occur in the home. The total reduction in ETS exposure was thus predicted to be 66 percent; if it were applied to estimated total ETS costs of \$58.7–106.9 billion, this reduction would yield the EPA's estimated cost benefits of \$39–71 billion. Given current cigarette sales of about 24 billion packs per year, this estimate implied that the per pack external costs of ETS were between \$2.45 and \$4.45. This estimate is likely to be low, because the short-term and long-term costs of fetal and perinatal exposure to ETS were not included in the EPA's computations.

Viscusi (1995), however, reached a much different conclusion in analyzing the social costs of smoking. This investigator updated much of the analysis by Manning and colleagues (1989, 1991), used a willingness-to-pay approach, and included the same ETS risks used in the EPA's analysis (Mudarri 1994). Viscusi, however, argued that the EPA approach overestimated the risks of ETS by failing to account for the change in the tar content of cigarettes and the changes in cigarette consumption per smoker. Noting that the average tar content of cigarettes declined from 46.1 mg per cigarette in 1944 to 12 mg per cigarette in 1994, Viscusi asserted that the health risks associated with cigarette smoking, as well as the risks from exposure to ETS, are linearly related to the tar content of cigarettes. Although presenting no evidence for either assertion, he contended that estimates of the health risks based on consumption of higher-tar cigarettes and exposure to ETS from highertar cigarettes need to be adjusted to reflect the decline in tar content. When not adjusting for tar, Viscusi obtained an estimate for the per pack external costs of cigarette smoking well above the average tax on a pack of cigarettes; when adjusting for tar, he concluded that current cigarette taxes exceed the external costs of smoking.

A clear consensus is lacking regarding the optimal tax on cigarettes. Optimal tax calculations from prevalence-based estimates that include the direct and indirect costs of smoking-related morbidity and mortality are likely to be inappropriate, because the calculations include lost productivity and other costs that should arguably be considered internal costs. Similarly, optimal tax calculations from the recent incidencebased estimates probably underestimate the optimal tax, because these calculations exclude many of the external costs of smoking. Nevertheless, because of the growing evidence of the substantial health consequences of exposure to ETS (including fetal and perinatal exposure), a tax that would generate sufficient revenues to cover all external costs from smoking is likely well above the current average of federal, state, and local taxes on cigarettes.

Cigarette Taxes and Health

As the review of studies on cigarette demand demonstrated, increases in cigarette prices lead to substantial reductions in cigarette smoking by deterring smoking initiation among youth, prompting smoking cessation among adults, and reducing the average cigarette consumption among continuing smokers. Because of the substantial health consequences of cigarette smoking and the health benefits of smoking cessation, these reductions in cigarette smoking would lead to significant improvements in health by reducing smoking-related morbidity and mortality. Thus, increases in cigarette excise taxes, which would result in increases in cigarette prices, would be an effective policy tool in improving health.

Several recent studies have provided some estimates of the health benefits resulting from cigarette tax increases. For example, Warner (1986) used published estimates of price elasticity (Lewit et al. 1981; Lewit and Coate 1982) to estimate the impact of higher cigarette excise taxes on smoking and health. The study predicted that a sustained, real 15 percent taxinduced increase in cigarette prices in 1984 (which would have been equivalent to restoring the federal tax to its real value in 1951—a nominal tax of 32 cents per pack) would deter 800,000 young people from smoking and encourage about 2.7 million adults to quit. Using the conservative assumption that one of every four lifelong smokers dies prematurely of a smoking-related illness, the researchers estimated that this tax increase would reduce premature deaths among persons 12 years and older by 860,000.

The GAO (1989) used the same estimates of price elasticity to predict the health benefits from a sustained,

real tax increase of 21 cents per pack in 1989 (which they estimated would raise the price by 15 percent). Using the one-in-four assumptions made by Warner (1986), the analysis estimated that this tax increase would reduce the number of youth who smoke by 500,000 and would subsequently reduce premature deaths from cigarette smoking among youth by 125,000.

Harris (1987) used various estimates of the price elasticity of demand in an analysis of the health implications of the 1983 tax hike and corresponding price increase. The analysis concluded that this tax increase deterred 600,000 young people from smoking. After reviewing the epidemiologic literature, Harris estimated that an additional 54,000 young people and a total of 100,000 people would survive to at least 65 years of age as a result of the tax increase.

Two recent studies directly examined the health benefits of increases in cigarette excise taxes (Moore 1995; Evans and Ringel 1999). Using annual state-level death rates from smoking-related diseases (including heart disease, lung cancer, cardiovascular disease, mouth and throat cancer, and asthma), the study directly estimated, through appropriate econometric methods, the impact of higher taxes on health. The resulting estimates implied that a 10-percent increase in cigarette excise taxes would save approximately 5,200 lives annually. Similarly, Evans and Ringel (1999), using data from the 1989–1992 Natality Detail files, concluded that higher cigarette taxes would significantly improve birth outcomes.

The CSH (1994) analyzed the health benefits of higher cigarette excise taxes by using relatively conservative estimates of the price elasticity of demand and of deaths related to cigarette smoking. The study estimated that, based on 1992 taxes and cigarette smoking data, an increase of 75 cents per pack in the federal cigarette excise would reduce premature deaths by 900,000. The study further estimated that a \$2.00 increase would save an additional 1 million lives.

Similarly, Chaloupka (1998) provided estimates of the effects of alternative cigarette tax and price increases contained in various national tobacco settlement proposals based on Chaloupka and Grossman's (1996) econometric analysis of youth smoking. For example, he estimated that a \$1.50 increase in cigarette taxes and prices, phased in over a relatively short period of time and then adjusted for inflation, would reduce overall cigarette consumption by approximately 30 percent, while cutting the prevalence of youth smoking nearly in half. Given the CDC's recent estimate that 16,620,878 youth in the 1995 cohort of 0- through 17-year-olds would eventually become smokers and

that 32 percent of regular smokers eventually die from a smoking-related disease, Chaloupka (1998) estimated that this tax would prevent approximately 2.5 million premature deaths in this cohort.

The substantial econometric literature clearly indicates that increases in cigarette prices will reduce both smoking prevalence and average cigarette consumption. Because of the well-documented health consequences of smoking, tax-induced increases in cigarette prices would generate substantial improvements in health. Thus, higher taxes on cigarettes and other tobacco products appear appropriate from a public health perspective. In addition, at a gathering convened by the CDC to evaluate the criteria for defining an optimal cigarette tax, economists raised two further reasons for higher cigarette taxes (Warner et al. 1995). First, to the extent that adolescents and young adults do not fully understand the addictive nature of cigarette smoking, the argument could be made that higher cigarette taxes can reduce smoking by youth before it is too late for them to quit easily. Second, to the extent that youth behave more myopically than adults (in particular, more than the adults that they will later be), young people are more likely to take on a habit with long-term health consequences. Thus, by discouraging smoking, the higher tax can help correct youth's myopic behavior.

Although higher cigarette taxes are likely to produce substantial improvements in health, several factors could mitigate the impact of these taxes. First, as the limited research on the demand for smokeless tobacco products suggests (Ohsfeldt and Boyle 1994; Ohsfeldt et al. 1997, 1999), increases in cigarette taxes not matched by similar increases in smokeless tobacco taxes may induce people to substitute other tobacco products with similar health consequences. For example, the large increases in Canada's cigarette excise taxes and the consequent increases in the differential between cigarette taxes and taxes on roll-your-own tobacco led to a sharp rise in the use of the latter (Department of Finance, Canada 1993). This substitution could easily be avoided by increasing all tobacco taxes simultaneously. Canada's experience also raises the issue of equalized taxes between nations, because relatively large tobacco tax hikes resulted in a bordercrossing black market in cigarettes and other tobacco products as well as in other efforts to avoid taxes. Alternatively, as Evans and Farrelly (1998) found, the higher taxes may lead smokers to change the kinds of cigarettes they smoke (i.e., they may switch to highertar and higher-nicotine cigarettes), thereby reducing the health benefits of higher cigarette taxes. The results of the study by Evans and Farrelly suggest that taxes based on the tar, nicotine, and carbon monoxide content of cigarettes (first suggested by Harris 1980) may be the most appropriate means to address the public health consequences of smoking.

Of course, cigarettes and other tobacco products are not the only goods that can be taxed on the basis of these arguments. Heavy consumption of alcoholic beverages, for example, also leads to health problems, unintentional injuries, property damage, and other consequences. Cook and Moore (1993) provide a detailed discussion of the rationale for higher alcoholic beverage excise taxes. A number of studies of the "optimal" tax on alcoholic beverages have concluded that current taxes are well below the level that would cover the social costs of alcohol abuse (Manning et al. 1989, 1991; Saffer and Chaloupka 1994).

Tobacco Taxation and Revenues

An alternative rationale for tobacco taxes is that they are a relatively simple way to generate revenues. Even some prominent proponents of the free market philosophy have supported tobacco taxes to generate revenues. "Sugar, rum, and tobacco," wrote Adam Smith in his 1776 economic treatise, *An Inquiry Into the Nature and Causes of the Wealth of Nations*, "are commodities which are no where necessaries of life, which are become objects of almost universal consumption, and which are therefore extremely proper subjects of taxation" (1976, Book V, p. 474).

As described earlier in this chapter (in "Rationales for Tobacco Taxation"), various levels of government have long used cigarette and other tobacco taxes to raise revenues. Such policy is supported by economic theory. An economically efficient way to raise revenues while minimizing the welfare losses associated with the price distortions resulting from taxes is to impose relatively higher taxes on goods with more inelastic demand (one for which the percentage reduction in demand is smaller than the percentage increase in price) (Ramsey 1927). As described earlier in this chapter (in "Effect of Price on Demand for Tobacco Products"), the numerous studies of cigarette demand and the limited studies of the demand for other tobacco products have implied that overall demand, at least in the short run, is inelastic. Thus, large increases in tobacco taxes can generate substantial increases in revenues, particularly in the short run.

Since 1960, the dollar amount of federal revenues generated by tobacco taxes has increased significantly, from \$1.9 billion to nearly \$5.9 billion in 1997. Over this same period, state revenues from tobacco have also increased significantly in nominal terms, from slightly

less than \$1 billion to more than \$7.5 billion. As new sources of tax revenues have been identified, however, tobacco revenues have constituted a smaller proportion of total revenues. Tobacco taxes accounted for 3.36 percent of all federal revenues in 1950, but they were only 0.44 percent of revenues in 1989 (CBO 1990). Similarly, total federal tobacco tax revenues as a share of the gross national product fell from 0.55 percent in 1950 to 0.08 percent in 1989.

Merriman (1994) considered whether cigarette excise taxes are set to maximize the revenues from these taxes. More specifically, Merriman tested the idea that elected officials, in an effort to maximize their own utility, may increase taxes on some goods to the point where revenues from these taxes begin to decline (Buchanan and Lee 1982). Using published estimates of cigarette demand (Becker et al. 1994), the study found that cigarette excise taxes in every state were well below the revenue-maximizing level of these taxes, at least as of 1985. Furthermore, these estimates of the marginal revenue effects of higher taxes were lower-bound estimates, because they held constant other states' taxes (a consideration that allowed for increases in the casual and organized smuggling of cigarettes in response to a tax hike in a given state). Coordinated state tax increases, as a result, would generate even higher revenues.

Grossman (1993) considered this issue of maximizing the federal excise tax on cigarettes. Using published estimates of cigarette demand (Chaloupka 1991; Becker et al. 1994), Grossman predicted that in the long run, a real federal tax rate of \$1.26 would maximize federal tax revenues at \$16 billion and would generate even larger immediate increases in revenues. Likewise, Becker and Grossman (1994) suggested that the long-run revenue-maximizing value of the federal cigarette excise tax is 95 cents per pack in 1994 dollars. This tax would generate approximately \$12 billion in total revenues and would raise considerably more than in the short run. These estimates were consistent with the prediction that a sustained real increase of 75 cents in the federal tax on cigarettes would in the long run lead to a net increase in cigarette tax revenues of just over \$16 billion (Gravelle and Zimmerman 1994).

Other studies, however, have predicted that higher federal taxes would generate much greater revenues (Harris 1994; Womach 1994a). For example, Harris has predicted that raising the federal tax to \$2.00 per pack would have generated nearly \$20 billion in additional revenues annually, on average, from 1995 through 1999, whereas Chaloupka (1998) estimates that a \$1.50 increase would, in the short run, raise \$22.5 billion annually.

The differences among the predicted revenue effects of higher cigarette taxes may be attributed to different assumptions used to obtain these estimates as well as to differences in the period for which the predictions are made. For example, two studies (Grossman 1993; Becker and Grossman 1994) have assumed a linear demand function for cigarettes. One of the implications of this function is that the price elasticity of demand rises as price rises. Thus, when the effects of a large increase in the cigarette excise tax are predicted, cigarette demand is assumed to become more responsive to price. This assumption implies that there is an inverted U-shaped relationship between cigarette taxes and revenues: increasing cigarette taxes from relatively low levels will initially lead to increased revenues; beyond some point, further increases in taxes will lead to even larger reductions in demand, thereby causing revenues to fall. The same basic argument is implicit in the well-known Laffer curve, which relates income tax rates to income tax revenues.

The assumption of a linear demand function for cigarettes is in contrast to the assumption made by some other analysts that the price elasticity of demand is constant over the range of prices under consideration. Because almost all of the studies described in this section found that the demand for cigarettes is inelastic, the assumption of a constant elasticity implies that even very large increases in taxes will always generate large increases in revenues.

The differences in revenues predicted by these two assumptions, although only minor when analyses predict the impact of relatively small cigarette tax increases, grow with the size of the tax increase. Because either assumption could be questioned, the revenue effects of a tax increase will likely fall somewhere between the predictions obtained from the two (Grossman et al. 1993). The limited evidence from the behavioral economics literature suggests, however, that the effects of large increases in cigarette prices will lead to larger reductions in cigarette demand than predicted by the assumption of a linear demand function (Bickel et al. 1991).

A second key factor leading to the differences discussed here is the distinction between the short-run and long-run effects of the tax hikes. Economic theory implies that the demand for most consumer goods will be more responsive to price in the long run than in the short run. For cigarettes and other tobacco products, additional factors increase the likelihood that the long-run effects of an increase in price on cigarette demand will exceed the short-run effects—that is, price elasticity will increase in a manner similar to the increase for other, nonaddictive goods and services. Increased

cigarette taxes will thus lead to smaller increases in revenues in the long run than in the short run.

That adolescents and young adults are more responsive to prices than older adults are and the fact that cigarette smoking is an addictive behavior are of particular importance when predicting the short-run and long-run revenue effects of higher cigarette taxes. Age difference in price elasticity implies that sustained real tax increases will lead to greater reductions in smoking prevalence and consumption as the number of adolescents and young adults who have not yet decided to smoke replaces the number of older adults who already smoke. The assumption of addiction implies that price has a cumulative effect on consumption: the price increase immediately reduces current consumption by discouraging young people from experimenting or continuing to experiment with smoking, as well as by encouraging current smokers to smoke less; future consumption is then reduced by the continuously fewer current smokers who also continue to smoke less in the face of a sustained real increase in price. The cumulative effect of price on consumption thus exceeds the immediate effect. This sequence ultimately leads to reduced revenues.

In summary, federal and most state excise taxes on cigarettes are undoubtedly well below their revenue-maximizing levels. Thus, relatively large increases in these taxes would lead to substantial gains in revenues, particularly in the short run. Moreover, because of the relatively inelastic demand for cigarettes, increases in cigarette taxes are an economically efficient means of generating substantial revenues while imposing relatively small welfare losses. But if there is little argument that large increases in cigarette taxes would generate substantial increases in tax revenues in the short run, there are some questions on the revenue-maximizing values of these taxes and the long-run stability of revenues generated by large increases in cigarette taxes.

Part of the difficulty in estimating the effects of large taxes on cigarettes is that there is little experience in the United States with relatively large increases. Similarly, it is unlikely that the long-run effects of the more recent large tax increases have been fully played out. The short-term experience in Canada is of limited use in addressing these issues. Cigarette taxes in Canada increased more than 500 percent between 1982 and 1992, which increased real cigarette prices by 170 percent, and total smoking fell by 38 percent (Sweanor and Martial 1994). Because of the effects of other, contemporaneous activities to reduce tobacco use, the impact of the large price increases on smoking were consistent with the estimates from the studies of U.S. cigarette demand

described in this chapter. Moreover, total federal and provincial revenues generated by Canadian cigarette taxes were 240 percent higher in 1992 than in 1981 even with the concomitant considerable black market in

cigarettes. This experience suggests that large increases in cigarette taxes in the United States would generate sizable tax revenues for many years.

Conclusions

- 1. The price of tobacco has an important influence on the demand for tobacco products, particularly among young people.
- Substantial increases in the excise taxes on cigarettes would have a considerable impact on the prevalence of smoking and, in the long term, reduce the adverse health effects caused by tobacco.
- 3. Policies that influence the supply of tobacco, particularly those that regulate international commerce, can have important effects on tobacco use.
- 4. Although employment in the tobacco sector is substantial, the importance of tobacco to the U.S. economy has been overstated. Judicious policies can be joined to higher tobacco taxes and stronger prevention policies to ease economic diversification in tobacco-producing areas.

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Chapter 7

Comprehensive Programs

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Introduction

A comprehensive approach to reducing tobacco use recognizes that individual behavioral choices occur in a larger, complex context: a social setting of family, community, and culture; a complex economic and physical environment; formal and informal government policy; and the prevailing legal atmosphere (Green and Richard 1993). The specific programs reviewed in prior chapters can be better understood as part of a general framework for health promotion (World Health Organization [WHO] 1986; Health Promotion International 1997). Using such a framework, this chapter will review community-based intervention studies and the current models for comprehensive tobacco prevention and control that are funded by specific excise taxes or by settlements with the tobacco industry.

The evaluation of multicomponent interventions and socioecological models of health promotion poses a special problem (Green and Kreuter 1991; Sanson-Fisher et al. 1996; Nutbeam 1998). The most effective models of health promotion are social movements that evolve (Kickbusch 1989; Allison and Rootman 1996; Downie et al. 1996; Nutbeam 1998). Thus, the nature and complexity of health promotion interventions do not fit the tightly defined, controlled, and presumably reproducible research model that is more suitable for epidemiologic testing (Elder et al. 1993; Mittelmark et al. 1993; Baum 1995; Allison and Rootman 1996;

Macdonald et al. 1996; Nutbeam 1996, 1998). Nonetheless, surveillance data, periodic surveys, and other administrative data from multiple sites permit these interventions, as well as "natural experiments," to be studied. Traditionally, per capita consumption data, adult prevalence surveys, and surveys of tobaccorelated behaviors among young people have been the core of this surveillance approach. Recently, a broader array of legislative, economic, media, and program data has emerged to enhance surveillance of the social environments that influence the use of tobacco products. For example, the WHO's Guidelines for Controlling and Monitoring the Tobacco Epidemic (WHO 1998) provides detailed recommendations on the types of data that should be monitored for both planning and evaluating tobacco control efforts. For the United States, the Centers for Disease Control and Prevention (CDC) has published background information on sources of national surveillance data (Giovino et al. 1994). The Federal Trade Commission provides annual estimates of trends in the tobacco industry's advertising and promotion expenditures. Surveillance data on protobacco influences are not well monitored, however, particularly at the state level. Finally, Wakefield and Chaloupka (1999) have provided a conceptual framework for the monitoring of comprehensive tobacco control programs, particularly those that focus on preventing teenage smoking.

Conceptual Frameworks

From its formation in the mid-1970s, health promotion has emerged as an approach that offers greater potential for change in the health-related behavior of populations than does health education (Green and Richard 1993; Downie et al. 1996; *Health Promotion International* 1997). Health promotion emphasizes social, economic, and other environmental influences as the primary determinants of health behavior change (WHO 1986; Downie et al. 1996; *Health Promotion International* 1997). Though such health promotion strategies have been characterized as a new approach

to public health, ecological and policy-oriented approaches are similar to the public health methods of the latter part of the 19th century and the early decades of the 20th century (Kickbusch 1989; Green and Richard 1993; Mullan 2000). As the role of individual risk behaviors, such as tobacco use, was increasingly understood in the middle of the 20th century, individually focused educational strategies gained primacy (Green and Richard 1993). These strategies produced some important changes in health behaviors, but their limits were realized in the cardiovascular disease

prevention programs that took place in the United States during the 1970s and 1980s (see "Community Intervention Trials," later in this chapter) (Green and Richard 1993; Luepker 1994; Winkleby 1994; Fisher 1995; Schmid et al. 1995; Susser 1995).

The shift from a health education approach that targets the individual to a health promotion approach that uses social, policy, and environmental strategies has several advantages. First, by recognizing that many environmental determinants of health behavior

are not under the direct control of the individual, the ecological focus avoids blaming persons who fail to modify their behavior. Second, many educational strategies are more effective with better-educated, wealthier persons and may thereby increase the disparities in health between population groups and fail to reach those in greatest need. Third, regulatory and policy interventions can be more cost-effective than multiple efforts to modify individual behavior.

Description of Comprehensive Programs

The importance of comprehensive economic, policy, and regulatory interventions to reduce tobacco use has long been recognized by international experts (WHO 1979). For example, the evolving WHO guidelines for such interventions have increasingly emphasized policy and legislative measures, stressing that these types of health promotion and health protection strategies are essential elements of any national effort to reduce tobacco use (WHO 1998). In an extension of the WHO's efforts, the National Cancer Institute (NCI) released a blueprint for related public health action in the United States (NCI 1991). This monograph stressed that the application of social environmental approaches should not compete with individual approaches but should be combined synergistically with them. Similarly, the Center for Substance Abuse Prevention (CSAP) of the Substance Abuse and Mental Health Services Administration (SAMHSA) published guidelines that provide the concept, structure, and operations of a community-based approach to reduce tobacco use among youth (SAMHSA 1998a,b). To further help states overcome common obstacles to enforcing youth access laws, CSAP also has provided a document that provides strategies to address problems such as interagency and intraagency issues, insufficient or uncoordinated resources, or lack of data sources (U.S. Department of Health and Human Services [USDHHS] 1999). More recently, the CDC (1999a) has synthesized a comprehensive framework for statewide programs to reduce tobacco use. This framework integrates four program goals with four program components; optimally, each of the goals would be fully addressed in the implementation of each of the components. The framework, described in the next section of this chapter, recognizes that comprehensive programs will continue to evolve, in response both to new

information and to new circumstances. In addition, the framework represents a distillation of evidence and judgment that have been discussed in detail in the earlier chapters of this report and that have been tested in the community-based trials and the comprehensive programs discussed later in this chapter.

Program Goals for Reducing Tobacco Use Statewide

- 1. *Prevent initiation among young people*. The hallmarks of this goal are
 - Decreasing young people's access to tobacco products.
 - Increasing prohealth messages.
 - Reducing protobacco messages.
 - Increasing the price of tobacco products.

Some of the mechanisms for decreasing young people's susceptibility to tobacco use are promoting youth empowerment activities, providing school health education, offering positive alternatives, deglamorizing tobacco use, and involving parents and families.

- 2. **Promote quitting among adults and young people**. An environment that supports efforts to quit using tobacco can be fostered by
 - Increasing access to culturally appropriate, effective cessation services (e.g., by expanding insurance coverage).
 - Increasing the price of tobacco products.
 - Increasing restrictions on environmental tobacco smoke (ETS).

- Increasing prohealth messages.
- Decreasing protobacco messages.
- 3. *Eliminate exposure to ETS*. The continued expansion of policies to eliminate exposure to ETS can be achieved by
 - Developing support for implementation.
 - Enforcing voluntary private policies.
 - Enforcing public policy and public regulation.
 - Expanding coverage of public areas.
- 4. *Identify and eliminate disparities among population groups*. Intrinsically linked to achieving the first three goals, eliminating disparities entails
 - Increasing the price of tobacco products through culturally acceptable programs.
 - Decreasing exposure to ETS.
 - Increasing prohealth messages.
 - Decreasing protobacco messages, particularly those aimed at population subgroups.
 - Increasing the availability of culturally acceptable cessation services.
 - Increasing protective factors among young people.
 - Decreasing young people's access to tobacco products.

Development, funding, and implementation of the major elements—some of which appear in several of these goals—are critically linked to community involvement and, as noted, to a culturally appropriate approach.

Program Components for Reducing Tobacco Use Statewide

 Community interventions. Working through social organizations, systems, and networks promotes an environment that facilitates individual health choices and establishes freedom from tobacco use as the norm. The term "community" encompasses a diverse set of entities, including medical societies; schools; school districts; departments of education; voluntary health agencies; civic, social, and recreational organizations; businesses and business associations; city and county governments; public health organizations; labor groups; managed care systems; faith communities; and organizations for racial and ethnic minority groups.

Community-based activities can include supporting legislated removal or restriction of stimuli to use tobacco (such as advertising and promotion,

- easy access to tobacco products via self-service display and vending machines, and ongoing exposure to ETS) as well as providing positive alternatives (such as promoting cessation, encouraging prevention advocacy, developing role modeling through parents and adults, and fostering youth empowerment). By changing the community setting and institutions with which adults and young people interact, community-based activities work to denormalize, deglamorize, and discourage tobacco use and to provide access to resources that increase users' ability to control their addiction and use of tobacco. This approach has the potential to effect substantial, sustained, populationwide change in tobacco use behavior.
- Countermarketing. Changing a social environment that fosters a norm of tobacco use is an essential element of national, state, and local programs. This change requires strategies to counter the billions of dollars spent in advertising and promotion that reach young people and adults with misleading images about tobacco. Countermarketing efforts can include using media advocacy, paid media, and counteradvertising; increasing prohealth promotions and sponsorships; and providing information on the tobacco industry's marketing and promotional tactics. These public health messages should use a strategy that targets all age groups and populations. In a comprehensive strategy, education messages will be mutually reinforcing: clean indoor air messages will provide added motivation for adults to quit smoking; cessation messages for adults will discourage tobacco use among young people and accentuate the problem of addiction; and youth prevention messages will increase the salience of the tobacco issue among parents and community leaders.
- 3. Program policy and regulation. Areas in which policy and regulation to reduce tobacco use have been applied include minors' access, tobacco pricing, advertising and promotion, clean indoor air, product regulation, product labeling, ingredient disclosure, and policies on insurance coverage for cessation services. Policies and regulations can be established at the federal, state, and local levels (see Chapter 5). Ideally, policies and regulations need to be implemented at both the community level and statewide. Educating the public about policies and regulation is crucial to acceptance, but such education must be supported by adequate enforcement.

4. Surveillance and evaluation. Surveillance and evaluation efforts are necessary to make the ongoing refinements that lead to more effective prevention strategies. In addition to traditional surveillance methods, nontraditional approaches—such as monitoring the promotional activity of the tobacco industry at the state and local levels, monitoring the economic impact of smoking laws and other ETS policies, and performing periodic surveys of public opinion on program interventions—are critical for reducing tobacco use.

The conceptual framework for comprehensive efforts to reduce tobacco use has been used to develop the current generation of statewide programs. However, even the most comprehensive programs

currently in place have not been able to fully implement all recommended components. Policy and regulation components are especially hampered, since many state and local actions are limited by federal mandates and preemptions (see "Preemption of Local Action by State Policy" in Chapter 5). Moreover, only two states, California and Massachusetts, have implemented comprehensive programs for a sufficient time to provide evaluation data on the overall efficacy of the emerging comprehensive model.

The following sections summarize the history and development of community-based, statewide, and other large-scale efforts to reduce tobacco use and conclude with a review of existing data on the efficacy of the comprehensive model.

Community Intervention Trials

Large-scale trials to prevent cardiovascular disease have been a major source of data on populationbased approaches to reducing tobacco use. An emphasis on the importance of addressing social and cultural determinants of smoking behavior grew directly out of early work on cardiovascular disease epidemiology. The Seven Countries Study, which was started in the mid-1950s by Keys and colleagues (Aravanis et al. 1970; Blackburn et al. 1970; Buzina et al. 1970; Fidanza et al. 1970; Kimura and Keys 1970; Taylor et al. 1970a,b), examined risk factors for cardiovascular disease in populations around the world and documented that disease rates and risk factors differed markedly across cultural and social environments (WHO 1982). In that study, more than 12,500 men aged 40-59 years from Finland, Greece, Italy, Japan, the Netherlands, the United States, and Yugoslavia were recruited for a prospective study of the relationship between personal behaviors (e.g., diet, physical activity, smoking) and risk of cardiovascular disease (Aravanis et al. 1970; Blackburn et al. 1970; Buzina et al. 1970; Fidanza et al. 1970; Kimura and Keys 1970; Taylor et al. 1970a,b). Although the most striking differences in lifestyle across cultures were in the composition of the men's diet, smoking was found to be a significant risk factor. This study, and many other early studies of cardiovascular disease epidemiology, encouraged researchers to start community trials to modify the identified risk factors in whole population groups (WHO 1982).

Two landmark community trials that began in 1972 grew directly out of the work of the Seven Countries Study investigators: the Stanford Three-Community Study (Farguhar et al. 1977) and the Finnish North Karelia Study (Puska et al. 1985). A third, less directly tied to this early work, was the Israeli Community Syndrome of Hypertension, Atherosclerosis and Diabetes (CHAD) program (Gofin et al. 1986) begun in 1971. In addition, two worksite trials focusing on populationlevel changes in cardiovascular disease risk factors developed out of the Seven Countries Study and from related early work on cardiovascular disease epidemiology: the Belgian Heart Disease Prevention Project (Kornitzer et al. 1980) and the United Kingdom Heart Disease Prevention Project (Rose et al. 1980). Though investigators in these initial studies recognized the importance of the social and cultural environment in modifying risk factors for cardiovascular disease, including smoking (Farquhar 1978; WHO 1979; Farquhar et al. 1981, 1985; Rose 1981; McAlister et al. 1982; Puska et al. 1985), the smoking cessation techniques of the time were primarily individually oriented (McAlister et al. 1976; Meyer et al. 1980).

The Stanford and North Karelia studies shared some community organizing and conceptual perspectives in their planning (WHO 1982). Logistical and cultural differences between the United States and Finland dictated significantly different implementation, however. In the Stanford study, an intervention that

primarily used mass media was compared with the same mass media intervention plus intensive face-to-face counseling for high-risk individuals and was also compared with a control community that received no intervention. In the initial results, the community cohort receiving both the mass media and the face-to-face counseling for high-risk smokers had a significantly greater decrease than the control community in the prevalence of smoking (–50 vs. –14.9 percent) and in the number of cigarettes smoked (percentage reduction of 51.6 vs. 21.0 percent) (Farquhar et al. 1977, 1985; Maccoby et al. 1977; Meyer et al. 1980).

In the Finnish study, the people of North Karelia province requested the intervention because of concerns raised by the results of the Seven Countries Study, in which residents of their province had participated (Puska et al. 1985, 1995). The intervention had a strong focus on community organizing and environmental modification, together with multiple educational components using mass media and other strategies (McAlister et al. 1982; Puska et al. 1985). Although the intervention's early efforts had a greater emphasis on increasing direct cessation services than on preventing smoking, the importance of nonsmoking environments and other environmental changes was clearly recognized and emphasized (Koskela 1981). The fiveyear follow-up results of the study found no significant difference in smoking prevalence between the North Karelia province and Kuopio, a comparison province with similar baseline smoking rates (Puska et al. 1979). Ten years on, a significantly greater reduction in smoking prevalence was observed among men in North Karelia than in Kuopio (Salonen et al. 1981; Puska et al. 1983a,b; Vartiainen et al. 1986). The intervention trial has been continued, and new prevention and population-based cessation strategies have been added (Vartiainen et al. 1986; Korhonen et al. 1992, 1993). Analyses of 20-year trends (from 1972 to 1992) in smoking in the two provinces found a significantly greater decline in smoking prevalence for adult men in North Karelia (from 52 to 32 percent) than in Kuopio (50 to 37 percent) and in southwestern Finland. Smoking prevalence for adult women increased at similar rates in both provinces (increasing from 10 to 17 percent in North Karelia and from 11 to 19 percent in Kuopio) (Vartiainen et al. 1998). The 20-year difference in trends in men between the two provinces appeared to be primarily related to cessation during the first 10 years and to prevention during the last 10

The CHAD program had a somewhat more individually focused intervention model directed at reducing the risk factors for cardiovascular disease among

residents in Israeli housing projects (Abramson et al. 1981). The health care providers serving the intervention communities provided risk factor screening and counseling for families, couples, and individuals living in the four adjacent housing projects. The residents of comparison housing areas received usual care from their providers. In the intervention communities, group discussions were held to provide social support and increase group influences on individual lifestyle changes. Comparisons between community health surveys conducted at baseline (1969–1971) and after five years (1975-1976) showed a significantly greater decline in smoking prevalence among men but not among women in the intervention communities than in control communities (Gofin et al. 1986). At the 10-year follow-up (1981), the prevalence of smoking had declined significantly between 1976 and 1981 among both men and women in the CHAD follow-up cohort, whereas no change or a slight increase in smoking had occurred among adults in Israel overall (Gofin et al. 1986).

The Belgian Heart Disease Prevention Project was a controlled, multifactorial trial involving men aged 40–59 years at baseline at Belgian worksites (Kornitzer et al. 1980). Thirty pairs of factories were studied, with one site from each pair randomly assigned to the intervention group and one site to the control group. At baseline screenings for risk factors for cardiovascular disease, individuals in the upper two deciles of risk were identified and received semiannual individual counseling from the medical staff. Medical advice to quit smoking was reinforced in the factories by antismoking posters, written messages, and health education conferences encouraging workers to quit smoking and to encourage the same to their friends who smoked. Changes in smoking prevalence at the intervention and control worksites were monitored among both the high-risk individuals and in random samples of the total worksite populations. After two years of intervention, a significantly greater percentage of the highrisk smokers quit in the intervention group than in the control group (18.7 vs. 12.2 percent), but no difference was observed in the random samples.

The United Kingdom Heart Disease Prevention Project was started in 1971 with 24 pairs of English and Welsh factories. Each member of the pair was randomly assigned to intervention or control status (Rose et al. 1980; Bauer et al. 1985). At baseline and in 1977–1978, risk factor screening for cardiovascular disease was conducted among men aged 40–59 years in the intervention sites and in a 10-percent random sample of similarly aged men at the control sites. Over a five-to six-year period, all men in the intervention sites

received healthy lifestyle advice by mail and by worksite posters. Men in the intervention sites found at baseline to be at high risk for cardiovascular disease were provided medical counseling on risk factor change, including smoking cessation. At the end of the intervention in 1977–1978, a small but significant reduction in smoking prevalence had occurred among the high-risk smokers in the intervention site (Rose et al. 1980). Five intervention and five control worksites were resurveyed in 1983, approximately 12 years after the baseline screening and at least 5 years after the end of the intervention program (Bauer et al. 1985). There was no significant difference in the prevalence of smoking between intervention and control factories, but the smokers at the intervention sites reported smoking significantly fewer cigarettes per day.

The initial design and implementation of the North Karelia and Stanford Three-Community trials led to the design of several other cardiovascular disease prevention trials around the world. These included the Swiss National Research Program from 1977 to 1980 (Gutzwiller et al. 1985), the South African Coronary Risk Factor Study from 1979 to 1984 (Steenkamp et al. 1991), and the Australian North Coast Healthy Lifestyle Programme from 1978 to 1980 (Egger et al. 1983). The early trials also influenced the development of two communitywide mass media-based smoking cessation trials implemented in Australia in the 1980s, in Sydney from 1983 to 1986 and in Melbourne from 1984 to 1986 (Pierce et al. 1986, 1990; Macaskill et al. 1992).

In the Swiss trial, two towns in the Frenchspeaking and two towns in the German-speaking regions of the country were assigned to either intervention or reference status (Gutzwiller et al. 1985). Baseline surveys of risk factors for cardiovascular disease were conducted among random samples of residents aged 16 to 69 years in all four towns in 1977–1978 and repeated at the final assessments in 1980-1981. In the interval, communitywide health education and health promotion interventions were conducted in the two intervention towns, including media campaigns, counseling of high-risk individuals, and community organization efforts to encourage environmental and social changes. The prevalence of smoking in the communities declined from 32.8 to 27.4 percent in the intervention towns and from 37.1 to 35.3 percent in the reference towns, a significant net effect of 3.6 percent decline.

In the South African Coronary Risk Factor Study, three rural communities, matched in size, socioeconomic status, and cultural factors, were assigned to low-intensity prevention, high-intensity prevention, and control status (Steenkamp et al. 1991). Both

the low- and the high-intensity sites received a mass media educational campaign using so-called small media, such as posters, billboards, mailings, and coverage in local newspapers. In the high-intensity community, high-risk individuals, including smokers, received personal interventions from health care providers. Risk factors for cardiovascular disease were measured in a cohort of residents aged 15 to 64 years from each community in 1979 and in 1983. The baseline prevalence of smoking was higher among men (49.2 vs. 44.4 percent) and women (17.0 vs. 14.5 percent) in the high-intensity intervention community than in the control community, but the difference was not statistically significant. After the four-year intervention, the net change in smoking prevalence in the highintensity community, relative to the control community, was not significant for men but was significant for women. Women in both the low- and the highintensity intervention communities had significantly higher rates of quitting than women in the control community, but no differences were observed for men.

The Australian North Coast Healthy Lifestyle Programme replicated the design of the Stanford Three-Community Study (Egger et al. 1983). In 1978, three communities in northern New South Wales, Australia, were assigned to a media intervention, media intervention plus community program, or control status. A two-year study for preventing cardiovascular disease was conducted, including a smoking cessation component called "Quit for Life." The media interventions used professional commercial media and advertising techniques and a social marketing and health promotion framework involving print, posters, radio, television, and other advertising techniques. The community programs for smoking cessation included promotions of smoking cessation organizations, kits handed out by doctors, distribution of self-help materials, and telephone help lines. The smoking cessation campaigns also incorporated other community activities—such as organized runs, stress management training, and computerized health testing—that conveyed the overall program's broader theme of healthy lifestyles. Risk factors for cardiovascular disease, including smoking, were measured in random samples of residents aged 18 years and older in each community in 1978 (baseline), 1980, and 1981. In the multiple logistic regression analysis model, which controlled for baseline differences among the three communities in age and sex distributions, there was a statistically greater decline in smoking in the two intervention communities than in the comparison community, with the largest differences among young smokers. Declines in the prevalence of smoking in the area assigned to media intervention plus community program ranged from 15.7 percent among men aged 18–25 years to 6.1 percent among women aged 65 years and older.

In the 1980s, a communitywide mass mediabased smoking cessation campaign was conducted in Sydney and Melbourne, Australia (Dwyer et al. 1986; Pierce et al. 1986). The Sydney campaign began in mid-1983, and the Melbourne campaign began one year later (during the preceding year, Melbourne was used as a control city for the Sydney campaign). The "Quit for Life" campaigns involved innovative and provocative smoking cessation messages delivered through paid spots on the radio, on television, and in newspapers. These messages were supported by a telephone "Quit Line," self-help "Quit Kits," and a hospital-based "Quit Centre," all of which were promoted at the end of the paid advertisements used in the campaigns. The campaigns were evaluated through monthly random telephone surveys in the two communities. In addition, a cohort of residents was interviewed in April-June 1983 and again in May 1984. In the cohort, 23 percent of smokers in Sydney and 9 percent in Melbourne quit during the initial (control) year before the campaign was begun in Melbourne (Pierce et al. 1986). The monthly prevalence estimates demonstrated an approximately 1-percent decline in Sydney in comparison with the rest of Australia (Dwyer et al. 1986). The media campaigns were continued through 1986, along with additional programs in conjunction with physician-, school-, and community-based activities. Long-term evaluation of trends in smoking in the two cities from 1981 to 1987 suggests that the sustained campaigns may have contributed to a decline in smoking prevalence of about 1.5 percentage points per year in both communities among men but had little impact on women (Pierce et al. 1990). An analysis of the campaign's potential differential impact across educational levels suggested that the Australian mass media and community campaigns did not contribute to an increase in the gap in smoking prevalence between educational groups (Pierce 1989; Macaskill et al. 1992).

The lack of a consistently positive effect from these initial community trials was attributed more to an incomplete understanding of comprehensive interventions and to the relatively weak, quasi-experimental designs of the studies than to concern about the efficacy of the overall approach (Farquhar 1978). The continuing enthusiasm for the potential efficacy of the communitywide approach was reflected in both national and international reviews and guidelines (Blackburn 1983; WHO 1982; USDHHS 1983; National Cholesterol Education Program Expert Panel 1988; Shea and Basch 1990a,b). Similarly, the positive results

from the Australian communitywide antismoking media campaigns and smoking cessation data from the North Karelia trial encouraged the planning of smoking-specific community efforts in the United States in the late 1980s.

Three major community-based trials for preventing cardiovascular disease were funded by the National Heart, Lung, and Blood Institute (NHLBI) in the early 1980s: the Stanford Five-City Project, the Minnesota Heart Health Program, and the Pawtucket Heart Health Program. Each had comparison and intervention communities and stronger designs and evaluation methodologies than the studies initiated in the 1970s. Each study was developed by an independent team of investigators, and the NHLBI maintained a collaborative research relationship among the studies (Winkleby et al. 1997). All three shared common intervention approaches that lasted five to eight years and focused on the major risk factors for cardiovascular disease (hypertension, cigarette smoking, high dietary fat, obesity, and sedentary lifestyle). Each project used mass media, community mobilization, and multiple educational channels, such as health care providers, schools, worksites, and voluntary agencies. The programs integrated individual and social change approaches, employing some combination of social learning theory, social network diffusion theory, and social marketing to guide the planning and implementation of the interventions (Bandura 1977; McGuire 1973; Rothman 1979; Rogers 1983). The three projects differed initially in their relative emphasis on specific modalities (Stanford emphasized media; Minnesota, population screening; and Pawtucket, community organizations) (Shea and Basch 1990a), but frequent collaborations among projects decreased these differences over time. Many innovative strategies were developed, and the process evaluations on specific smoking prevention and cessation interventions were positive (Glasgow et al. 1985; Sallis et al. 1985; Altman et al. 1987; Elder et al. 1987, 1993; King et al. 1987; Lando et al. 1990, 1991; Perry et al. 1992; Pechacek et al. 1994). Nonetheless, the overall impact of the three interventions on smoking prevalence was modest.

The Stanford Five-City Project began with baseline surveys in 1979. Five cities in Northern California were selected on the basis of location, size, and media markets (Farquhar et al. 1985). Monterey and Salinas shared a media market and were assigned to the intervention group. The three control cities (Modesto, San Luis Obispo, and Santa Maria) were isolated from the media market of the intervention communities. The communitywide educational campaigns began in 1980 in collaboration with existing community

organizations. The two treatment cities received continual exposure for five years; each year, four to five separate risk factor education campaigns took place, one of which focused on smoking. Evaluations included independent, cross-sectional population samples aged 25 to 74 years surveyed at baseline and at 25, 51, and 73 months, as well as a cohort formed from the baseline survey that was resurveyed at 17, 39, and 60 months. Initially, the cohort samples in the intervention communities experienced a significantly greater decline in smoking prevalence than those in the control communities (-7.66 vs. -3.76 percent) (Farguhar et al. 1990; Fortmann et al. 1993). By the end of the intervention in 1986, the cross-sectional surveys showed no such difference in declining prevalence. At the final follow-up in 1989–1990, a more rapid though nonsignificant decline was detected in the control communities than in the intervention communities (Winkleby et al. 1996).

In the Minnesota Heart Health Project, three pairs of communities were selected, with one of each pair assigned to educational intervention and the other to comparison status (Jacobs et al. 1986; Murray et al. 1994). The communities were matched on size, community type, and distance from the Minneapolis-St. Paul metropolitan area. After a 16-month baseline assessment period, a 5- to 6-year intervention program was started in November 1981 in the first education site, Mankato, Minnesota (Luepker et al. 1994). The second and third education sites, Fargo-Moorhead on the North Dakota-Minnesota border and Bloomington, Minnesota, were started 22 and 28 months later in 1983. The staggered entry allowed for a gradual development of the intervention program and a stronger evaluation design (Luepker et al. 1994). Starting in 1980, annual cross-sectional surveys among residents aged 25 to 74 years were conducted in all six sites. A random sample of residents surveyed before the start of the education program was resurveyed. For long-term smoking cessation, the cross-sectional survey data provided evidence of an intervention effect for women but not for men; no such effect was observed for either sex in the cohort sample (Luepker et al. 1994; Lando et al. 1995). Unexpectedly, large declines in smoking prevalence, especially among men, were observed in comparison communities.

In the Pawtucket Heart Health Program, the impact of a communitywide program for reducing risks for cardiovascular disease in Pawtucket, Rhode Island, was compared with trends in a nearby matched community in southern Massachusetts (name withheld to honor a confidentiality agreement with the city government) (Carleton et al. 1995). Pawtucket was selected

as the intervention site from among a pool of nine potential northeastern New England cities; the comparison site had similar sociodemographic characteristics. Surveys of risk factors for cardiovascular disease were conducted with random samples of residents aged 18 to 64 years in the two communities at two-year intervals, beginning in 1981 and continuing until 1993. Communitywide educational strategies emphasized public awareness campaigns, behavior change through existing community resources and volunteers, and community activation to promote involvement and environmental changes (Elder et al. 1987, 1993; Lefebvre et al. 1987). During the sevenyear intervention program from 1984 to 1991, more than 500 community organizations were involved, including schools, religious and social organizations, larger worksites, and city government departments. Overall projected risk for cardiovascular disease declined significantly in Pawtucket during the educational program, but the prevalence of cigarette smoking declined only slightly and did so more in the comparison than in the intervention community (Carleton et al. 1995).

Concurrent with the community-based cardiovascular disease prevention trials in the United States, an antitobacco community education program was initiated in India (Anantha et al. 1995). The trial was conducted between 1986 and 1992 in the Karnataka State. One intervention area (117 villages) and two control areas (136 and 120 villages) were selected within the Kolar District. A baseline survey was conducted in 1986, and follow-up surveys were conducted two and five years later. Villages were randomly sampled in each of the three areas, and the tobacco use habits of all residents of each household were assessed. A subsample of the villages selected at baseline was resurveyed two and five years later to provide cohort follow-up. After the baseline survey, a three-year educational campaign used health worker staff from Primary Health Centres to visit each village at least once a week and deliver health education messages about the risks of cigarette smoking and other forms of tobacco use, particularly chewing. Handbills, photographs, posters, and films in multiple languages were used to reinforce health education counseling delivered to individuals and small discussion groups. Among tobacco users in the intervention area, prevalence declined 26.5 percent for men and 36.7 percent for women. The proportional reduction in the prevalence of any tobacco use was significantly greater in both men and women in the intervention area than in the two control areas (10.2 vs. 2.1 and 0.5 percent for men and 16.3 vs. 2.9 and 0.6 percent for women).

The Federal Republic of Germany began the German Cardiovascular Prevention (GCP) Study in the mid-1980s (GCP Study Group 1988). The seven-year prevention campaign in the GCP Study targeted more than 1 million people in six intervention regions whose demographic and socioeconomic structure reflected that of the West German population. The reference population was sampled from the total West German population. The goal of the campaign was to reduce four risk factors for cardiovascular disease (hypertension, hypercholesterolemia, smoking, and obesity) by using a multifaceted prevention program. Public health services, voluntary welfare federations, institutions for adult education, sports and consumer associations, and other existing community resources and facilities were used extensively. The campaigns sought the involvement of health care providers and emphasized consumers' access to them. Special emphasis was placed on improving community knowledge and awareness of healthy nutrition, the benefits of physical activity, and the importance of quitting smoking. To identify persons at high risk for hypertension and hypercholesterolemia, screenings were conducted at social events, in factories, and at other community settings in close cooperation with physicians, pharmacists, and health insurance companies. To discourage smoking, nonsmoking restrictions were extended in public places, and educational campaigns were conducted in the media and in community settings to promote smoking cessation and to help smokers quit. For the evaluation of risk factor trends, representative samples of residents aged 25-69 years from the intervention regions and of the national population of West Germany were surveyed before the intervention (May 1984 to March 1986), at midstudy (February 1988 to April 1989), and at the end of the intervention (April 1991 to April 1992) (Hoffmeister et al. 1996). In the national reference sample, the prevalence of smoking declined from 34.0 percent at baseline to 33.5 percent at the end of the study. In the intervention region, the prevalence of smoking declined from 35.4 percent at baseline to 32.5 percent at the end of the study, for a net change of -6.7 percent (P < 0.001). The decline occurred exclusively among men (net change of -7.9 percent, P < 0.001). Among women, the prevalence of smoking increased in both the intervention regions and nationwide, and no intervention impact was noted (net change of –1.8 percent).

Using a somewhat different design, the Community Intervention Trial for Smoking Cessation (COMMIT) was started in the late 1980s (COMMIT Research Group 1991). COMMIT focused solely on smoking cessation and built on the initial experience in the

ongoing trials to prevent cardiovascular disease. COM-MIT was planned as a randomized community trial with 11 pairs of communities and had adequate statistical power to detect relatively small intervention effects (Gail et al. 1992). One community of each pair was randomly allocated to the intervention program, and the other was monitored as a control. The 11 intervention communities received a four-year educational program that focused on adult cessation, with special emphasis on "heavy" cigarette smokers (those who smoked 25 or more cigarettes per day). The intervention philosophy of the trial assumed that a comprehensive communitywide strategy would make it difficult for residents in the 11 targeted sites to avoid exposure to messages about the importance of nonsmoking and would alert smokers to the many opportunities for cessation. Interventions focused on four primary educational channels: media-based and communitywide events, health care providers (e.g., physicians and dentists), worksites and other organizations, and cessation resources. Within these channels, the centrally developed protocol specified 58 mandated activities, designed to be carried out largely by community volunteers and local staff or agencies with limited external resources (Lichtenstein et al. 1990-1991). Intervention activities started after the baseline survey and randomization, beginning with community mobilization in January 1989 and continuing with protocol-defined intervention through December 1992. A telephone survey was conducted in each of the 22 sites to estimate baseline prevalence and identify cohorts of heavy and light-to-moderate smokers. Cohort members were contacted annually by telephone, with a final assessment in early 1993. A final prevalence survey was conducted in all 22 communities from August 1993 to January 1994.

There was a high degree of community ownership within the 11 intervention sites (Bracht et al. 1994; Lichtenstein et al. 1996), and program staff and community organizations diligently delivered the 58 mandated activities. Hence, the modest effects observed in this trial were sobering for the public health community (Fisher 1995; Susser 1995). No cessation effect was observed for the "heavy" smokers for whom the trial was specifically designed (COMMIT Research Group 1995a). Among the evaluation cohort of lightto-moderate smokers, a significantly greater proportion guit in the intervention than in the control communities (30.6 vs. 27.5 percent) over the four-year intervention period, and the effect was strongest among the less educated residents of the communities. Overall the prevalence of smoking declined

slightly (but nonsignificantly) more in the intervention communities (3.5 percentage points) than in the comparison communities (3.2 percentage points) (COMMIT Research Group 1995b). The quality and statistical power of the overall trial design (Gail et al. 1992) make it unlikely that any true intervention effects were missed. The COMMIT intervention protocol sought to apply the most effective smoking cessation strategies as defined by the published literature (Lichtenstein et al. 1990-1991; COMMIT Research Group 1991). The investigators were limited, however, in their ability to be involved in many of the recommended ecological and policy-oriented health promotion strategies (WHO 1979; Green and Richard 1993) because of restrictions imposed by federal funding of the study (Fisher 1995; Susser 1995). In addition, process data showed that implemented protocol did not have a significant impact on many important intermediate variables (e.g., physician and dentist counseling rates, worksite smoking bans, public attitudes toward smoking) (Glasgow et al. 1997; Ockene et al. 1997; Taylor et al. 1998). Therefore, the failure of the COMMIT interventions to use certain strategies or to change intermediate social and policy variables suggests that the study was not an adequate test of the efficacy of the social-environmental approach to reducing to-bacco use.

Several reviewers have provided some perspectives on the modest smoking cessation effects observed in these community trials (Green and Richard 1993; Luepker 1994; Winkleby 1994; Fisher 1995; Susser 1995). Common themes are (1) the difficulty in observing intervention effects because of the large secular declines in risk factors for cardiovascular disease, including smoking, that occurred during the period when the trials were implemented and (2) the need for a more comprehensive health promotion approach. A more complete understanding is needed of why such modest and mixed smoking cessation effects have been observed in numerous well-designed and well-implemented communitywide trials.

Statewide Interventions

Concurrent with the implementation of the community intervention trials, a broader national movement to reduce tobacco use began to emerge in the 1980s. Unlike the community intervention trials, this movement, and the large-scale interventions that developed from it, was not structured around research hypotheses and preplanned evaluation designs. Rather, the movement was characterized by community mobilization at the national, state, and local levels and encompassed the principles of health promotion as a social movement that evolves (Kickbusch 1989; Allison and Rootman 1996; Downie et al. 1996; Nutbeam 1998). Funding for these efforts came from both federal and private sources; however, an important manifestation of this national movement was the establishment of statewide interventions funded by increases in cigarette excise taxes or settlements with the tobacco industry. Such increases were the result of voter initiatives, beginning with those in California in 1990 and Massachusetts in 1993. The next section of this chapter reviews the main elements of the national movement.

Community Mobilization

A significant step in organizing the movement to reduce tobacco use was the founding in 1981 of the Coalition on Smoking OR Health, which consisted of representatives from three major volunteer health agencies: the American Cancer Society (ACS), the American Heart Association, and the American Lung Association. The formation of a national coalition prompted state-and local-level leaders of these organizations to form similar triagency coalitions. Some of these state and local coalitions expanded to include representatives from other groups, such as medical societies, other volunteer health organizations, and state health departments. These coalitions were among the first efforts to mobilize communities at the state and local levels.

The consensus of the 1985 International Summit of Smoking Control Leaders in Washington, DC, was that only unified, broadly based, strategically coherent, and flexible national movements for reducing smoking were destined to be successful. To help build such movements, the summit participants recommended producing a handbook on coalition building.

The resulting ACS publication, *Smoke Fighting: A Smoking Control Movement Building Guide* (Pertschuk and Erickson 1987), examined the strengths and weaknesses of networks and coalitions and gave suggestions for building and strengthening these forums. This guide was one of the earliest produced on community organizing to reduce tobacco use.

A survey conducted by the Association of State and Territorial Health Officials determined that as of December 31, 1989, coalitions for reducing tobacco use had been formed in 46 states and the District of Columbia (CDC 1990). Only Hawaii, Kentucky, Mississippi, and South Carolina did not have state-level coalitions at that time. Of the 47 coalitions, 44 concentrated on reducing tobacco use; the remaining 3 addressed tobacco use, as well as other chronic disease risk factors. Although Colorado established the first tobacco-related coalition in 1963, coalitions in 28 states were not established until after 1984. Coalition activities included lobbying, providing public education, educating health care professionals, conducting research and evaluation, and developing and implementing a state plan for reducing tobacco use (Pertschuk and Erickson 1987).

Until recently, the United States remained without a national program for tobacco-related risk reduction analogous to those established for hypertension and hypercholesterolemia. During the 1990s, three nationally funded programs—two by the federal government and one by a private foundation—and one federally funded research project have helped states and localities mobilize for reducing tobacco use. As noted, several states provided funds for state and local community organizing.

National Programs

ASSIST

The American Stop Smoking Intervention Study (ASSIST) for Cancer Prevention is a partnership between the NCI and the ACS to establish coalitions that focus on using public policy change to reduce tobacco use (see also "Community Programs" in Chapter 4). The ASSIST project was developed after many NCI consultants had recommended that community-based coalitions for reducing tobacco use be established in entire states or in large metropolitan areas. The ASSIST guidelines provided both the rationale for the coalition model and the flavor of the overall project:

- Smoking is a public health problem that affects everyone in a community, not only smokers. The solution to the smoking problem requires the active involvement of a broad range of groups and individuals.
- Significant and enduring changes in smoking behavior require a change in social norms, that is, that smoke-free environments and lifestyles are preferred and encouraged among all social groups. Changes in social norms occur over time with the involvement and support of a broad representation of interest groups.
- Tremendous resources are invested each minute of every day to encourage young people to begin smoking as a normal and acceptable behavior. The resources required to counter this effort and to effect a significant change in smoking behavior far exceed the funds available through this [ASSIST] project. A large contribution of direct and in-kind support in the form of time, energy, volunteers, and other resources will be required. Only through the commitment of a variety of groups and organizations can adequate resources be made available.
- The intent of ASSIST is not to create a new institution devoted to smoking control but rather to increase the capacity for existing groups and organizations to sustain and enhance their role as smoking control agents beyond the life of ASSIST. Activities by different groups will be coordinated and efforts thereby magnified, and strategies and training will be disseminated and institutionalized in each coalition member group (NCI 1991, pp. 1–2).

ASSIST included an initial planning phase (1991– 1993) and a subsequent implementation phase (1993– 1998) for the 17 states chosen for participation. The implementation phase was then extended to September 1999. During the planning phase, the coalitions performed comprehensive site analysis and developed a plan for reducing tobacco use. For planning, each state received approximately \$400,000 per year to develop its own comprehensive, five-year plan (Manley et al. 1997a). During the implementation phase, states have been receiving an average of approximately \$1.2 million per year to carry out the action steps in accordance with NCI guidelines and ASSIST program objectives. Intensive training of state health department and voluntary agency personnel in the ASSIST states was a primary activity during the planning phase and

early years of the implementation. This training focused on the program objectives, including policy changes, media advocacy, and community mobilization. An interim evaluation of impact (Manley et al. 1997b) found that per capita cigarette consumption and inflation-adjusted cigarette prices were nearly identical in the 17 ASSIST states and the remaining non-ASSIST states (excluding California) before 1993, when full funding for the ASSIST intervention began. By 1996, per capita consumption in the ASSIST states was about 7 percent less than in the non-ASSIST states. This decrease occurred in the face of a general decline in cigarette prices during the period of evaluation. These interim results suggest that the ASSIST program has been associated with a significant decrease in cigarette consumption and that increased price from taxation may not be the only program influence.

IMPACT

In its Initiatives to Mobilize for the Prevention and Control of Tobacco Use (IMPACT) program, the CDC has funded the District of Columbia and 32 states that do not receive funding from the ASSIST project. The exception is California, which is not funded by ASSIST or by the CDC but since 1989 has had a tobacco control program funded by the state excise tax on cigarettes. (The California program is described later in this chapter.) A portion of IMPACT funds supports community mobilization at the state and local levels, with particular focus on racial and ethnic minority groups and women. The IMPACT program also provides extensive training to representatives of state coalitions in subjects such as media advocacy, policy advocacy, and coalition building.

Recently, the IMPACT program has been expanded to include key national organizations to help them mobilize their constituencies in efforts to reduce tobacco use. Funds have been especially directed to organizations that serve populations targeted by the tobacco industry's marketing plans and that are historically underrepresented in the movement to reduce tobacco use (Farquhar et al. 1985; USDHHS 1998).

SmokeLess States Program

In 1994, the Robert Wood Johnson Foundation initiated the SmokeLess States program to provide additional funds to state coalitions. In the initial round of funding, the program awarded more than \$13 million in either four-year implementation grants or two-year capacity-building grants to 19 state coalitions and also funded a youth-specific project in Tucson, Arizona

(Robert Wood Johnson Foundation 1994). Two years later, funding for the SmokeLess States program was expanded to \$20 million. In this second round of funding, awards were made to 13 new states; in addition, implementation grants were made to some of the states that had previously received capacity-building grants. In 1998, SmokeLess States funded another \$6 million in grants to eight states that had been funded for four years each. Currently, the SmokeLess States program funds 28 states and 2 cities at a total of \$39 million per year. The SmokeLess States program focuses on helping state coalitions develop policy options, including prevention programs similar to those in place in California and Massachusetts (as discussed later in this chapter) and other efforts aimed at reducing tobacco consumption, especially among young people. Administered by the American Medical Association (1998), this grant program differs from ASSIST and IMPACT in that it does not have strict requirements concerning the makeup of the coalition, although community mobilization is a required program activity.

National Programs to Reduce Youth Access to Tobacco

In 1996, SAMHSA issued regulations to implement the Synar Legislation. These regulations and the provisions of the Synar Amendment to the 1992 ADAMHA (Alcohol, Drug Abuse, and Mental Health Administration) Reorganization Act established a nationwide effort to reduce youth access to tobacco by requiring states to have and enforce laws prohibiting the sale of tobacco products to anyone under age 18. Failure to meet the requirements of the Synar legislation could result in penalties against a state's Substance Abuse Prevention and Treatment Block Grant. The full discussion of the state efforts to meet these requirements is provided in Chapter 5. By establishing a coordinated program in all 50 states and the District of Columbia to address this problem, SAMHSA has provided a core resource to the tobacco control effort across this country.

In 1996, the Food and Drug Administration (FDA) issued a rule mandating that tobacco retailers not sell tobacco to anyone under age 18 and that they require a picture identification card from anyone under the age of 27 who attempts to purchase tobacco (Federal Register 1996). In support of this rule, the FDA entered into contracts with state agencies to institute compliance checks of retailers and has implemented mass media and direct education campaigns to inform retailers of this rule. However, the March 21, 2000, ruling of the United States Supreme Court held that

the FDA lacks jurisdiction to regulate tobacco products as customarily marketed. Following this decision, the FDA immediately began the process of terminating the contracts with state agencies and shutting down its enforcement program. The full discussion of this program is provided in Chapter 5.

States Currently Funded in the Nationwide Program to Reduce Tobacco Use

In 1998, 49 state health departments and the District of Columbia received funding from the USDHHS for activities to reduce tobacco use. The NCI's ASSIST project provided 17 states with approximately \$21.5 million, and the CDC's IMPACT program funded 32 states and the District of Columbia with approximately \$12 million. In February 1998, the CDC and the NCI were given joint responsibility to assist states and national organizations in amalgamating the findings of comprehensive research projects, the CDC and NCI programs, and the state and local programs funded by tax initiatives and legal settlements with the tobacco industry. This process will continue the evaluation of a national program that includes all states, the District of Columbia, territories, and tribes and aims to bring synchrony and coherence to the efforts of all groups working to reduce tobacco use.

In May 1999, the CDC launched the National Tobacco Control Program (NTCP) transitioning funding through various federal initiatives into one national program. The purpose of the NTCP is to build and maintain a coordinated national effort to reduce the health and economic burden of tobacco use. Federal funding is intended to support core public health tobacco control functions or to enhance existing tobacco control programs within state and territorial health departments. The program framework is based on the comprehensive tobacco control framework outlined earlier in the chapter (see "Description of Comprehensive Programs"). The NTCP funds tobacco control programs in all states, the District of Columbia, and seven U.S. territories. The NTCP also includes initiatives to fund American Indian tribal organizations to develop or improve tobacco-related regional resource networks and outreach to tribes. In 2000, the NTCP launched a new initiative to aid in the elimination of disparities in health status and outcomes among populations as it relates to tobacco use. In fiscal year 1999, the NTCP awarded \$50 million to 50 states, the District of Columbia, and seven territories for a five-year cooperative agreement starting June 1, 1999, to May 30, 2004. In fiscal year 2000, funding to the states, the District of Columbia, and territories totaled \$59 million. The average award for states and the District of Columbia is \$1.13 million. The average award for territories is \$140,000. The total includes supplemental awards of \$499,400 for asthma and ETS, funded in conjunction with the Environmental Protection Agency, and \$244,000 for Smoke-Free Kids and Soccer. The state awards almost close the funding gap between the former NCI-funded states (ASSIST) and the other states. States with excise tax or settlement-funded programs are required to match federal funds 4 to 1. For all others, the match is 1 to 10.

Examples of Major State Programs

State coalitions have encouraged both legislation and voters' initiatives to raise state excise tax levels on tobacco products and earmark some portion of the new revenue for tobacco prevention and control programs (Shultz et al. 1986; Nicholl 1998). In 1985, the Minnesota Coalition for a Smoke-Free Society 2000 led a legislative effort that was the first to pass tobacco use prevention legislation that centered on an increase in the state cigarette excise tax. Since 1985, more than 40 other states have increased their excise tax on cigarettes; as part of the appropriations process, some of these states have also funded selected tobacco control activities with this revenue increase. One such state— Maine—in May 1997 legislated an excise tax increase that earmarked funds for a more comprehensive tobacco control program.

In some states, voters' initiative process, rather than the legislative process, has been the primary mechanism by which new revenue from an excise tax increase of tobacco products has been earmarked for tobacco prevention. Voters in 24 states and the District of Columbia are permitted to sign petitions that place a proposed law on the state ballot for referendum (Nicholl 1996). Since 1988, in eight such states, coalitions have tried to use the voters' initiative process to fund statewide tobacco control programs. State coalitions were successful in winning voter approval in four of these states: California in 1988, Massachusetts in 1992, Arizona in 1994, and Oregon in 1996. Initiatives were unsuccessful in Montana (1990), Nebraska (1992), Arkansas (1992), and Colorado (1994) (Moon et al. 1993; Ross 1996; Nicholl 1998).

The four state programs funded by successful voters' initiatives are described in the next sections of this chapter. They follow discussions of the two state programs (in Minnesota and Maine) that were established by legislated appropriations for a comprehensive tobacco control plan.

Minnesota

In 1975, Minnesota was one of the first states that passed statewide comprehensive legislation for clean indoor air. In 1983, the Commissioner of Health formed the Center for Nonsmoking and Health, which oversaw the development of *The Minnesota Plan for Nonsmoking and Health* (Minnesota Department of Health 1984) by a multidisciplinary technical advisory committee in 1984. In that same year, nearly 30 public and private organizations within the state formed the Minnesota Coalition for a Smoke-Free Society 2000.

By drawing increased attention to the hazards of smoking and of ETS exposure, the Minnesota Department of Health, together with civic and community leaders, stimulated legislation to implement the recommendations of The Minnesota Plan for Nonsmoking and Health. The legislative history and debate surrounding the passage of the resulting 1985 comprehensive legislation for preventing tobacco use have been summarized by Shultz and colleagues (1986). The legislation provided for an increase in the state cigarette excise tax from \$0.18 to \$0.23, with one cent of the revenue increase earmarked for a public health fund, approximately one-half of which was to be set aside for preventing tobacco use. Further, this legislation authorized the Commissioner of Health to launch a major statewide initiative—the Minnesota Tobacco-Use Prevention Initiative—to promote nonsmoking and established state aid for school-based programs to prevent tobacco use.

The legislation allocated funding to support the school-based programs at the rate of \$0.52 per student during the 1985–1986 school year and \$0.54 per student during future years. School districts were authorized to use these new funds for staff in-service training, curricula and materials, community and parent awareness programs, and evaluation.

Three principles guided the state's tobacco control programs. First, a broad base of public support was developed by the collaboration of the Minnesota Coalition for a Smoke-Free Society 2000, the Association for Nonsmokers—Minnesota, voluntary health agencies, health professionals, and insurers. Second, the program maintained a positive approach that stressed the consequences of tobacco use rather than attacked the tobacco industry or blamed smokers. Third, the program focused on preventing tobacco use among adolescents and young women who had not yet become addicted to cigarettes or smokeless tobacco.

The mass media campaigns were the most visible component. The campaigns included paid television, radio, and outdoor/transit advertising directed at two target populations: 12- to 13-year-old boys and girls and 18- to 24-year-old women. The goal of the media campaign was to change a social climate that encouraged the use of tobacco. Advertisements focused on increasing the awareness of the negative aspects of tobacco use that are most important to young people—unpleasant social and personal consequences, such as bad breath, smelly clothes, and addiction.

To foster community tobacco control programs, *The Minnesota Plan for Nonsmoking and Health* recommended that schools, health services, and other community organizations be involved in providing prevention and education programs about tobacco use. A granting program was established in 1986 to fund 21 proposals from local organizations that could demonstrate a coordinated approach for involving multiple local organizations in the prevention effort. A second cycle of local projects was funded in 1988.

Schools throughout the state were involved in an intensive effort to plan, implement, and evaluate effective programs for students from kindergarten (K) to grade 12 and in technical institutes. Since the start of these programs in the 1986–1987 school year, the percentage of school districts addressing smoking in grades K–4 steadily increased but remained fairly constant in grades 5–10. The number of school districts in the state with a tobacco-free policy, however, steadily increased.

Each of the main program elements funded by the Minnesota Tobacco-Use Prevention Initiative has been evaluated (Minnesota Department of Health 1989, 1991). Youth and adults targeted by the program were aware of the media campaign, and the evaluation data suggested that the campaign improved young people's attitudes toward tobacco use (Minnesota Department of Health 1991). There was a steady increase in the number of school districts whose curricula included components for preventing tobacco use (Minnesota Department of Health 1991). Nonetheless, a prospective study indicated that schools using the prevention curricula were not more effective in reducing adolescent tobacco use than were a randomized control group of schools (Murray et al. 1992). In that study, a comparison of trends in adolescent tobacco use in Minnesota and Wisconsin between 1986 and 1990 found a slightly larger (but nonsignificant) net decline in Minnesota. The investigators suggested that greater reach and penetration of preventive efforts may be required to produce statewide reductions in adolescent tobacco use (Murray et al. 1992).

California

In November 1988, the Tobacco Tax and Health Promotion Act (Proposition 99) was passed by California voters, thus mandating the start of California's Tobacco Control Program. The program is the largest and most comprehensive undertaken in the United States to reduce tobacco use. Initially, the program defined three long-term objectives: (1) to reduce the initiation of cigarette smoking by children and youth under age 19 from the 1987 rate of 26.4 percent to no more than 6.5 percent by 1999, (2) to reduce cigarette smoking among adults aged 20 years and older from the 1987 rate of 26.0 percent to 6.5 percent by 1999, and (3) to reduce smokeless tobacco use among males aged 12-24 years from the 1987 rate of 8.9 percent to no more than 2.2 percent by 1999 (Tobacco Education Oversight Committee 1991). The excise tax rate on cigarettes in California rose from \$0.10 to \$0.35 on January 1, 1989, when Proposition 99 was implemented. On January 1, 1994, the tax increased to \$0.37, where it remained in 1999. Funding for tobacco control efforts began during fiscal year 1989 (July 1989-June 1990). The fiscal year 1999 budget in California was \$126.8 million (\$3.90 per capita) for tobacco control activities funded by the Department of Health Services and the Department of Education.

The NCI's planning framework (NCI 1991) was used to establish the program's target groups, intervention channels, and interventions to reach them (Bal et al. 1990). Community mobilization is a key part of California's extensive program for reducing tobacco use. Community-based programs are the responsibility of the California Department of Health Services and 61 local health departments (58 county and 3 city). These local agencies, advised by local coalitions, established multiple subcontracts with communitybased organizations to conduct events, programs, and presentations for diverse racial and ethnic groups (Tobacco Education Oversight Committee 1991). Local lead agencies have been a cornerstone of the program by mobilizing communities to eliminate exposure to ETS, by closing channels for minors' access to tobacco, and by advising local policymakers. The local lead agencies receive approximately 20 percent of funds allocated for education programs to achieve these ends.

The statewide media campaign, which receives about 12 percent of funds, has been the program's most visible element. Launched in 1990, the media campaign has focused primarily on changing public opinion to denormalize tobacco use. In particular, it has sought to raise public awareness of the tobacco industry's manipulative and deceptive marketing

tactics and of the dangers of ETS. Although young people are a direct target audience for some campaign messages, the campaign has focused more on changing social norms and reducing adult tobacco use to influence youth, many of whom begin using tobacco to be more adultlike. Funding for the statewide media campaign was about \$24 million (\$0.75 per capita) in 1998 but has varied considerably over the years, as is discussed later in this section.

About 16 percent of education funds are spent on competitive grants to community-based organizations. More than two-thirds of these grants have targeted racial and ethnic minority communities. The competitive grants program has had multiple funding cycles, and 46 separate projects were funded in 1993. In addition, the competitive grants program funds several statewide projects, such as the Tobacco Education Clearinghouse of California, which distributes library and video materials, and the California Tobacco Control Resource Partnership, which provides technical assistance and training to local lead agencies. The competitive grants program has also been used to establish regional linkages among local governments and local nongovernmental organizations. Twenty-four percent of the education funds go to school-based programs to prevent tobacco use and are distributed through the California Department of Education. The project estimated that it would reach approximately 350,000 students through programs implemented between 1994 and 1996.

The single largest share, by far, of the education funds—59 percent through 1996—goes to the medical care programs. This percentage is notably higher than the 45 percent specified by the legislation (Novotny and Siegel 1996). As a result of this redistribution, the portions of the program that deal with reducing tobacco use—designated for 20 percent of the fund have never been fully financed. In the first year, 16.5 percent of funds were allocated for such program efforts; in the second cycle, 12 percent were allocated; in the third, 10 percent. This diversion of funds was the result of executive decisions and was strongly supported by the tobacco industry and the California Medical Association. After the third diversion, civil action was initiated by Americans for Nonsmokers' Rights, supported by the American Lung Association and the ACS, to prevent the reallocation. The Sacramento Superior Court found in favor of the plaintiffs in early 1995. The state appealed, and the judgment for the plaintiffs was upheld in December 1996 (Americans for Nonsmokers' Rights v. State of California).

The complicated course of these events, as detailed by Novotny and Siegel (1996), has highlighted

the role of the tobacco industry in countering efforts to reduce the use of its products and the opposing strategy of health advocates. Begay and colleagues (1993) have pointed out that since Proposition 99 passed, the tobacco industry's political expenditures in California have risen tenfold, from \$790,050 in the 1985–1986 election to \$7,615,091 in the 1991-1992 election, during which the tobacco industry contributed more heavily to candidates for the California legislature than to candidates for the U.S. Congress. In a further analysis, this same research group (Traynor et al. 1993) detailed the specific industry strategies to prevent local control of tobacco use. Using case studies, they documented the industry's use of front groups to conceal its involvement, its organization of local referenda to defeat or suspend local ordinances, and its financing of local election campaigns to repeal ordinances by popular vote. Glantz and Begay (1994) have also analyzed the relationship between campaign contributions and votes on individual tobacco-related bills in the California legislature. Using a "tobacco policy score" (p. 1178) that ranked legislators according to their stance for or against reducing tobacco use, they found a significant relationship between the amount of money received from tobacco sources and a protobacco position. This ongoing documentation of tobacco industry influence, though not a formal part of the California Tobacco Control Program, has been one of its notable features, and it provides a model of health advocacy for other states and localities.

The program, which has evolved considerably since 1989, remains a multifocal, multichannel approach to the broad range of issues that confront large-scale efforts to reduce tobacco use (Tobacco Education and Research Oversight Committee 1995; Pierce et al. 1998a). In 1993, the California Tobacco Control Program was revised, and program priorities were refocused (Pierce et al. 1998a). Four broad priority areas, or policy themes, were established for use in the program planning and funding decisions:

- Protecting people from exposure to ETS.
- Revealing and countering tobacco industry influence.
- Reducing young people's access to tobacco products.
- Providing cessation services.

The California Tobacco Control Program continues to place its primary emphasis on a broad statewide infrastructure that reaches into communities across the state. The program's basic structure is composed of a

state-level office and several statewide and regional programs that foster a collaborative grassroots approach to serve a decentralized structure of community programs across the state (Pierce et al. 1998a).

Surveillance and evaluation activities to assess program performance and impact were established as part of the initial program structure (Bal et al. 1990; Tobacco Education Oversight Committee 1991). The evaluation is composed of large triennial surveys (Pierce et al. 1994, 1998a) and smaller ongoing surveys (Pierce et al. 1998b), a more targeted evaluation of program components (Independent Evaluation Consortium 1998), and a wide array of local program evaluation efforts. Evaluation is complicated, however, by the multiplicity of prevalence surveys available and by potential error from using data from surveys with differing methods (Novotny and Siegel 1996; Siegel et al. 2000). Establishing specific relationships between large-scale social interventions and a change in tobacco use is difficult, but the temporal relationship between the decline in California's tobacco consumption and the efforts generated by Proposition 99 can be clearly observed.

Per Capita Cigarette Consumption

Before the implementation of the program in 1989, the rate of decline in monthly per capita cigarette consumption was 0.42 packs, which was significantly greater than the rate of 0.36 in the rest of the country (Pierce et al. 1998a,b). From January 1989 through December 1993, the decline in California increased significantly, to 0.65 packs, while the decline in the rest of the United States increased nonsignificantly, to 0.45 packs. Until early 1992, the media program was the only part of the tobacco control program that was fully implemented. An econometric analysis (Hu et al. 1995) has estimated that of the 1,051-million pack decrease in sales between 1990 and 1992, approximately 232 million (22 percent) were attributed to the media campaign and the remaining 819 million (78 percent) to the excise tax increase. Between 1993 and 1996, the rate of decline in per capita consumption in California slowed significantly, to 0.17, but virtually halted altogether in the rest of the country (at 0.04 packs) (Pierce et al. 1998b). Consumption decreased more rapidly in California than in the rest of the country, even though the California cigarette excise tax changed only slightly during this period (from \$0.35) in 1993 to \$0.37 in 1994). Between 1993 and 1996, however, expenditures for tobacco control were reduced by more than 50 percent from their initial funding levels in fiscal year 1990 and 1991. During 1989-1993, spending for advertising and promotions by the tobacco industry exceeded tobacco control expenditures in California by a ratio of about 5 to 1; from 1993 to 1996, that ratio increased to nearly 10 to 1 (Pierce et al. 1998b).

Adult Smoking Prevalence

Data on adult patterns of smoking prevalence are not as consistent or as easy to evaluate as consumption trends (Novotny and Siegel 1996). Nevertheless, the trends in these data are consistent with the patterns noted in the per capita consumption analyses. From 1989 to 1993, smoking prevalence declined in California almost twice as rapidly as in the rest of the country (Pierce et al. 1998b). However, from 1994 to 1997, the rate of decline in California appeared to slow. Overall, smoking prevalence has declined from 26.7 percent in 1988 to 16.7 percent in 1995 in California and from 30.2 percent in 1988 to 24.7 percent in 1995 in the rest of the country (CDC 1996; Pierce et al. 1998b). A recent analysis of trends in adult prevalence of smoking in California compared with the rest of the United States observed a significant decline in smoking prevalence in California from 1985 to 1990 and a slower but still significant decline from 1990 to 1994, a period in which there was no significant decline in the remainder of the nation (Siegel et al. 2000).

Youth Tobacco Use Prevalence

The lack of consistent youth smoking surveillance data between California and other states has impeded the evaluation of program impact on tobacco use among young people in California. However, one multivariate analysis of data from the school-based Monitoring the Future survey of 8th-, 10th-, and 12thgrade students showed that from 1992 to 1994, the increase in youth smoking rates that was experienced nationwide was slowed significantly in California (P < 0.001, controlling for price, smoking policies, andother nonprogram effects) as a result of the combined effect of the tax increase in 1994 and the implementation of the state's tobacco control programs (Chaloupka and Grossman 1996). Pierce and colleagues (1994) have concluded that the media campaign was successful in stopping the rise in teen smoking that had been occurring in California before the campaign launch.

Results from other analyses of youth tobacco use data are consistent with the result found by Chaloupka and Grossman (1996). In data reported by the California Independent Evaluation Consortium, between 1991 and 1996, rates of smoking during the past 30 days among California youth in the 8th and 10th grades in the Monitoring the Future survey increased, but the

increase in California was less pronounced than in other states (Independent Evaluation Consortium 1998). Among 8th-grade youth, since 1993 the prevalence of smoking during the past month has varied from 12 to 14 percent in California while steadily increasing from 17 to 22 percent in the rest of the country. Similarly, among 10th-grade youth, past-month smoking prevalence in California has been about 18 to 19 percent since 1992 while increasing from 22 to 32 percent in the rest of the country. Data from the telephone-based California Youth Tobacco Survey indicate that the prevalence of smoking during the past 30 days among 12- to 17-year-olds increased from approximately 9 percent in the early 1990s to 11.9 percent in 1995. Prevalence declined gradually after 1995, to 10.9 percent in 1997, while increasing in the rest of the country (Pierce et al. 1998a).

Other Findings

Since the start of the program in 1990, numerous changes in intermediate outcomes have been noted related to changes in social norms; clean indoor air policies in public places, worksites, and bars; and voluntary policies to ban smoking in homes.

Massachusetts

In November 1992, Massachusetts voters approved an initiative petition known as Question 1, establishing the Health Protection Fund with revenue generated from a 25-cent increase in the state's cigarette excise tax and a 25-cent increase in the wholesale price of smokeless tobacco products. Revenues have been used to fund the Massachusetts Tobacco Control Program, a comprehensive set of activities and services that emphasize prevention programs at the local level and that focus on young people. The Massachusetts program was modeled, in part, on California's program. The overall goal of the program was to reduce tobacco use in Massachusetts by 50 percent by the end of 1999 (Abt Associates Inc. 1995). With the passage of Question 1, the excise tax on cigarettes in Massachusetts rose from \$0.26 to \$0.51 on January 1, 1993. This tax was fully absorbed by the industry through wholesale price reductions (CDC 1996). However, in October 1996 the cigarette tax increased to \$0.76 per pack (with comparable increases on smokeless tobacco products), where it currently remains.

Funding for tobacco control efforts began with a large media campaign in October 1993. In late 1993 and early 1994, funding for local agencies was begun, and several statewide initiatives were undertaken to provide direct services, as well as technical assistance,

training, and materials for localities. Starting in late 1994, with the first year of complete implementation, the program received \$43.1 million (33.7 percent) of the \$127.8 million placed in the Health Promotion Fund created by the revenues from the excise tax increase. Other key programs receiving appropriations from the Health Promotion Fund were those for comprehensive school health education (\$28.8 million, or 22.5 percent of the Health Promotion Fund in fiscal year 1995), drug education (\$5.0 million, or 3.9 percent), and other health-related programs (\$50.7 million, or 39.7 percent) (Abt Associates Inc. 1995). After the first funding year, the program's budget declined to \$41.8 million in 1995-1996 and to \$36.8 million in 1996–1997. Funding was increased for other programs receiving appropriations from the Health Promotion Fund (Abt Associates Inc. 1997).

Community-based education activities and prevention activities are two main elements of the Massachusetts program. The state's 10 regionally based, primary care Prevention Centers have added a component for reducing tobacco use and provide ongoing technical assistance and training to local community programs. Local community initiatives have included programs to increase community awareness about the hazards of tobacco use, to promote tobacco-free workplaces and public facilities, and to enforce local regulations and ordinances for reducing tobacco use; needs assessments in the community; mobilization of youth service agencies to prevent and reduce tobacco use among children and adolescents; funding of community-based agencies to work with at-risk adult populations, including cultural and linguistic minority groups, women of childbearing age, and blue-collar workers; and funding of school-based health centers (Abt Associates Inc. 1995).

Per Capita Cigarette Consumption

As in California, Massachusetts has experienced a persistent pattern of decline in per capita cigarette consumption. Before the 1993 implementation of these tobacco control programs, per capita cigarette consumption was declining in Massachusetts at a rate approximately equivalent to that of the rest of the country (6.4 percent in Massachusetts and 5.8 percent in the states other than California [CDC 1996]). Between 1992 and 1997, per capita consumption in Massachusetts declined by 31 percent (from 117 to 81 packs per adult), while the decline in the remaining 48 states was only 8 percent (Abt Associates Inc. 1997). Between 1993 and 1996, the decline in per capita consumption has been more consistent in Massachusetts than in California (CDC 1996). Although program funding declined about

15 percent in Massachusetts from 1995–1996 to 1996–1997 (Abt Associates Inc. 1997), it declined less than in California.

Adult Smoking Prevalence

Adult smoking prevalence has been monitored in Massachusetts both by the annual survey conducted through the Behavioral Risk Factor Surveillance System (BRFSS) and by special Massachusetts Adult Tobacco Surveys conducted in 1993, 1996, and 1997. Data from the BRFSS indicate that adult smoking prevalence in Massachusetts declined from an average of 23.5 percent for 1990–1992 to 20.6 percent in 1997. In the rest of the country (excluding California), prevalence declined from 24.1 percent in 1990-1992 to 23.4 percent in 1993-1995 (CDC 1996; Abt Associates Inc. 1997). The Massachusetts survey produced different prevalence estimates but corroborated a similar decline in the prevalence of smoking among adults in Massachusetts (from 22.6 percent in 1993 to 21.1 percent in 1996 and 20.6 percent in 1997) (Abt Associates Inc. 1997).

Youth Tobacco Use Prevalence

As in California, the observed nationwide increase in the prevalence of smoking among young people from 1992 to 1994 was significantly less evident in Massachusetts (Chaloupka and Grossman 1996). Follow-up data from the Youth Risk Behavior Survey (YRBS) indicated that the prevalence of current smoking among Massachusetts high school students (grades 9 to 12) declined from 35.7 percent in 1995 to 34.4 percent in 1997 while increasing from 34.4 to 36.4 percent nationwide (CDC 1996, 1998). Data from the YRBS and other survey sources suggest a differential pattern by age: the prevalence of current smoking increased in Massachusetts among older students in a manner similar to that of the rest of the country but declined among younger students. Between 1993 and 1996, the prevalence of smoking during the past 30 days among 8th-grade students in Massachusetts declined from 26.5 to 26.0 percent but increased from 16.7 to 21.0 percent nationwide (Briton et al. 1997). For Massachusetts, the prevalence of current smokeless tobacco use among 9th-12th graders decreased from 8.4 percent in 1995 to 6.0 percent in 1997; for males, the decline was from 15.1 to 10.3 percent (Kann et al. 1998). In the nation as a whole between 1993 and 1996, lifetime use of smokeless tobacco among 9th-12th graders decreased from 25 to 20 percent, and current use decreased from 9 to 6 percent (Briton et al. 1997). The most recent data from the 1999 YRBS in Massachusetts indicated a continuing decline in the prevalence of current smoking, down to 30.3 percent among 9th–12th graders (Goodenow 2000); however, national comparison data for 1999 are not yet available.

A 1996 survey of 12- to 14-year-olds in Massachusetts and a national comparison sample (Houston Herstek Favat, Youth exploratory 1996, Massachusetts Department of Public Health, presentation of findings, unpublished data) found that Massachusetts youth had significantly higher levels of agreement with issues addressed in the state media campaign. For example, 59 percent of Massachusetts youth but only 35 percent of youth in the national sample agreed with the statement, "Smoking cigarettes decreases your stamina and smokers have a hard time keeping up in sports." Results from a longitudinal survey of Massachusetts youth provided additional support for the efficacy of the Massachusetts antismoking media campaign (Siegel and Biener 2000). In a four-year follow-up of youth aged 12 to 15 years in 1993, this study found that among the younger adolescents (aged 12 to 13 years at baseline), those exposed to antismoking advertisements were significantly less likely to progress to established smoking. However, among older adolescents (aged 14 to 15 years at baseline), exposure did not prevent progression to established smoking.

Other Findings

There have been multiple changes in intermediate measures of program impacts related to youth access, protection of nonsmokers from ETS, and availability of cessation services (Abt Associates Inc. 1999). For example, by 1999, nearly two-thirds of Massachusetts residents lived in cities and towns with some kind of smoking restriction in restaurants, and 26 percent were protected by complete bans. Prior to the start of the program, less than 1 percent of Massachusetts residents lived in towns with complete bans. Additionally, the local restaurant smoking restrictions were found to be more restrictive in communities receiving funding from the Massachusetts Tobacco Control Program.

Arizona

In November 1994, Arizona voters passed Proposition 200, which increased the state cigarette excise tax from \$0.18 to \$0.58. Revenues from the tax increase were earmarked for the state's Medicaid program (70 percent of revenues), for programs for preventing and reducing tobacco use (23 percent), for research on prevention and treatment of tobacco-related disease and addiction (5 percent), and for an "adjustment account" (Arizona Tobacco Tax and Health Care Act 1994, sec. 2C4) to offset lost revenue to other state programs

currently funded by revenue from the existing \$0.18 excise tax (2 percent). The petition drive to place the initiative on the November 1994 state ballot and the campaign to win voter approval was led by the Arizona for a Healthy Future coalition. Although public support for the initiative was strong when it was first proposed in 1993 (71 percent in favor, with 56 percent indicating strong support), the initiative was vigorously opposed in a well-funded advertising effort on television, in posters, and by direct mail. Proposition 200 was narrowly approved, garnering approximately 51 percent of the vote (Nicholl 1998).

With the passage of Proposition 200, analysts estimated that the revenues earmarked for tobacco prevention and education programs would be approximately \$25 million per year (Meister 1998). However, measures passed during the 1995 session gave the legislature control over the funds and limited expenditures to \$10 million per year (Madonna 1998). Additionally, multiple restrictions were placed on how the funds could be used, and an advisory committee was appointed that included legislative and business representatives hostile to the program (Meister 1998). Although the Coalition for Tobacco-Free Arizona led an effort to keep the goals of the newly created Arizona Tobacco Education and Prevention Program (AzTEPP) "comprehensive," the program efforts were narrowed to a focus on youth prevention; adult cessation activities were restricted to pregnant women and their partners. Not until the fiscal year that began on July 1, 1997, with a new governor and health department director, were the programmatic restrictions lifted from the health department and the program allowed to proceed with the implementation of the "draft" comprehensive tobacco control plan originally proposed by the Coalition for Tobacco-Free Arizona.

The expenditures of AzTEPP reflect the political history of the program: \$9.7 million in fiscal year 1996, \$18.2 million in 1997, and \$28.2 million in 1998. Although the countermarketing campaign has expanded (with spending increasing from \$7.4 million in 1996 to \$13.2 million in 1998) (Riester and Linton 1988), the greatest expansion in the program has been in the scope and focus of the local programs (Meister 1998) (with funding increasing from \$1.7 million in 1996 to \$9.4 million in 1998). Recent program efforts have focused on all of the elements in the coalition's draft comprehensive tobacco control plan (Meister 1998), thereby expanding its adult cessation activities (discussed at the fourth annual AzTEPP meeting in February 1999), but one of the factors that had been minimized in early health department efforts was

evaluation. Only recently have baseline data collection surveys been initiated (Meister 1998); as a result, no outcome data have been reported on the program, and subsequent evaluation efforts will be compromised by the lack of baseline data collected before the start of the multiple large-scale program efforts.

Respondents to an initial statewide telephone survey conducted in 1998 (Arizona Cancer Center 1998), about two and a half years after the media campaign's launch, reported that the advertising campaign, which stressed how damaging tobacco use is and how unappealing it is to the user, to peers, and to the opposite sex, had influenced their attitudes in the intended direction. For example, 80 percent of young people reported that the advertisements made them think about the negative aspects of tobacco use, and 58 percent of pregnant or postpartum women said the advertisements made them uncomfortable around smokers. Young people who had been exposed to the television advertisements in the previous 30 days were less likely to be susceptible to using tobacco than were youth who had not seen the advertisements. The campaign's impact on reported behaviors is less clear, especially among young people. Among respondents who were using tobacco at the start of the campaign, 23 percent of adults, 37 percent of pregnant or postpartum women, and 27 percent of young people said the advertising campaign had convinced them to try quitting. However, 23 percent of young people also reported that the campaign had convinced them to increase their tobacco use. Cummings and Clarke (1998) noted that such an unintended effect, if it is real, might represent young smokers' negative reaction to a narrowly focused youth campaign with no messages directed at changing broader social norms.

In response to a request from the Arizona Joint Legislative Audit Committee, the State Auditor General conducted a performance audit of the AzTEPP (State of Arizona, Office of the Auditor General 1999). This audit noted that evaluations of the state and local levels of programs have not yet produced an adequate assessment of the program's tobacco control efforts. Thus, the audit recommended that the program needed to improve its evaluations to measure its effectiveness in preventing youth from starting to use tobacco, encouraging and assisting tobacco users to quit, and reducing exposure to secondhand smoke. Specifically, the audit found that the program had been unable to establish a baseline on tobacco use among youth and had only preliminary assessments in place to assess cessation services. The program has established adequate methodologies to measure the prevalence of adult smoking; however, follow-up results are not yet available. Thus, the audit concluded that "The program's evaluation approach to date leaves it far short of knowing whether its programs are working" (p-ii).

In response to this audit, the Arizona Department of Health Services (AzDOHS) has implemented changes in its surveillance and evaluation systems. Expanded surveillance systems for youth have been planned and will be implemented in 2000; however, no baseline data are available on youth smoking rates. For adults, a baseline survey of adults was conducted in 1996 and repeated in 1999. Using methodology similar to that used by the state BRFSS, the 1996 and 1999 Arizona Adult Tobacco Surveys were conducted by telephone interviews on representative samples of more than 4,500 adults in Arizona aged 18 years and older. Results from these surveys indicate that the prevalence of smoking among adults declined from 23.8 percent to 18.8 percent overall (AzDOHS 2000). Among adults aged 18 to 24 years, a significant decline was observed also, from 27.5 percent in 1996 to 21.0 percent in 1999. Both of these rates compare very favorably to national trends, where rates overall among adults have not declined in recent years and rates among younger adults have been increasing. Finally, smoking rates among Hispanics declined from 23.5 percent to 14.6 percent, which was the largest decline seen in any race/ethnic group in the state. Multiple other indicator variables suggest that these changes may be related to increases in smoke-free policies, advice from doctors and dentists, and exposure to television antismoking information. Finally, these declines in smoking prevalence are consistent with declines in per capita sales (Orzechowski and Walker 2000) that indicate that declines in Arizona since 1996 are larger than those observed in the rest of the country.

Oregon

On November 5, 1996, Oregon voters approved Measure 44, raising the state cigarette excise tax from \$0.38 to \$0.68 (with a proportional increase in the tax rate on other tobacco products) and designating 90 percent of the increased revenue for the Oregon Health Plan (to expand insurance for medically underserved state residents) and the remaining 10 percent for a statewide tobacco prevention and education program managed by the Oregon Health Division. Survey data indicated that support for the initiative was increased by having the new revenue earmarked in this way (CDC 1997; Nicholl 1998). The Oregon campaign to place the initiative on the November 1996 ballot was initially led by the Committee to Support the Oregon Health Plan, which represented

primarily the private health care sector. Nonprofit and public health organizations added their support and worked in a loosely organized network led by the ACS. Later in the campaign, both groups combined efforts and resources. The measure had strong support from state media (receiving endorsements from all major newspapers and a majority of the smaller ones), from leading business groups, and from the governor, who conducted a three-day supportive media tour before the election.

The Oregon Health Division used its existing Oregon Tobacco Control Plan as the model for the new statewide program. Revenue from Measure 44 during the 1997–1999 biennium was projected to be \$170 million; of this, 10 percent (approximately \$17 million) per biennium was appropriated to fund the Tobacco Use Reduction Account administered by the Oregon Health Division. The resulting Oregon Tobacco Prevention and Education Program has eight elements: (1) local community-based coalitions, (2) comprehensive school-based programs, (3) statewide public awareness and education campaigns, (4) a cessation help line, (5) tribal tobacco prevention programs, (6) multicultural outreach and education, (7) demonstration and innovation projects, and (8) statewide leadership, coordination, and evaluation.

The 1997–1999 biennium budget for these eight elements is combined into five categories: (1) local coalitions—\$6.5 million (38 percent), (2) public awareness and education—\$4.6 million (27 percent), (3) statewide and regional projects—\$2.75 million (16 percent), (4) schools—\$2 million (12 percent), and (5) statewide coordination and evaluation—\$1.2 million (7 percent).

Evaluation data from Oregon indicate that the program has successfully implemented each of the program elements and is achieving its performance objectives (Oregon Health Division 1999). Local community-based coalitions were created in all 36 Oregon counties. Twenty-four school projects were funded, reaching 58 of the 198 (30 percent) school districts in the state. Surveys indicated that approximately 75 percent of adults and 84 percent of the young people recalled seeing the state's public awareness campaign. In January 1999, more than 1,500 Oregonians called the cessation help line. All nine federally recognized Indian tribes in Oregon are now receiving funding to implement prevention and education programs to reduce tobacco use. Multicultural outreach and education programs have been established for Hispanic, Asian/Pacific Islander, and African American populations in Oregon. Five demonstration projects have been funded focusing on pregnant women, health care delivery systems, and creative ways to reach youth audiences. The program has also established a comprehensive and multifaceted surveillance and evaluation system and has strengthened program management.

Trends in per capita consumption in Oregon were compared with the remainder of the country (excluding California, Massachusetts, and Arizona) for the period before program implementation (1993–1996) and after (1997–1998). From 1993 to 1996, consumption increased 2.2 percent in Oregon and decreased 0.6 percent in the rest of the country (CDC 1999b). In 1997 and 1998, per capita consumption declined 11.3 percent in Oregon (from 92 to 82 packs per adult). Between 1996 and 1997, per capita consumption in the rest of the country declined only 1.0 percent (from 93 packs per adult to 92 packs per adult).

Smoking prevalence among adults in Oregon has been consistent with the observed declines in per capita consumption. Data from the BRFSS indicate that the prevalence of smoking among adults aged 18 years and older in Oregon declined from 23.4 percent in 1996 to 21.9 percent in 1998 (Oregon Tobacco Prevention and Education Program 1999). The proportion of women who smoked during pregnancy, as reported on state birth certificates, dropped from 17.7 percent in 1996 to 15.2 percent in 1998. Data suggest that smoking rates among young people are continuing to increase as in the rest of the country.

Maine

In June 1997, the Maine legislature approved H.P. 1357, An Act to Discourage Smoking, Provide Tax Relief and Improve the Health of Maine Citizens, which increased the state cigarette excise tax from \$0.37 to \$0.74 and earmarked the increased revenue for the Tobacco Tax Relief Fund. The act established the Tobacco Prevention and Control Program within the Maine Bureau of Health and provided \$3.5 million in funding for fiscal years 1998 and 1999. The legislative effort to gain passage of the act was a combined effort of the state public health community, legislative leadership, and executive branch support.

The Bureau of Health has developed the Maine Tobacco Prevention and Control Program to expand the existing ASSIST program structure and to meet the legislative requirement of the 1997 state statute. The legislation specified that the program include an ongoing, major media campaign; grants for funding community-based programs; program surveillance and evaluation; and law enforcement efforts regarding transportation, distribution, and sale of tobacco products. The program's initial \$4.35 million annual

budget included \$1.6 million for a multimedia campaign, \$1.25 million for community and school grants, \$625,000 for statewide cross-cutting activities, \$400,000 for state staffing, \$400,000 for evaluation, and \$75,000 for enforcing youth access provisions.

In April 2000, legislation was passed in Maine that appropriated additional funds to expand the Maine Tobacco Prevention and Control Program; a total of \$18.3 million from the settlement is going to tobacco control. Of this total amount, \$8.35 million will be used for community and school-based grants, funding communities and schools to achieve the goal of reducing tobacco addiction and use and resulting disease, with a focus on those at highest risk such as youth and disadvantaged populations. About \$6.75 million will be used for cessation and statewide multimedia campaigns; \$1.2 million is for evaluation for independent program evaluation, research, and outcomes monitoring; \$200,000 funds five positions in the Bureau of Health for administering the programs; and \$1.8 million for improved prevention and treatment of tobacco-related diseases for those with Medicaid Insurance.

Programs Funded by State Settlements With the Tobacco Industry

As was discussed earlier in this report (see "Legislative Developments" and "Master Settlement Agreement" in Chapter 5), all 50 states, the District of Columbia, and five commonwealths and territories have settled lawsuits with the tobacco industry to reclaim statewide costs spent treating Medicaid patients for diseases related to tobacco use. Four of those states settled their individual lawsuits with the industry—Mississippi in July 1997, Florida in September 1997, Texas in January 1998, and Minnesota in May 1998—and the remaining parties jointly settled in November 1998 in the multistate Master Settlement Agreement.

Because of a "most favored nation" clause (explained in "Recovery Claims by Third-Party Health Care Payers" in Chapter 5), the four separate settlements have been closely linked, particularly in how the terms of their awards affect the kind of comprehensive programs discussed in this chapter. Most notably, when the State of Florida received in its settlement \$200 million that was earmarked for a two-year pilot program to reduce tobacco use among young people, the State of Mississippi, though it had settled its lawsuit earlier, received \$62 million for the same type of pilot program specified in its lawsuit. Texas and Minnesota received no such additional

award, because their lawsuits did not specifically set aside funds for a parallel pilot program, although Minnesota received funds earmarked for smoking cessation and tobacco-related research. Language in the Texas and Minnesota settlements, however, released Florida and Mississippi from existing requirements to use their pilot program funding within two years and to direct their programs exclusively to young people.

Because program planning in Florida and Mississippi was already in place when the youth-only restriction was removed, an emphasis on preventing tobacco use among young people has been evident in their pilot programs' first years of activities. These activities are described in the next two sections of this chapter. Brief descriptions of settlement-funded plans in Texas and Minnesota follow. This report does not attempt to describe the various plans and legislative proposals that are developing (at the time of this writing) in the 46 states, the District of Columbia, and the five commonwealths and territories included in the joint settlement of January 1998.

Mississippi

The Partnership for a Healthy Mississippi, a nonprofit corporation representing a broad range of public and private interests, plans and manages the state's pilot program. The program's mission is to create a youth-centered, statewide collaboration dedicated to fostering a healthier Mississippi and eliminating tobacco use among Mississippi youth. The partnership will award grants in five designated areas: (1) community/school/youth activities and partnerships, (2) law enforcement, (3) public awareness, (4) health care services and research, and (5) evaluation.

In the first year, with a budget of \$23.7 million, approximately 25 community and youth partnership coalitions were funded, and more are planned for the second year. Local coalitions—one-quarter of whose membership must be young people—are among the statewide and regional organizations supported by community assistance statewide partner grants to provide training, tobacco prevention activities for racial and ethnic minority groups, and other technical assistance. Specific programs that have been funded by the partnership are 4-H Youth Programs, Frontline (an advocacy organization for 14- to 18-year-olds), comprehensive school health programs, and a comprehensive school health nurses pilot project. In the first two years, \$4 million has been allocated to these activities.

The law enforcement program has awarded grants to municipalities to enforce the Mississippi Juvenile Tobacco Access Prevention Act of 1997. These

awards will range (according to population size) from a minimum of \$5,000 per municipality to a maximum of \$250,000. A total of \$12.65 million has been budgeted over the first two years of the program for these awards. The grants will require municipalities to conduct periodic enforcement checks on the illegal sale of tobacco to minors, provide retailer education programs, provide education programs in schools, organize youth partnerships, and work with community coalitions on enforcement issues. Other enforcement activities are being performed statewide by the Mississippi Attorney General's Office.

The partnership has budgeted \$12.5 million for a countermarketing media campaign and other public awareness activities to be conducted during the first two years. The health care services and research component focuses on nicotine addiction and cessation among young people. An expenditure of \$5 million is anticipated for the first and second years for training health providers in cessation counseling, for researching childhood and adolescent tobacco abuse, and for coordinating cessation services in the state, including a telephone help line. The Mississippi State Department of Health will manage the evaluation of the pilot program and will focus on program effectiveness in preventing initial tobacco use among young people, helping young people quit smoking, and reducing young people's exposure to ETS. An expenditure of \$2 million is anticipated for the first and second years' evaluation activities.

Since 1998, the Partnership for a Healthy Mississippi has managed the pilot program to reduce youth tobacco use through a seven-member Board of Directors (www.healthy-miss.org) (McMillen et al. 1999). The major youth programs that have been implemented have included (1) the Reject All Tobacco (RAT) program among students in grades K–3, (2) the Students Working Against Tobacco (SWAT) Program for students in grades 4–7, and (3) the Frontline youth advocacy movement. Community programs have involved 26 community/youth partnership grants, targeted programs in collaboration with statewide organizations, and the school nurse program in 52 Mississippi school districts. Grants have funded 245 municipalities and 74 counties to empower the local law enforcement agencies to reduce sales to minors. Cessation services have included the Adolescent and Child Tobacco Treatment Center and a Mississippi Tobacco Quitline. Finally, a "Question It" public awareness campaign has focused on the 12- to 17-year-old audience.

The Mississippi State Department of Health has established a consortium of evaluation contracts involving multiple state universities to implement program evaluation efforts. The overall coordination is being managed by the Social Science Research Center at Mississippi State University, with the evaluation of the media component conducted by the University of Mississippi, community programs conducted by Jackson State University, law enforcement component by Mississippi State University, and the school nurses component by Mississippi State University (McMillen et al. 1999). A baseline Social Climate Survey of Tobacco Control and Tobacco Use was conducted in 1999 among 3,040 adults aged 18 years and older that provided benchmark data on several social norm intermediate indicator variables (McMillen et al. 1999). Surveillance of youth tobacco use patterns is being conducted by the Mississippi State Department of Health. The Youth Risk Behavior Survey was conducted among students in grades 9 to 12 in 1993, 1995, 1997, and 1999 and among students in grades 6 to 8 and 9 to 12 in 1998 and 1999. Results indicate that in Mississippi, smoking rates among students in grades 9 to 12 had been increasing, as in the rest of country, between 1993 and 1997 (Mississippi State Department of Health 2000). Between 1997 and 1999, smoking rates among students in grades 9 to 12 appear to have stopped increasing and leveled off. Among students in grades 6 to 8, smoking rates did not decline between 1998 and 1999.

Florida

Program planning and implementation initially were managed by the Governor's Office, with direct leadership provided by Governor Lawton Chiles, who was a party to the state's lawsuit and a member of the small team who negotiated the settlement agreement. The Florida Tobacco Pilot Program is now managed by the Office of Tobacco Control within the Florida Department of Health. The program has sought the input of Florida youth in planning the program focus and materials and in working toward the main goals of changing young people's attitudes about tobacco use, increasing youth empowerment through community involvement, reducing young people's access to tobacco products, and reducing youth exposure to ETS. These four goals will be addressed through program components similar to those of the Mississippi program:

 Marketing and communications initiatives are planned to directly counter the tobacco industry's marketing efforts. A commercial advertising firm, working closely with teen advisors, has developed the "Truth" campaign, a direct attack on the image of smoking as cool and rebellious. The campaign's multichannel approach—based on techniques used by the tobacco industry—includes television, print, and billboard advertising, as well as consumer items, such as "Truth"-imprinted T-shirts and stickers.

- Youth programming and community partnership activities recruited young people to a Teen Tobacco Summit in early 1998 to advise on the overall development of the program. Chapters of Students Working Against Tobacco are currently active in all 67 counties.
- Education and training programs focus on schoolaged children. Conducted in partnership with communities, schools, voluntary agencies, professional organizations, and universities, these programs ensure that effective tobacco prevention curricula are presented in middle and high schools across the state and that tobacco prevention strategies are being implemented in grades K–12 in conjunction with the Sunshine State Standards.
- Enforcement initiatives are aimed at improving Florida's efforts to reduce the accessibility of tobacco products to minors. The Florida Department of Business and Professional Regulation, Division of Alcoholic Beverages and Tobacco, provides enforcement, educational, and marketing initiatives to ensure compliance with all tobacco laws.
- The evaluation and research component monitors the performance of each of the program initiatives and the progress of the overall program in meeting goals and objectives. Under the leadership of the Florida Department of Health, and with the consultation of the University of Miami, baseline data were collected by Florida universities in all major areas before the pilot program began in early 1998.

In the first full year of operation, the program budget was approximately \$70 million, with program component allocations of approximately \$26 million for marketing and communications, \$10 million for youth programming and community partnerships, \$13 million for education and training, \$8.5 million for enforcement, and \$4 million for evaluation and research. An additional \$5 million was budgeted for programs targeting minority populations and \$3.5 million for administration and management. In the second year, approximately \$45 million more was appropriated for program operations; however, there were significant unexpended funds from the first year of operations that enabled major program components, such as the marketing and communications activities, to continue a level of expenditure similar to the first year.

Youth Tobacco Use Prevalence

Between 1998 and 1999, the prevalence of current cigarette use among middle school students (grades 6 to 8) declined from 18.5 to 15.0 percent (CDC) 1999c). Among high school students (grades 9 to 12), current cigarette use declined from 27.4 to 25.2 percent. However, these declines were significant only for non-Hispanic white students; the change in current smoking among non-Hispanic black and Hispanic middle and high school students was small and nonsignificant. Current cigar use declined significantly only for middle school students (from 14.1 to 11.9 percent), and this decline was almost entirely among males. Similarly, current smokeless tobacco use declined only among middle school students (from 6.9 to 4.9 percent) and remained unchanged among high school students.

In early 2000, additional declines in youth tobacco use were observed (Florida Department of Health 2000). Current cigarette use among middle school students declined to 8.6 percent, or an overall 54-percent decline since the 1998 baseline. Among high school students, current cigarette use declined to 20.9 percent, or an overall 24-percent decline since the 1998 baseline. Although declines between 1998 and 1999 were significant only for non-Hispanic white students, the declines observed in 2000 were significant among all racial/ethnic groups, except among the non-Hispanic black and "other" categories of high school students. Declines in current tobacco use, which include the use of cigars and smokeless tobacco, also were significant. Since the 1998 baseline survey, current cigar use declined by 46 percent among middle school students and 21 percent among high school students. Smokeless tobacco use declined by 54 percent among middle school students and by 19 percent among high school students. Declines in current tobacco use were consistent across grade, gender, and ethnicity as well.

Using additional data collected as part of the overall program evaluation, the Florida Tobacco Control Program has connected the declines in youth smoking prevalence with program activities (University of Miami 1999). Results suggest that students who reported receiving elements of a comprehensive tobacco use prevention education in school had greater declines in smoking between 1998 and 1999 than those students who reported not receiving such education in school. Similarly, the Community Partnerships in the 67 Florida counties were classified as "excellent," "average," or "needing improvement" based upon program record data, and these ratings were linked to data from the Florida Youth Tobacco Survey for

1998 and 1999 in those counties. Declines in smoking prevalence were related to the classification, with the greatest declines among middle and high school students in counties rated as "average" or "excellent." Similar ratings of counties on the level of local enforcement of youth access laws were related to youth smoking prevalence, with the highest levels of enforcement in counties with the lowest prevalence. Finally, data from the Florida Anti-Tobacco Media Evaluation (FAME) have indicated that the "Truth" campaign is producing impressive awareness among youth and changes in attitudes and knowledge consistent with the campaign themes. Between 1998 and 1999, the prevalence of Florida youth aged 16 years and under with antitobacco attitudes increased from 59 to 64 percent but decreased slightly nationwide.

National data against which to compare the Florida data from 1998 and 1999 are not yet available, but some data suggest that the prevalence of tobacco use among young people may have peaked nationwide and could be starting to decline (University of Michigan 1998). In addition, the impact of state excise tax increases that have occurred since the 1998 baseline data collection might be assessed.

Adult Smoking Prevalence

In 1998, the Florida Behavioral Risk Factor Surveillance System (BRFSS) expanded its assessment of tobacco issues. The tobacco module will enable changes to be assessed in tobacco use prevalence, cessation behaviors, family rules about tobacco use, environmental tobacco smoke exposure at home, and workplace policies regarding smoking.

Texas

The legislative plan developed by the Texas Interagency Tobacco Task Force (1998) incorporated the CDC recommendations for community and school-based programs to reduce tobacco use. The plan includes a public awareness campaign, cessation and nicotine addiction treatment, programs for diverse or special populations, enforcement of laws to reduce minors' access, surveillance and evaluation, and state-wide program administration. The plan requests \$20.75 million for fiscal year 2000 and \$61.25 million for fiscal year 2001 to implement, evaluate, and administer the programs proposed.

In the fall of 1999, the Texas legislature created an endowment fund of \$200 million and requested the Texas Department of Health to conduct a pilot study based upon recommended interventions included in the 1998 tobacco task force plan. This pilot would be

funded by investment revenue from the endowment fund, approximately \$9 million per year. In response to this requirement, the Texas Department of Health has begun an Intervention Effectiveness Pilot Study in conjunction with universities in the state.

To assess the impact of tobacco use prevention activities in the state, the Texas Department of Health has conducted the Texas Youth Tobacco Survey in 1998 and 1999 among middle and high school students from a sample of students statewide and in eight regions of the state. Results from the 1998 survey indicated 31 percent of middle school students and 43 percent of high school students were currently using some form of tobacco products (Texas Department of Health). For cigarettes alone, 21 percent of middle school students and 33 percent of high school students were current smokers.

Minnesota Settlement Program

In Minnesota, the Minnesota Partnership for Action Against Tobacco, the Tobacco Work Group of the Minnesota Health Improvement Partnership, and the Minnesota Blue Cross and Blue Shield (which received a separate \$469-million settlement award [see "Recovery Claims by Third-Party Health Care Payers" in Chapter 5]) all have developed plans for the statewide effort to reduce tobacco use. In the 1999 Omnibus Health and Human Services appropriation bill, the Minnesota legislature set aside \$968 million from the state's tobacco settlement to establish two health-related endowments: one for preventing tobacco use and supporting local public health efforts (\$590 million) and the other for tobacco-related medical education and research (\$378 million). The interest earned from these endowments will support long-term programs.

The 1999 Minnesota Omnibus Health and Human Services bill established an ambitious goal to reduce tobacco use among young people by 30 percent by the year 2005. In response to this, the Minnesota Department of Health developed the *Minnesota Youth Tobacco Prevention Initiative: Strategic Plan* (Minnesota Department of Health 1999). This plan defined major activities that will be funded from January 1, 2000, through June 30, 2001, in four component areas: Statewide Public Information and Education Campaign, Statewide Programs, Community-Based Prevention Programs, and Youth Leadership Projects. The strategic plan established "initial indicators of success" for each program component to enable program performance to be assessed.

The Statewide Public Information and Education Campaign will have a proposed budget of \$7.5

million for the 18-month period. The campaign will include both a media component and grassroots organizing efforts focused on the target audience of 12- to 17-year-old youth. The Statewide Programs will be budgeted at \$3.55 million for the initial 18-month period. Evaluation activities, training, and technical assistance services will be funded along with statewide organizations to support the community-based efforts. The Community-Based Prevention Programs will be budgeted at \$4.4 million for the initial 18-month period. Community-based prevention efforts will include tobacco-use prevention activities at the local level and projects that focus on populations at risk. Finally, the Youth Leadership Projects will be budgeted at \$1 million for the initial 18-month period and will work in conjunction with the community-based prevention efforts. These activities will seek to empower Minnesota's youth to take leadership in the planning and implementation of tobacco prevention and control programs at the local level. The Minnesota Department of Health has established an evaluation plan to track progress of the initiative, with the first comprehensive report on program effectiveness to be delivered to the legislature in January 2003.

Programs Meeting the Needs of Special Populations

The recent Surgeon General's report *Tobacco Use Among U.S. Racial/Ethnic Minority Groups* provided a summary of the various approaches that have been used to prevent and control tobacco use among racial/ethnic minority groups in the United States (USDHHS 1998). This report highlighted the need for more research on the effect of culturally appropriate programs to address this problem. Few new findings have emerged since the publication of that report; hence, the elimination of disparities in health among population groups remains hampered by the lack of culturally appropriate programs of proven efficacy. Below are some examples of community-based interventions that have proven to be effective and that may serve as examples for the development of future program initiatives.

Uniting and mobilizing the movement to reduce tobacco use among racial/ethnic groups have not been easy. Tension frequently occurs between various organizations within the community regarding appropriate strategies to achieve particular goals, "turf" disagreements, competition for fund-raising dollars, and other issues. Many of these problems were identified during the 1989–1992 COMMIT trial. Though COMMIT researchers did not attribute to internal dissension the

program's inability to reach its goals (Thompson et al. 1993), internecine rivalry can splinter community mobilization efforts and greatly impair the effectiveness of any program trying to reduce tobacco use.

Diverse views and dissent are an expected part of organizing activity. A more serious issue for community mobilization has been a lag in engendering support from all segments of society. Historically, the movement to reduce tobacco use has been dominated by organizations composed of middle- and upper-class white Americans and often led by white males (see Chapter 2). For many years, participation in the movement was further limited to organizations concerned with health and medical issues and nonsmokers' rights.

In the early 1980s, increasing dissatisfaction was voiced by women and underrepresented communities who felt that their issues and contributions were not adequately integrated into mainstream efforts to reduce tobacco use (Jacobson 1983). In recent years, a number of persons and organizations representing more diverse perspectives have assumed a greater role (see the text boxes "Uptown," "X," and "Dakota"). Particularly in view of the tobacco industry's targeted marketing to women, African Americans, Hispanics, and young people (USDHHS 1994, 1998), such heightened activity is of critical importance to ensure a nonsmoking norm within diverse communities. In some instancesexemplified by the low and declining smoking prevalence among African American youth (USDHHS 1994)—such a norm may have already taken hold.

Programs for the African American Community

Several leadership groups, such as the National Black Leadership Initiative on Cancer, which is funded by the NCI, and the National Association of African Americans for Positive Imagery, funded in part by the CDC, have begun to have a voice in activities to reduce tobacco use in the African American community. For example, in 1989, a strong coalition guided community mobilization efforts to mount a successful campaign against the test-marketing of Uptown, a new brand of cigarettes targeting African Americans (see the text box "Uptown"). A similar community-organized campaign in 1995 resulted in the withdrawal of X, another new brand seemingly intended for the African American community (see the text box "X").

In 1992 and 1993, the ACS provided funds for community demonstration projects to use *Pathways to Freedom: Winning the Fight Against Tobacco*, a self-help guide for African American smokers (Robinson et al.

Uptown

n mid-December 1989, R.J. Reynolds Tobacco f LCompany announced that on February 5, 1990, it would begin test-marketing a new cigarette in Philadelphia, Pennsylvania. The cigarette, to be named Uptown, was the first to be marketed directly to African American smokers. Within 10 days of this announcement, the Coalition Against Uptown Cigarettes (CAUC) was formed. Using existing church and community organizations and word of mouth, the coalition grew to include 26 diverse organizations representing health, religious, and community groups. The group's leaders were African Americans with long-standing ties to the Philadelphia African American community. The Philadelphia chapter of the National Black Leadership Initiative on Cancer, an organization funded in part by the National Cancer Institute and dedicated to reducing cancer in the African American community, and the Committee to Prevent Cancer Among Blacks facilitated the coalition's formation. Also active in the CAUC were several other organizations that addressed local issues on cancer control. These groups included chapters of the American Cancer Society and the American Lung Association, as well as the Fox Chase Cancer Center.

The CAUC decided that its initial goal would be to limit R.J. Reynolds' ability to use Philadelphia as a test market by convincing African American smokers to boycott the new cigarette. The coalition mobilized both smokers and nonsmokers in support of this goal by focusing on R.J. Reynolds' strategy to promote tobacco use among African Americans. The coalition initially used local media to reinforce the messages being sent through grassroots channels and did not seek out national coverage, which the coalition members believed would hinder their goal of

building a local, grassroots constituency. On behalf of the CAUC campaign, Dr. Louis Sullivan, then Secretary of Health and Human Services, addressed the University of Pennsylvania School of Medicine on January 18, 1990. In his remarks, Secretary Sullivan said that "at a time when [African Americans] desperately need the message of health promotion, Uptown's message is more disease, more suffering and more death for a group of people already bearing more than its share of smoking-related illness and mortality" (quoted in Heller 1990, pp. 32–3).

The national media embraced the story. Secretary Sullivan's remarks were prominently featured in the evening news and were front-page headlines across the country. R.J. Reynolds initially responded by defending their targeted marketing strategy, but the company later claimed that Uptown was not aimed specifically at African Americans. On January 19, 1990, R.J. Reynolds canceled the Philadelphia test-marketing of Uptown. On January 31, 1990, the company canceled production of the cigarette.

The course of events suggests that the Uptown coalition played a decisive role in altering R.J. Reynolds' targeting strategy. A united response from Philadelphia's African American community, an organized local grassroots effort, the strategic alliance with a national figure, and media management were associated with product cancellation less than two months after introduction. The episode highlights the importance of timing in measures to reduce tobacco use. In this instance, a marketing campaign appears to have been derailed in its beginning stages by short-term, high-intensity media advocacy (see "Media Advocacy," later in this chapter).

1992). Awardees used *Pathways to Freedom* to bring tobacco control efforts to the African American community. Through these demonstration projects, many ACS divisions began or enhanced their work in the African American community.

A recent study in three predominately lowincome, African American neighborhoods has demonstrated that culturally appropriate interventions can produce significant declines in smoking behaviors (Fisher et al. 1998). The Neighbors for a Smoke Free North Side organized residents in wellness councils to encourage nonsmoking in their areas. A citywide advisory council, composed mostly of African Americans, carried out central planning for the program and provided linkages to community resources and technical assistance to neighborhood councils. The program implemented a wide range of activities over a 24-month period, including smoking cessation classes, billboard public education campaigns, door-to-door campaigns, and a "gospelfest." A quasi-experimental

X

 \mathbf{I} n early 1995, the memory of the grassroots victory against Uptown cigarettes (see the previous text box, "Uptown") served as a rallying cry in the African American community in Boston against the potential threat of a new brand—X cigarettes. As with Uptown in Philadelphia, the first information about this cigarette brand came in local mediain X's case, in articles in the Boston Globe and the Boston Herald.

This distinctive menthol cigarette brand was packaged in the Afrocentric colors red, black, and green and featured a prominent "X," a symbol frequently associated with the well-known, deceased African American leader Malcolm X. Community leaders in Boston and throughout the United States thought that the product had the potential to attract young African Americans—a group whose smoking rates had dropped dramatically in recent years. The use of "X" on a cigarette brand also was seen as a defamation of Malcolm X, a noted nonsmoker. Although manufactured and distributed by two companies without large marketing budgets, there was a fear that even a small success with X cigarettes would stimulate the creation of similar products by the major tobacco companies, which would have significant resources for advertising and promotion in African American communities.

The National Association of African Americans for Positive Imagery (NAAAPI) and the Bostonbased organization Churches Organized to Stop Tobacco took the lead in opposing X cigarettes. Two NAAAPI leaders, Reverend Jesse W. Brown, Jr., and Charyn D. Sutton, both of whom had been involved in the Coalition Against Uptown Cigarettes, spoke in Boston in February 1995 about the need for communities to mobilize against tobacco marketing. Their visits were covered extensively by print and broadcast media. As a result of NAAAPI's organizing efforts, the manufacturer and distributor of X cigarettes received calls from around the country, most notably from the organizations involved in the African American Tobacco Education Network of California.

Because the brand's marketing seemed to be confined to the Boston area, NAAAPI decided to demand in writing that X cigarettes be withdrawn immediately to prevent any wider distribution. The manufacturer (Star Tobacco Corporation, Petersburg, Virginia) and distributor (Stowecroft Brook Distributors, Charlestown, Massachusetts) both responded within 10 days to that request, although they continued to insist that the cigarette brand had not been specifically targeted to the African American community. On March 16, 1995, news conferences were held in Boston and Los Angeles by tobacco advocates to announce the withdrawal of X cigarettes from the market.

The course of events suggests that the actions of activist groups had direct influence on the outcome. As was the case with the Uptown protest, the X experience suggests the critical role of a rapid but organized community response in efforts to prevent the targeted marketing of tobacco products to racial and ethnic minority groups.

design was used to evaluate the impact of this program. The three intervention neighborhoods in St. Louis were matched by ethnicity, income, and education with three comparison zip code areas in Kansas City, Missouri. Baseline and follow-up random-digit dialing telephone surveys were conducted among adults (aged 18 years or older) in the three intervention and three comparison areas in 1990 and in 1992. Smoking prevalence declined significantly in the St. Louis neighborhoods, from 34 to 27 percent, but declined only slightly in the Kansas City comparison areas, from 34 to 33 percent. Thus, the results of this trial suggest that a culturally appropriate communityorganizing approach to smoking cessation that emphasizes local authority and involvement in program planning can have a significant impact on the smoking behavior among residents of low-income, African American neighborhoods.

Programs for Women

The Women vs. Smoking Network, a project of the Advocacy Institute, was the first national network of women's organizations and women's leaders to focus on reducing tobacco use among women. With financial support from the NCI, the network provided technical assistance and information to women's organizations in an effort to interest them in the movement

to reduce tobacco use. The network also focused on obtaining media coverage for issues concerning women and smoking. The network's most notable effort was the release of a plan by R.J. Reynolds to market cigarettes to young, uneducated women (see the text box "Dakota"). Subsequent media attention made this one of the most widely covered tobacco stories of 1990 (Pertschuk 1992). The network was short-lived (1989–1991), however, because of lack of funding. The International Network of Women Against Tobacco (INWAT) was established in 1990 as an international organization to counter the marketing and promotion of tobacco products to women and to foster the development of programs for the prevention and cessation of tobacco use among women. Through support from the American Public Health Association, INWAT has worked to draw attention to issues concerning women and tobacco and has sought to unite and inform women's advocates around the world. As a record of its Herstories project, INWAT assisted in preparing an issue of World Smoking and Health (INWAT 1994) that was a collection of brief essays about the role of tobacco in women's lives in various countries. INWAT has also published and distributed an international directory that lists women who are advocates for reducing tobacco use and includes their areas of specialization (American Public Health Association 1994). The National Coalition for Women Against Tobacco, whose sponsoring organization is the American Medical Women's Association, provides educational materials and advocacy messages to counteract tobacco industry marketing and combat tobacco use among women and girls (http://www.womenagainst.org).

Federal and State Programs

At the federal level, the CDC's IMPACT program awarded three-year cooperative agreements in 1994 to selected national organizations to enhance their work in reducing tobacco use at the national, state, and local levels. Organizations were chosen on the basis of their ability to provide services and outreach to young people, women, blue-collar and agricultural workers, African Americans, Hispanics, Asian Americans and Pacific Islanders, and American Indians.

Among the states, California has made a concerted effort to involve racial and ethnic minority groups and women in its efforts funded—by Proposition 99—to reduce tobacco use (see the section on California, earlier in this chapter). In 1990, four organizations were funded to form networks among Hispanics, African Americans, Asian Americans and Pacific Islanders, and American Indians. Members of the networks convene

meetings, share experiences, participate in the development of culturally appropriate materials, and help community organizations reach their respective communities. These networks currently conduct programs and campaigns to build a strong statewide coalition among their respective populations (Tobacco Education Oversight Committee 2000). California also has funded a statewide organization, Women and Girls Against Tobacco, to focus on tobacco product marketing that targets females. Created in 1992, the organization focuses on empowering women's and girls' organizations to divest themselves of tobacco industry sponsorship and funding and on eliminating tobacco advertising in leading magazines with readership among young women (Women and Girls Against Tobacco, n.d.).

Religious Organizations

Although not specifically representative of minority or underserved groups, some religious organizations that have an important impact in minority communities have had long-standing involvement in issues related to reducing tobacco use. The Interfaith Center on Corporate Responsibility, a coalition of 250 Roman Catholic and Protestant institutional investors, pioneered the corporate responsibility movement in the early 1970s. The value of their combined portfolios is estimated at \$40 billion. In 1981, the Province of St. Joseph of the Capuchin Order was the first member of the coalition to file a shareholder resolution with a tobacco company on the issue of smoking and health. Since then, the coalition has filed numerous shareholder resolutions with the major tobacco companies. These resolutions are a unique opportunity to engage in a public dialogue with executives of major tobacco companies; the shareholder meetings frequently receive media attention.

A more recent effort to involve religious organizations and thereby diversify efforts to reduce tobacco use is the formation of the Interreligious Coalition on Smoking OR Health. The stated purpose of the group is

to mobilize the faith communities in the United States to improve the effectiveness of public policy concerning tobacco. The Coalition is concerned with policies affecting United States corporations involved in the manufacture and sale of tobacco products. The primary focus of the Coalition is educating policy makers within both the legislative and executive branches of the United States federal government (Interreligious Coalition on Smoking OR Health 1993, p. 1).

Dakota

The Women vs. Smoking Network, under the **L** aegis of the Advocacy Institute, was a project aimed at informing and uniting women's organizations to oppose the tobacco industry's efforts to market its products specifically to women. In November 1989, the network sent a letter to the editor of more than 100 newspapers nationwide. Several newspapers printed the letter, which responded to a Philip Morris advertisement that had previously run in these newspapers as a mock apology to women for alleged "shortages" of their new cigarette, Virginia Slims Super. As a result, several major national papers and ABC News subsequently ran stories on tobacco advertising that targeted women. Soon thereafter, the controversy and media coverage surrounding the planned test-marketing of Uptown cigarettes to African Americans began (see the text box "Uptown"). In response, many journalists wrote stories on the related issue of targeted marketing to women. These stories prepared the public for the events that followed.

In February 1990, an anonymous source sent the Women vs. Smoking Network copies of confidential marketing documents for a new cigarette brand, Dakota. The cigarette, produced by R.J. Reynolds Tobacco Company, was scheduled for test-marketing in April 1990. The marketing documents, entitled "Dakota Field Marketing Concepts," consisted of more than 200 pages of test-marketing proposals from two different advertising firms. The marketing documents described Dakota, which was

code-named Project Virile Female, as a cigarette explicitly for young women (18–20 years old). The demographic and psychological profile prepared by Trone Advertising Inc. of the typical Dakota smoker described her as a "caucasian female, 18–20 years old, with no education beyond high school, working at whatever job she can get" (Butler 1990, p. 1, citing Trone Advertising Inc.). She aspired to have an ongoing relationship with a man and "to get married in her early twenties and have a family." She spent her free time "with her boyfriend doing whatever he is doing." The marketing documents also included specific promotional strategies to attract young women to the new cigarette.

Recognizing the value of the documents, staff of the Advocacy Institute negotiated with the Washington Post for front-page coverage of the story in exchange for initial exclusive release of what the institute staff called "Dakota Papers." The Washington Post ran the story on Saturday, February 17, 1990, with the headline, "Marketers Target 'Virile Female': R.J. Reynolds Plans to Introduce Cigarette" (Specter 1990). The Advocacy Institute held back further details on the documents until Tuesday, February 20, so that the director of the Women vs. Smoking Network could appear on CBS This Morning with Dr. Louis Sullivan, then Secretary of Health and Human Services, to "release" the story of the documents. Secretary Sullivan strongly condemned R.J. Reynolds' plans to target women in its marketing strategies.

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The coalition was formed in cooperation with leading organizations within the mainstream tobacco control community. As of January 1994, the coalition had enlisted 16 main religious organizations, including Catholic, Muslim, and Protestant denominations, in the effort to support a large increase in the federal excise tax on a pack of cigarettes (Interreligious Coalition on Smoking OR Health 1994).

Special Efforts to Reduce Chewing Tobacco Use

In 1995, Oral Health America established the National Spit Tobacco Education Program (NSTEP),

an effort aimed at reducing the use of smokeless tobacco among youth in sports. Oral Health America teamed up former major league baseball players, such as Joe Garagiola, Hank Aaron, and Bill Tuttle, to help get the message out that smokeless tobacco products are not a safe alternative to smoking. The components of NSTEP include in-stadium events, public service announcements that have been televised during major league baseball games, printed materials, and educational videos. An external evaluation of NSTEP is being developed to address all levels of the program and its public health impact.

Significant successes of the program include the inclusion of spit tobacco on the national tobacco policy agenda, with specific credit to NSTEP and national

continued

Within the next few weeks, representatives of the Women vs. Smoking Network appeared on NBC Nightly News, CBS This Morning, CBS Evening News, the MacNeil-Lehrer NewsHour, Nightwatch, and Nightline. Representatives were also interviewed by major national newspapers, including USA Today; by numerous local papers; by CBS Radio Network, the Black Radio Network, and National Public Radio; and by local talk shows. Last, representatives were asked to testify on the topic at congressional hearings. The network followed up on the publicity by spotlighting several different projects, including a petition to the tobacco companies to adhere to their own voluntary code of corporate ethics.

Even the cigarette's proposed name drew criticism. Groups in North Dakota and South Dakota objected to the name, as did Sioux tribal organizations, because "Dakota" means "friend" or "ally" in the Sioux language. These groups formed a coalition of more than 40 organizations and collected 25,000 signatures on a petition objecting to the use of the word and demanding that R.J. Reynolds cease

selling the cigarette, which had been test-marketed, as planned, beginning in April 1990. The Women vs. Smoking Network provided strategic counseling and technical support to the grassroots coalition and was instrumental in helping arrange a press conference in Washington, DC, in June 1990, which featured then Surgeon General Antonia Novello, Senator Larry Pressler (R-SD), and others objecting to the marketing plan.

Although advocacy groups were able to generate considerable community and media mobilization, R.J. Reynolds continued test-marketing. Advocates felt they had raised national concern about the targeting of cigarette advertising, although this impression was not directly verified through survey research. Dakota cigarettes were withdrawn two years later, however, because the brand did not sell as well as officials had hoped (*American Medical News* 1992). In this instance, although advocates might attribute the end result to the effective use of the media to promote the agenda for reducing tobacco use, the demise of the Dakota brand was probably more attributable to market forces.

chairman Joe Garagiola by lawmakers and Secretary of Health and Human Services Donna Shalala. More than \$70 million in electronic media coverage has been generated directly from NSTEP efforts. In addition, NSTEP activities appear to have substantially increased the coverage of smokeless tobacco issues in the print media. Before NSTEP there were approximately 500 print articles annually devoted to smokeless tobacco; since NSTEP that number has climbed to

more than 5,000. One article alone appeared in more than 800 newspapers on a given weekend, and NSTEP estimated the value of this media coverage at \$15 million. A recent survey of major league baseball players and coaches found that more than 44 percent of smokeless tobacco users want to quit in the next six months, perhaps attributable to NSTEP's active participation in educating ballplayers during spring training.

Components of Community Programs

Community Advocacy and Mobilization Electronic Networking

Interactive communication technologies, such as computer networks, have been used extensively by advocacy groups for reducing tobacco use. For example, daily communications played an important part in the response to Philip Morris' Bill of Rights Tour (see the text box later in this chapter). Many active, functioning networks now provide communication services to assist in efforts to reduce tobacco use.

The Institute for Global Communications, based in San Francisco, was an early provider of issuespecific networks to the general public. PeaceNet and

EcoNet, which were developed in 1986, are among the most widely used and well known of the institute's networks. As of October 1994, the institute reported a combined membership of 12,000 people from 130 countries (Moore 1994). Within these networks, and others like them, are smaller groups focused on a specific aspect of an issue or a particular policy. For instance, among HandsNet's 2,500 member organizations, which span the nonprofit sector, is a forum linking 200 community coalitions on substance abuse. This forum, managed by the Boston-based group Join Together and supported by the Robert Wood Johnson Foundation, provides on-line technical assistance to these coalitions. The forum also provides news summaries and information available on funding opportunities and proposed legislation.

Several networks link people who work in healthrelated areas. In 1993, the Public Health Network provided forums, e-mail service, and databases for its membership, which was composed of nearly 600 users from state and local health agencies and of program directors who were members of the CDC's Public Health Leadership Institute. In 1998, this network was replaced by the Information Network for Public Health Officials. Established by the CDC's Public Health Practice Program Office, the network links the public health community to the Internet and provides access to on-line information. Planned Parenthood Federation of America hosts PPXNet, a network for its affiliates in regional and national offices, primarily for communication within the organization itself. During the 1990s, the CDC offered the electronic resource WONDER to public health officials, academicians, and others so that they were able to communicate via e-mail with and have access to the CDC's databases of health data. The advent of the Internet, including Web-based e-mail and list serv technology, has facilitated the exchange of public health information for health professionals and the public. CDC now offers its health data, materials, databases, electronic journals, and other resources on its Web site at www.cdc.gov.

In 1990, the Advocacy Institute founded SCARCNet, a multiuser interactive bulletin board that served the tobacco control community. (The history of the bulletin board's sponsoring organization—the resource center known by the acronym SCARC—is discussed in "Impact of Direct Advocacy," later in this chapter.) When SCARCNet ceased in January 2000, it had more than 1,000 subscribers and was circulated to thousands of readers throughout the world on various networks. SCARCNet's most popular feature was the "Daily Bulletin," which each day summarized

major newspaper and journal stories on reducing tobacco use (Advocacy Institute 1994). The "Daily Bulletin" was accompanied by a "Morning Briefing," which put these news stories in perspective for the tobacco control community. The contents of the "Daily Bulletin" stories were retained and stored in a database that is currently available for searching at www.tobacco.org. Another notable feature of SCARCNet was the publication of "Action Alerts." These two-page summaries of current issues requiring immediate action included objectives for action, suggested actions, media bites, quotes, and talking points and were sent to SCARCNet as needed (on average, twice per month). The conferencing section on SCARCNet, called the "Strategy Exchanges," provided a forum for planning, counseling, and experience sharing. The technology allowed for concurrent but separate discussions on discrete issues, such as clean indoor air, tobacco advertising and promotion, tobacco pricing policies, and minors' access to tobacco products. Since its inception in 1990 to its final edition on January 31, 2000, SCARCNet, along with its global counterpart GLOBALink, became an important resource for the tobacco control community. In February 2000, the American Legacy Foundation began its support of a newly designed and enhanced news service system that harnesses advances in Web technology to build on SCARCNet's valued features. This system provides users with the leading national news stories and also includes a news service that allows users to receive a customized selection of other stories based on their geographic location and specialty areas of greatest personal interest (e.g., advertising, enforcement, etc.).

SCARCNet has served as a model for other public health advocacy networks. Examples include Safety Net (an advocacy network for violence prevention) and the Marin Institute's ALCNet (a network for alcohol control advocates), which is modeled closely after SCARCNet. ALCNet has been used for media advocacy as well, particularly to facilitate strategy development to counteract certain alcohol products and promotions.

As with other modalities used for social change, the precise role of on-line networks—one element in a multifaceted approach—is difficult to define. Although process measures are available (e.g., frequency of interactions and message traffic), they do not assess the basic value of computer links in furthering the agenda for reducing tobacco use, nor is it likely (as is noted at the beginning of this chapter for social interventions overall) that their efficacy can be precisely estimated. Current enthusiasm for the mechanism,

however, will probably ensure its continuation, and accrued anecdotal experience—to date, quite positive—will provide the ultimate judgment.

Direct Advocacy

History and Activities

National-level activities, including the work of the Coalition on Smoking OR Health (see "Further Regulatory Steps" in Chapter 5; see also "Community Mobilization," earlier in this chapter) and others (see Chapter 2 and USDHHS 1989b), have played a prominent role in the evolving policy changes concerning the reduction of tobacco use. Of equal interest, from the point of view of the potential impact of advocacy, are decentralized grassroots organizations.

The nonsmokers' rights movement originated in the early 1970s (see "From Antismoking to Nonsmokers' Rights" in Chapter 2). It consisted of individuals acting on their own and of small grassroots organizations of people irritated by ETS or convinced that their health suffered from it. During this period, the documented adverse health effects of ETS were first being brought to the public's attention (Steinfeld 1972; U.S. Department of Health, Education, and Welfare 1972). As research documenting these health hazards accumulated, nonsmokers' rights organizations grew in number and strength.

Many of the early grassroots organizations used the acronym GASP to represent similar titles, including the Group Against Smokers' Pollution, the Group Against Smoking Pollution, the Group to Alleviate Smoking in Public Places, and Georgians Against Smoking Pollution. Other acronyms were also used, including FANS (Fresh Air for Nonsmokers), TAPS (Texans Against Public Smoking), and ANSR—pronounced "answer"—(Association for Nonsmokers Rights). Organizations were small, poorly funded, and often run from home by volunteers.

Initially, many nonsmokers' rights organizations simply provided a forum for nonsmokers to express their concerns about smoking and ETS. These groups helped legitimize their members' complaints and empower them to take protective actions. Such actions required courage, assertiveness, and no small measure of tact, since smoking in public areas was normative at the time. Group members might thus learn how to politely ask people to refrain from smoking; or to obviate direct confrontation with smokers, groups might provide members with signs, cards, or buttons asking people not to smoke in their presence.

Early in the movement, nonsmokers' rights associations adopted public policy change as an

important goal. Groups began to work for passage of measures to restrict public smoking. Such regulations are often referred to as clean indoor air laws (see "Clean Indoor Air Regulation" in Chapter 5). To encourage these measures, an early GASP organization produced a "Bill of Rights" that stated, in part, that

Non-Smokers have the right to breathe clean air, free from harmful and irritating tobacco smoke. This right supersedes the right to smoke when the two conflict. Non-Smokers have the right to express—firmly but politely—their discomfort and adverse reactions to tobacco smoke. . . . Non-Smokers have the right to take action through legislative channels, social pressures or any other legitimate means—as individuals or in groups—to prevent or discourage smokers from polluting the atmosphere and to seek the restriction of smoking in public places (Group Against Smokers' Pollution, n.d.).

Over time, many organizations moved to encompass broader policy goals for reducing tobacco use—in particular, they sought ways to decrease tobacco use by minors. Largely as a consequence of those efforts, direct advocacy and public policy change became important parts of these organizational strategies.

In some communities, nonsmokers' rights organizations worked in isolation. In others, they formed associations with medical societies, voluntary health associations, and other organizations; the result was a more intense effort to ensure passage of desired legislation. Despite initial obstacles, in many communities nonsmokers' rights associations were a driving force in moving their allies toward a legislative approach to reducing tobacco use. For example, one of the earliest and most influential nonsmokers' rights organizations was California GASP, founded in 1976, which eventually became Americans for Nonsmokers' Rights (ANR). ANR is now the principal national-level tobacco control group devoted primarily to promoting legislation for clean indoor air. In California, ANR helped support the passage of such ordinances in many localities. Partly as a result of ANR's work, California has more local ordinances for clean indoor air than any other state. ANR has served as a national consultant to other groups pursuing such legislation.

Impact of Direct Advocacy

In retrospect, the grassroots organizations can be seen as having worked to diminish the legitimacy of tobacco use in the eyes of the public and the credibility of the tobacco industry. The passage of ordinances

against public smoking (see "Clean Indoor Air Regulation" in Chapter 5) occurred over several years, during which a shift in public opinion about smoking became evident. During the 1960s and 1970s, the right to smoke was largely unquestioned. In more recent years, declining smoking prevalence and public opinion polls have indicated an increasing intolerance for public smoking (USDHHS 1989b). The work of nonsmokers' rights organizations is coeval with these legal, epidemiologic, and social changes. Sorting out cause and effect is difficult, but the nonsmokers' rights movement seems to have contributed to the changing social norm (Glantz 1987).

There were, however, some important exceptions to the emerging nonsmoking norms. By the mid-1980s, it was apparent that both the traditional educational efforts and the passage of ordinances to protect nonsmokers from ETS had a limited effect on young people's smoking-related attitudes and behaviors (USDHHS 1994). Efforts to reduce smoking appeared unable to reduce the prevalence of smoking among teenagers (Lynch and Bonnie 1994), and smoking prevalence among white females began increasing sharply during the 1970s, as did the prevalence of smokeless tobacco use among males.

The failure to decrease smoking among young people is as difficult to assess as is the success observed among adults (particularly among adult men). Analyzing the effect of prevention activities on young people must include weighing the hampering effects of advertising and promotional efforts backed by the tobacco industry's enormous marketing budget (see "Advertising and Promotion" in Chapter 5; DiFranza et al. 1991; Pierce et al. 1991; Lynch and Bonnie 1994; USDHHS 1994). Whatever the interplay of the forces involved, the result is that protobacco activity directed at those entering the market has been generally successful. An exception is the continued decline in prevalence among young African Americans, particularly among young women (USDHHS 1998).

Perhaps some of the shortfall in grassroots efforts to reduce tobacco use is associated with the early isolation of these groups from the established national advocacy organization. Anecdotally, there is evidence of a culture clash. When the nonsmokers' rights movement emerged in the 1970s, many medical and voluntary health organizations decried what they perceived as the unprofessional, indecorous, confrontational approach that these activists took to an issue that had previously fallen in the domain of the traditional public health structure. Some traditional organizations in the public health arena may also have felt that

grassroots organizations were infringing on their "turf" and their fund-raising base.

For their part, nonsmokers' rights associations objected to what they saw as the overly cautious, measured approach of researchers, medical associations, and volunteer health associations, whose efforts seemed to have done little to solve the problems of day-to-day exposure to ETS. The grassroots organizations urged voluntary health organizations to examine their mission statements and dedicate appropriate resources to cost-effective solutions to reducing to-bacco use.

In time, both approaches acknowledged that the lack of coordination and cohesion was a significant barrier to their efforts. The groups noted that, in contrast, the tobacco industry operated as a monolith through the coordinated efforts of the Tobacco Institute, a lobbying and public relations organization representing the industry. This insight led to the emergence of several groups—somewhat disparate in their approaches—that attempted to bridge some of the distance between the grassroots and national approaches to reducing tobacco use.

Among the oldest of these groups is DOC (Doctors Ought to Care), which was founded in 1977 as a national coalition of health professionals, students, and concerned individuals. DOC groups take an activist approach to public health problems and sponsor community projects and events on reducing tobacco use and other issues. From the outset, members chose confrontational programs, such as counteradvertising and picketing industry-sponsored sports events, to delegitimize the tobacco industry and focus attention on its activities by involving both physicians and young people in advocacy activities. DOC groups use satire, ridicule, and parody in their work to appeal to children and teenagers (Blum 1982); for example, they have sponsored "Emphysema Slims" tennis matches featuring appearances by "Martina Nosmokanova." DOC also maintains a large archive of activities related to the tobacco industry, including past advertising campaigns and marketing strategies (Mintz 1995). The activities of DOC are similar in style, if not content, to those of the Australian organization Billboard Utilising Graffitists Against Unhealthy Promotions (BUGA-UP), which was founded in 1979. BUGA-UP members, some of whom are physicians, have used unconventional tactics, such as spray-painting billboards that advertise tobacco products (Jacobson 1983).

Another group is Stop Teenage Addiction to Tobacco (STAT), which was founded in 1985 with the aim of reducing tobacco use among minors. From its inception, STAT aimed to unite the medical and scientific arm and the grassroots arm of the movement to reduce tobacco use. Although STAT frequently approaches tobacco issues from the activist perspective, the organization has long included key members of the medical and public health establishment in its leadership. DOC, STAT, and other groups have attempted to make the activist, confrontational approach to reducing tobacco use acceptable to the more conservative medical and voluntary health organizations. Partly because of these efforts, an activist approach is now an important component of the movement (see the text box "Bill of Rights Tour").

Another impetus for a more unified movement was the establishment of the Smoking Control Advocacy Resource Center (SCARC) at the Advocacy Institute in 1987. The Advocacy Institute's mission—to study, analyze, and teach public interest advocacy included a focus on smoking reduction as a model public interest movement. The institute received funding from the Henry J. Kaiser Family Foundation to establish SCARC. Rather than be a frontline organization, SCARC proposed to help build the movement's infrastructure. As such, SCARC would be viewed as a neutral player and would not vie with the movement's other organizations in seeking media, voluntary, or funding sources. Since its formation, SCARC has served three important roles as convener, tobacco industry monitor, and center for strategic development, training, and counseling (Butler 1990).

Media Advocacy

Media advocacy for reducing tobacco use was developed during the 1980s by a small number of activists working primarily in the United States, Canada, Australia, and the United Kingdom. The attendees at the September 1985 International Summit of Smoking Control Leaders resolved to produce a handbook that would provide guidance on using the media to support tobacco control. The resulting document, Smoke Signals: The Smoking Control Media Handbook (Pertschuk 1987), describes many of the important themes and skills needed for using what would later be dubbed "media advocacy." In January 1988, the Advocacy Institute convened a two-day consensus workshop, sponsored by the NCI, that produced a second handbook on media advocacy, Media Strategies for Smoking Control: Guidelines (USDHHS 1989a), which formally recognized the importance of media advocacy in reducing tobacco use (and in which the term "media advocacy" was first employed).

Media advocacy has been defined as the strategic use of mass media to advance a social or public

policy initiative (NCI 1991). In contrast to the goal of traditional health communications efforts, the goal of media advocacy is to change public policy and thereby generate a broader impact on tobacco use by creating an environment in which smoking is not normative. Smoke Signals articulates six critical tasks the media must perform to help accomplish this goal: (1) educate the public about the severity of the risks of smoking, the susceptibility of every smoker, and the health benefits of quitting; (2) educate the public about the health risks of ETS; (3) alert citizens and policymakers to injurious public policies that promote smoking, including insufficiently regulated advertising and promotion of cigarettes, as well as unrestricted smoking in public areas and the workplace; (4) respond to and counteract the propaganda and disinformation campaigns of the tobacco industry; (5) counter the economic and political influence of the tobacco industry, which thwarts the adoption of remedial policies; and (6) reinforce evolving social nonsmoking norms (Pertschuk 1987).

Media advocacy campaigns have been likened to political campaigns "in which competing forces continuously react to unexpected events, breaking news, and opportunities" (Pertschuk et al. 1991, p. 3). Such campaigns require both presenting the public health side of an issue and negating the opposing side. Like political campaigns, media advocacy campaigns require quick reactions that contrast with the carefully planned, fixed agendas of traditional media programs.

Media advocacy recognizes the potential of the press to place on the public agenda issues concerning the reduction of tobacco use and to either advance or retard progress toward policy goals. Successful media influence requires gaining access to the news and framing or shaping coverage of the resulting story. These strategies are interrelated, since the framing of a story helps determine whether a journalist will agree to cover it.

The use of media advocacy has two daunting limitations: it is a new technique that requires complex skills and an understanding of the news media, and it demands a large investment in time (Wallack 1990). But another apparent barrier—the reliance on an outside party (the media) to achieve program goals—is also a source of considerable strength: media advocacy is a means by which public health practitioners can indirectly confront and compete with forces that are traditionally beyond their policy and financial reach. These forces represent powerful vested interests—the tobacco industry, advertising industry, retail establishments that sell tobacco, and others. The financial and political influence of these entities can limit the ability of public

Bill of Rights Tour

In fall 1989, Philip Morris, the largest U.S. manufacturer of cigarettes, contracted with the U.S. National Archives and Records Administration to sponsor a commemoration of the 200th anniversary of the Bill of Rights. The commemoration involved a national advertising campaign, including commercials on prime-time television and full-page advertisements in major newspapers, asking Americans to "Join Philip Morris and the National Archives in celebrating the 200th anniversary of the Bill of Rights" (cited in Advocacy Institute 1989, p. 1). Philip Morris soon announced plans to transport Virginia's copy of the Bill of Rights to all 50 states in cooperation with the Virginia State Library and Archives.

Advocates for reducing tobacco use interpreted Philip Morris' effort as an attempt to link smoking with the national freedoms guaranteed by the Bill of Rights. These groups believed that Philip Morris would use its association with the Bill of Rights Tour, which highlighted themes of liberty and freedom of expression, to gain public support for the company's claim of a First Amendment right to advertise. Philip Morris' project with the National Archives raised concern in the U.S. House of Representatives, which held hearings on the issue but did not intervene. Advocates for reducing tobacco use began using the 16-month tour schedule to coordinate local efforts to counter what they considered to be a tobacco-marketing plan.

The Washington state chapter of Doctors Ought to Care (DOC) built a countersymbol, the "Statue of Nicotina," to travel with the tour. At a press conference, comments from the president of the chapter, Dr. Robert Jaffe, captured the flavor of the symbol's proposed use:

Nicotina is modeled [on] the Statue of Liberty. She's holding a cigarette in her upheld hand, instead of a torch, and her eyes are closed, the symbol of shame that she's been . . . made a symbol of tobacco. The chains from her cigarettes in the pack help to illustrate to all of the children who are going to see the Bill of Rights Tour that this is a dangerous, addictive drug. At her feet are the words, "Give me your poor, your tired, your women, your children yearning to breathe free . . ." (quoted in Wallack et al. 1993, p. 185).

The Advocacy Institute published an advance schedule of the national tour, including dates and specific locations for each of the tour's stops. The institute also tracked activities in various states and disseminated strategic information through *Action Alerts* posted on SCARCNet, the institute's computer network dedicated to sharing information on reducing tobacco use. SCARCNet (see "Electronic Networking," earlier in this chapter) was a key mechanism for advocates to share information and develop strategies. In addition, the American Lung Association and the American Medical Association provided materials and strategic support to its interested affiliates.

Initially, Philip Morris responded to protests at tour sites by establishing a "speaker's corner" that restricted protesters to a site away from the exhibit hall. At first, this strategy successfully muted attacks and deflected positive attention from protesters. Indeed, by appearing to encourage protesters, Philip Morris was portrayed by some media reports as being faithful to the spirit of the Bill of Rights. As the tour continued, however, groups opposed to the sponsorship learned from experience in other states. The groups refined their message, learned how best to respond to Philip Morris' spokespersons, discussed public reaction to their protests, and modified their tactics appropriately. They developed a simple slogan, "Bill of Rights Yes/ Philip Morris No" (cited in Wallack et al. 1993, p. 186), to clarify the theme of their protests.

With the changed approach, advocates reported improved media coverage of the protests. At almost every tour stop, advocates staged press conferences before the opening of the exhibit and displayed the Statue of Nicotina, which was transported from state to state. By February 1991, five months into the tour, Philip Morris scaled down the number of scheduled stops. The tour, accompanied by advocates for reducing tobacco use, continued through its conclusion in Richmond, Virginia, in December 1991.

The ultimate effectiveness of this advocacy effort is difficult to judge, but the effort played an obvious role in muting the public relations benefits to the tobacco industry. At the very least, the resources invested by the industry did not appear to bring the expected return.

(as well as private) agencies to use confrontational tactics. In addition, many communities prefer consensus building to confrontation with powerful opposition parties. However, because the visible products of media advocacy—the media reports themselves—emerge from a disinterested party (the media) rather than from parties for or against reducing tobacco use, this newest form of social intervention can be successful in previously problematic areas.

As with other social interventions, the precise contribution of media advocacy to the effort to reduce tobacco use is difficult to judge. Events like those surrounding the marketing of the cigarette brands Uptown, X, and Dakota and the Philip Morris-sponsored Bill of Rights Tour demonstrate the role that media advocacy can play in the overall effort.

Countermarketing

Mass Media in Tobacco Control

In contemporary society, the mass media are the most important means of educating and informing the public and, through public response to media, policymakers. By design or not, the media plays an enormous role in influencing the smoking behavior of individuals and the actions of policymakers in both the public and the private sector (Pertschuk 1987). Public health programs have used various health communication programs to inform and influence the behavior of the general public. Traditionally, communication programs intended to reduce tobacco use have tried to influence the behavior of individuals. Most such media campaigns have focused on influencing the behavior of adult smokers—and hence have focused more on smoking cessation than on prevention. Flay (1987) describes three prominent types of mass media programs and campaigns designed to influence smoking-related knowledge, attitudes, and behavior: (1) those that inform the public of the negative health consequences of cigarette smoking and try to motivate smokers to quit, (2) those that promote specific smoking cessation actions to those smokers motivated to quit (e.g., smokers are encouraged to call a help line or to request specific materials, such as a tip sheet or a self-help manual), and (3) those that promote smoking cessation self-help clinics for those smokers who desire to quit. A smaller number of campaigns have focused on youth, either encouraging young people to avoid using tobacco products or convincing young people who smoke to try to quit (USDHHS 1994).

A factor that has limited the success of traditional mass media campaigns is the small size of the campaign budgets compared with the advertising and marketing budgets of the tobacco industry (Flay 1987; USDHHS 1994). In addition, these campaigns to reduce tobacco use have experienced drawbacks because of their traditional reliance on public service announcements (PSAs). Although PSAs have been an integral part of such efforts for many years, the number of PSAs on any subject provided to broadcasters has increased, whereas the amount of donated air time available for PSAs has decreased. Also, the advent of cable technology, which has increased the number of channels through which people can be reached and therefore has diffused the audience, has further hampered efforts to reach targeted groups efficiently. By the mid-1980s, it had become apparent that the role of the media in the effort to reduce tobacco use required reevaluation. In the following sections, the uses of mass media approaches for tobacco control are summarized.

Effects of Protobacco Advertising and Promotion

The effect of tobacco advertising and promotion activities on both adult consumption and youth initiation has been the subject of considerable research over the past decade (see "Advertising and Promotion" in Chapter 5). While noting that existing evidence suggests that tobacco marketing increases the level of tobacco consumption, the 1989 Surgeon General's report Reducing the Health Consequences of Smoking: 25 Years of Progress concluded that the issue is so complex that a sufficiently rigorous study capable of providing definitive scientific evidence is not available and that "none is likely to be forthcoming in the foreseeable future" (USDHHS 1989b, pp. 516–7). The 1994 Surgeon General's report *Preventing* Tobacco Use Among Young People similarly noted the absence of a definitive longitudinal study of the direct relationship of tobacco advertising to adolescent smoking. However, acknowledging the value of recent nonlongitudinal studies focused on young people, the report offered this major conclusion: "Cigarette advertising appears to increase young people's risk of smoking by affecting their perceptions of the pervasiveness, image, and function of smoking" (USDHHS 1994, p. 6). Also in 1994, the Institute of Medicine concluded that the preponderance of evidence suggests that tobacco marketing encourages young people to smoke (Lynch and Bonnie 1994).

In its rule to restrict the access and appeal of tobacco products to young people, the Food and Drug Administration (FDA) reviewed the quantitative and qualitative evidence and concluded that cigarette advertising is causally related to the prevalence of smoking among young people (*Federal Register* 1996). The agency also cited statements from internal documents of the tobacco industry to show the importance of the youth market segment to the industry's continued success. More recently, a 1998 Report to the United Kingdom's Chief Medical Officer by the Scientific Committee on Tobacco and Health concluded unanimously that tobacco advertising and promotion influence young people to begin smoking (Scientific Committee on Tobacco and Health 1998).

Survey data show that among children who smoke, most use the most heavily advertised brands of cigarettes, whereas many adult smokers buy generic or value category brands, which have little or no image advertising (CDC 1994). A major econometric marketing study found that young people are three times more affected by advertising than are adults (Pollay et al. 1996). Research has also pointed to the impact of other tobacco promotional activities, such as sponsorship of public entertainment events and distribution of specialty or premium items. These activities constitute the largest (and an increasing) share of tobacco marketing expenditures. The CDC has estimated that today's U.S. teens already have been exposed to more than \$20 billion in imagery advertising and promotions since age 6, creating a "friendly familiarity" for tobacco products and an environment in which smoking is seen as glamorous, social, and normal (Eriksen 1997). Although the effect of this exposure is difficult to quantify, especially nationwide, one study has estimated that 34 percent of all youth experimentation with smoking in California between 1993 and 1996 can be attributed to tobacco promotional activities (Pierce et al. 1998). A recent study found that teenagers who can readily name a cigarette brand and who own a tobacco-company-sponsored promotional item are more than twice as likely to become established smokers than adolescents who do neither (Biener and Siegel 2000).

Effects of Tobacco Countermarketing

In light of ubiquitous and sustained protobacco messages, countermarketing efforts of comparable intensity and duration are needed to alter the social and environmental context of tobacco use. Evidence of effectiveness comes from three main sources: (1) the natural experiment of the counteradvertising campaign that occurred during the late 1960s as the result of a Fairness Doctrine ruling (also discussed in "Broadcast Advertising Ban" in Chapter 5), (2) school and community intervention studies incorporating mass media approaches (see "Supplemental Programs" in Chapter 3), and (3) recent experience with large paid

media campaigns in several U.S. states and with a nationwide campaign funded by the FDA. Because of the special sensitivity of young people to tobacco marketing and the high rates of tobacco use among teenagers, the subsequent review in this chapter will focus on countermarketing media campaigns that include prominent youth-targeted components. The literature provides strong evidence of the value of mass media campaigns to inform the public at large—including young people—about the hazards of smoking, to promote specific cessation actions and services (such as telephone help lines), and to provide cessation clinics to adult smokers (Flay 1987; Pierce 1995).

The Fairness Doctrine campaign. In 1967, the Federal Communications Commission (FCC) applied the Fairness Doctrine (discussed in "Broadcast Advertising Ban" in Chapter 5) to cigarette advertising and required broadcasters to provide a significant amount of airtime to antismoking messages—a requirement interpreted by the FCC at that time to be about one antismoking message per three tobacco advertising messages). This requirement resulted in the only sustained nationwide tobacco control media campaign to date. From mid-1967 through 1970, roughly \$200 million in commercial airtime (in 1970 dollars) or \$75 million per year was donated for antismoking messages on television and radio (Warner 1986; USDHHS 1989b).

The campaign produced significant reductions in both adult and youth smoking behaviors (Hamilton 1972). For the first time in the 20th century, adult per capita cigarette consumption fell for more than three consecutive years. Teenage smoking prevalence was 3 percentage points smaller during the Fairness Doctrine period than it was in the 16 months before the campaign, and the campaign was associated overall with a 3.4-percentage point reduction in teen smoking prevalence. Perhaps the ultimate indicator of the campaign's impact was a change that followed the campaign's end: with the 1971 enactment of congressional legislation banning tobacco commercials from television—and with them, the Fairness Doctrinemandated counteradvertisements—per capita cigarette consumption immediately resumed its upward trend (see "Broadcast Advertising Ban" in Chapter 5).

Hamilton (1972) suggested that during the Fairness Doctrine period, the antismoking campaign messages had an effect that was nearly six times that of cigarette advertisements. Warner (1979) noted that the government's broadcast ban—and the consequent end of the countermarketing campaign—was especially detrimental to the ongoing effort to prevent young

people from smoking. Cigarette promotion remained highly visible in the print media and in tobacco companies' sponsorship of sporting events at the same time the broadcast ban "virtually eliminated mass promotion of the antismoking cause" (p. 445).

Community intervention studies. As described in "Research on Multifaceted Programs" in Chapter 3, multicomponent youth-directed programs that include a prominent mass media component have shown longterm success in postponing or preventing smoking onset in adolescents. In the University of Vermont School and Mass Media Project, the study featuring the most intensive paid counteradvertising campaign, the preventive effect actually increased during the twoyear intervention period among the adolescents at higher risk for smoking (Flynn et al. 1997)—a rare outcome for most campaigns trying to change health behaviors. The authors noted that counteradvertising can effectively reach higher-risk youth because of their greater exposure to the mass media, particularly radio and television. It is also likely that higher-risk youth make their decisions about tobacco use earlier in life than lower-risk youth; mass media influences can be especially powerful in shaping attitudes and normative perceptions at early ages.

State-based media campaigns. Mass media campaigns are standard components of the well-funded, ongoing tobacco control programs in California, Massachusetts, Arizona, Florida, and other states receiving money for counteradvertising programs from state excise tax increases or tobacco settlement allotments (as was discussed in "Example of Major State Programs," earlier in this chapter). Although it is difficult to sort out the effectiveness of media campaigns from other program components, evaluations of these statewide public education programs, particularly in California and Massachusetts (see "Supplemental Programs" in Chapter 3), have shown their success in reducing tobacco use among adults, slowing the uptake of tobacco among youth, and protecting children from exposure to ETS (CDC 1996). A recent study of the Massachusetts media campaign in 1993 and 1997 found that among younger adolescents (those aged 12-13 years in 1993), those who had been exposed to the counteradvertising campaign on television were about half as likely to have become smokers as those who had not been able to recall campaign advertisements (Siegel and Biener 2000).

Food and Drug Administration campaign. In 1998, the FDA launched a national advertising campaign to help retailers comply with the age and photo identification provisions of the FDA's rules to prevent tobacco sales to children and adolescents. The

campaign began with a test in Arkansas and by year's end was active in 42 states. Funded annually at about \$9 million, the campaign featured radio spots, bill-boards, newspaper advertisements, posters, and store signage. The overall approach was to use humor to relieve the discomfort clerks may feel when checking young people's identification/proof-of-age cards and to increase awareness of the rule provisions among retailers, underage youth, and the general population. One counter card, for example, reads, "Our cashier really stinks at guessing ages. So if you want cigarettes, can we see some I.D.?"

A campaign tracking survey (Market Facts 1998) in nine states with test and control sites found that during the first year of the campaign, knowledge of age 27 as the cutoff age for checking identification increased from 34 to 54 percent in test sites and from 31 to 40 percent in control sites. Most important was a small but significant decline in the average number of times minors tried to buy tobacco. According to retailer self-reports, this number declined from 3.4 times each day before the campaign to 2.8 times daily after the media effort. In control sites, the frequency of underage purchase attempts did not decrease from before (2.4 times daily) to after (2.7 times daily) the time of the campaign. For customers from whom identification was requested in the test sites, retailers reported that the proportion of those who were "often" or "always" irritated declined from 34 percent to 28 percent.

Counteradvertising and entertainment media. The increase in movie depictions of tobacco use is a powerful media influence promoting use among teens (Stockwell and Glantz 1997). In focus groups, young people are not able to recall antismoking messages on television or in the movies, but they recall specific movies that portray smoking and can identify actors and actresses who smoke in their entertainment roles (Crawford et al. 1998). Counteradvertising holds promise for helping denormalize and deglamorize these portrayals in the entertainment media. In an experimental study, Pechmann and Shih (1999) found that placement of a 30-second California Department of Health Services tobacco counteradvertisement before the popular movie Reality Bites served to inoculate teenagers against the movie's pervasive prosmoking cues without detracting from their enjoyment of the film. Because paid advertising in movie theaters is a highly efficient method of reaching adolescents, the authors recommend this tactic as a nationwide cost-effective prevention strategy.

Research on best practices. Although producers of counteradvertising campaigns use formative research techniques to develop products, inconsistent

testing methods hinder comparison of the effectiveness of different messages. This situation has helped create the impression that there is little agreement over "what works" in tobacco counteradvertising, as typified by this *Washington Post* headline: "The Anti-Smoking Campaign's a Many Splendored Thing, and That's the Problem" (Teinowitz 1998).

Goldman and Glantz (1998), using available focus group data and research reports obtained from a number of states, concluded that two message strategies, industry manipulation and the hazards of ETS, are the most effective for denormalizing smoking among young people and reducing consumption among adults. The researchers reported that addiction and cessation messages can also be effective, but that four strategies are not effective: youth access, short-term health effects, long-term health effects, and romantic rejection. They also characterized California's counteradvertising campaign as more "confrontational with the industry" (p. 772) than Massachusetts' "more youth-oriented approach" (p. 772), citing this difference as a major reason for their finding that the California media campaign was relatively more cost-effective. This paper elicited some strong responses. The University of Vermont School and Mass Media Project investigators (Worden et al. 1998) emphasized the limitations of focus group results and the importance of audience age in reactions to messages. They argued that for young people aged 10 to 12 years (the age group in which they recommended starting prevention efforts), presenting messages that foster positive social influence and social norms have proved most effective in reducing tobacco use among youth. Balch and Rudman (1998) responded that young people participating in 110 focus groups in five different states considered numerous concepts and judged five to be more credible, relevant, and persuasive: addiction, short-term health effects, athletic performance, role model for younger siblings, and effects on family. From Massachusetts, Connolly and Harris (1998) noted that industry manipulation and ETS themes constituted 32 percent of all youth-targeted messages and 37 percent of all messages in the Massachusetts tobacco control media campaign and that on a per capita basis, the state actually outspent California on these messages. Moreover, the researchers reported that Massachusetts experienced a larger decline in per capita cigarette consumption than did California for the period 1990–1996.

To obtain data in a more quantitative way, Pechmann and Shih (1999) created a typology based on 196 youth-oriented antismoking television advertisements. They identified three main types—fear appeals, peer norms, and tobacco marketing-and further subdivided these into seven main messages: (1) smokers may face serious health problems, (2) tobacco company deception results in disease and death, (3) smokers endanger their family members, (4) smoking is unattractive, (5) smokers are perceived by peers as misguided, (6) most young people choose not to smoke, and (7) advertisement shows how tobacco companies market their products. The investigators tested a sample of 56 of their advertisements in a group of ethnically diverse 7th, 9th, and 10th graders. After viewing a selection of test and placebo advertisements, study participants completed an evaluation survey to assess the effect of each category on their intent to smoke and on other pertinent measures, such as attitudes toward smoking and knowledge of tobacco marketing tactics. Results showed that only three of the seven messages were highly effective in reducing teenagers' intent to smoke: those that conveyed that smokers endanger their family members, that smokers are perceived by peers as misguided, and that most young people choose not to smoke.

In the Massachusetts campaign study (Siegel and Biener 2000), the authors tested eight smoking-related knowledge and attitude variables corresponding to campaign themes. Only one variable, perceived youth smoking prevalence, changed significantly with exposure to the media campaign at baseline and was associated with the reported reduction in tobacco uptake. Exposed youths were more than twice as likely than their unexposed peers to have an accurate perception at follow-up that fewer than half of the students at their high school were smokers. Variables that did not change were knowledge and attitudes related to lowtar cigarettes, environmental tobacco smoke, chemicals, wrinkles, tobacco company tactics, dating, and sports. This finding points to the power of the mass media, especially television, to set social norms and supports the effectiveness of counteradvertising messages that denormalize tobacco use.

As part of a three-year study exploring racial/ethnic and gender differences in teen tobacco use, a group of 11 CDC-funded university-based Prevention Research Centers conducted a series of focus groups during 1996–1997 to explore potentially effective counteradvertising strategies and messages. Six of the 11 centers used television spots from CDC's Media Campaign Resource Center for Tobacco Control to elicit reactions and stimulate discussion. For the most part, different centers used different advertisements, and they did not attempt to "test" the advertisements in any standardized way to determine relative effectiveness. Nevertheless, the conclusions that emerged from

Teen Focus Group Response to Counteradvertising Messages

(Findings from 11 Prevention Research Centers)

- Without an overall context provided by ongoing advertising and other program elements, the message that tobacco companies are manipulating young people to smoke ("they're lying to you") has relatively low interest and salience among teens and may be miscomprehended.
- Attempts to explain the concept of nicotine addiction and make it personally relevant for young nonsmokers is difficult because most have not experienced the physical cravings of addiction and tend to take messages literally.
- The television spot shown to the most focus groups (about physical performance and featuring the U.S. Women's National Soccer Team) was easily understood, attention getting, and credible and may be generalizable (with some effort) to nonathletic endeavors.
- Young people did not like advertisements that feature text.
- Young people, particularly whites, were sharply critical of any advertisement they perceived as corny, "cute," staged, or unhip.

- As advertising professionals have reported in the research literature, humor was found to be a double-edged sword: it can be very effective, but if used inappropriately can be seen as trivializing the issue. In some focus groups, humorous advertisements obtained both the highest and the lowest scores.
- Young people reacted emotionally and favorably to true, nonpreachy stories about the impact of smoking on a person's or family member's life (such as a television spot from California featuring a man whose wife had died from exposure to his smoking).
- Cartoons tend to have low "stopping power" because teens have seen so many, whereas the use of surprising characters like animals (such as the "Animals" and "Butts" spots from Minnesota) can rivet attention. These attentiongetting spots do not necessarily communicate an effective countermessage, however.
- Messages that portray the negative social effects of tobacco use perform well among teens; messages that focus on health effects can be effective if they are presented dramatically but realistically (such as a California spot featuring a laryngectomy patient smoking a cigarette).

this research (Tobacco Network, unpublished data) give some indication of the complexity of people's response and the considerable challenges to crafting effective messages (see the text box "Teen Focus Group Response to Counteradvertising Messages").

Audience targeting. The use of counteradvertising aimed only at young people rather than the use of a general marketing approach has been controversial. Glantz (1996) criticized the public health community's "preoccupation with youth" (p. 157), particularly youth access campaigns, as an ineffective strategy and one that diverts energy from reducing adult smoking and creating a smoke-free society. Cummings and Clarke (1998) warned that campaigns focused exclusively on young people may be counterproductive if the messages make smoking more appealing to youth by promoting it as something that is

not for them. Indeed, a chief criticism of the tobacco industry-funded booklet Tobacco: Helping Youth Say No was that it portrayed tobacco use as a forbidden fruit and a badge of maturity, thereby increasing its attraction to youth (DiFranza and McAfee 1992). The Institute of Medicine noted that "as adolescents venture more and more into the community, their perceptions that certain norms seem to apply only to them and not to adults may promote health-compromising behaviors" (Lynch and Bonnie 1994, p. 87). Young people participating in focus groups conducted during the third year (1997-1998) of the CDC-funded Tobacco Network project reported that they respect and regard policies targeted to the public at large, such as clean indoor air laws, but resent policies specific to them, such as youth access restrictions. They also resented the inconsistent enforcement of general

Tips for Success in Health Promotion Campaigns

- Target young people in grades six and nine (ages 11 and 15). These years define critical periods in most children's social development, times when many young people change schools and peer groups.
- Target adults with complementary, noncontradictory messages. In a comprehensive strategy, media messages that inevitably spill over from one audience to another can be mutually reinforcing and synergistic. Clean indoor air messages can provide added motivation for adults to quit smoking. Cessation messages for adults can affect young people's perception of norms and highlight the problem of addiction. Prevention messages for young people can increase the salience of the tobacco issue among parents and community leaders.
- Highlight nonsmoking as the majority behavior.
 Most young people overestimate the number of their peers who use tobacco. Campaigns should not seek to correct this misperception and highlight an increasing "problem" of kids who smoke.
- Present realistic tobacco-free lifestyles as practiced by diverse, appealing, and interesting persons. Youth behaviors are driven by how young people perceive the behaviors of people like them. Having a repertoire of social choices is a fundamental need for teens, who are going through a period of profound social and environmental transition.

- Provide constructive alternatives to tobacco use and discourage destructive alternatives.
 Sports and other youth-oriented activities associated with the tobacco-free lifestyle can provide some of that positive social repertoire.
- Communicate the relevant dangers of tobacco. Certain dangers of tobacco, if explained in a creative and memorable manner, resonate with young people—for example, addiction portrayed as a loss of control, the carcinogenicity of environmental tobacco smoke, the toxic chemicals in tobacco products and smoke, and the tangible suffering and visible disfigurement from tobacco-related diseases. Communicate health messages through personal testimonies (tell a story) and creative executions that break through young people's sense of immortality and their (and adults') resistance to traditional health messages.
- Encourage youth empowerment and control.
 Teens need to be offered information and anecdotal experience from which they can begin to understand the world and take control of their own lives.
- Abandon the search for the "magic-bullet" message. There is no single best motivator for preventing or reducing tobacco use. Campaign messages for both young people and adults should feature a variety of themes, appeals (fear, humor, satire, testimonials, etc.), and executional styles. Maximize the number, variety, and novelty of messages rather than communicating a few messages repeatedly.

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policies, such as allowing teachers but not students to smoke on school property.

Worden (in Cummings and Clarke 1998), referring to the research literature on multifaceted education campaigns, noted that reducing the demand for tobacco among young people requires a combination of direct (to youth) and indirect (to adults) messages and careful attention to audience segmentation. He stressed that young people and adults need separate media campaigns that do not contradict each other. For example, a youth-directed television spot that communicates the

message "most kids don't smoke" can be neutralized by an adult-aimed but youth-viewed spot that says "more and more kids are smoking every day."

Characteristics of Successful Campaigns

Though debate continues over the relative effectiveness of strategies employing specific messages, the experience reviewed in preceding sections suggests consensus that counteradvertising campaigns must have sufficient reach, frequency, and duration to be

continued

- Use multiple nonpreachy voices. Not only do different teens require different appeals and creative executions, but diversity of messages is itself a sophisticated message. Teens strongly reject attempts by anyone to dominate or direct them. Messages about industry manipulation, if they are to be relevant and acceptable to youth, should be delivered by nonauthoritarian sources (such as Florida's "Truth" campaign teenagers), not with melodramatic appeals. Avoid highlighting a single theme, tagline, identifier, or sponsor.
- Use a complementary, reinforcing mix of television, radio, print, and outdoor advertising. The campaign should also explore the various alternative media options available (e.g., movie trailers, the Internet, other computer resources, video games, materials for schools and community groups). The media mix is especially important in view of today's proliferating fragmented media market.
- Involve parents and families in activities that will reduce risk factors and promote protective factors for young people at risk for tobacco use. Parents and other family members have substantial influence on the perceptions and behaviors of young people.

- Maximize use of existing high-quality media materials produced by the government, voluntary agencies, and a number of individual states. (Anew, high-quality television spot commonly costs more than \$100,000 to produce.) A large collection of advertisements is currently available through the CDC's Media Campaign Resource Center for Tobacco Control. The cost of placing an advertisement will vary significantly by state and media market.
- Include grassroots promotions, local media advocacy, event sponsorships, and other community tie-ins to support and reinforce the counteradvertising campaign (see "Media Advocacy," earlier in this chapter). Work in concert with other interventions to promote policies that aim to change social norms regarding tobacco. A local "look" for local media messages (e.g., featuring people of ethnic or geographic representation similar to the viewing audience) appears to be more important for adults than for youth, because young people tend to share and be shaped by a more universal, multiethnic youth "media world."

successful. The 1967–1970 media campaign, enabled by the Fairness Doctrine, achieved high frequency (one antismoking advertisement per three cigarette advertisements), extended reach (virtually complete audience penetration through three [pre-cable television] national networks), and long duration (three and a half years). The youth-aimed media campaign of the University of Vermont School and Mass Media Project exposed 50 percent of the target population to each television and radio spot about 6 times each year over a four-year period (about the midpoint in the recommended exposure range of 3 to 10 times per year). This level of exposure is possible only through paid media placement.

Another lesson from health promotion campaigns is the need for research at every phase of campaign planning and implementation. Campaigns should be grounded in the extensive literature on psychosocial risk factors for initiating, continuing, and stopping tobacco use and should be guided by expertise in

communications theory and practice. Media materials should undergo rigorous audience pretesting to ensure they achieve predetermined communication objectives with their target audiences. Ongoing measurement of the communications' impact is needed to evaluate the effectiveness of the campaign and to guide midcourse corrections.

Through the Columbia University Prevention Research Center in New York City, the CDC convened a panel of youth marketing and research experts in 1996 to advise the agency on effective countermarketing approaches to prevent tobacco use among young people. Over two years, the expert panel reviewed the literature, interviewed experts in tobacco control and health promotion, and drew on their private-sector experience and resources to develop a set of strategic guidelines for such a campaign (McKenna et al. 2000). This work, supplemented by other reviews of counteradvertising campaigns (USDHHS 1994; Pechmann 1997; Siegel 1998; Teenage Research

Unlimited 1999; Pechmann and Reibling 2000), yielded recommendations for effective media campaigns to prevent tobacco use (see the text box "Tips for Success in Health Promotion Campaigns").

These recommendations serve as general guidance for tobacco counteradvertising efforts, but further research is needed to refine our understanding of the role and effects of mass media. Relevant areas for further investigation include determining the impact of counteradvertising on tobacco use behaviors, on readiness to quit, on attitudes toward tobacco advertising and tobacco use, and on other predictors of initiation and cessation; identifying the most effective themes, techniques, and messages; tailoring messages to highrisk groups; exploring the role of new communication tools, such as the Internet; attributing impact; and examining the interaction of media campaigns with private and public tobacco control policies.

Summary

The conceptual framework described at the start of this chapter defines the basic components of the health promotion intervention model. The statewide tobacco control programs being funded either by increases in cigarette excise taxes or settlements with the tobacco industry are creating a new laboratory to test many of these conceptual models for comprehensive tobacco control. Recently, both the Institute of Medicine (IOM) and researchers have released reviews of the emerging data from these statewide tobacco control efforts. In their report, the IOM (2000) noted that it is difficult to attribute a reduction in tobacco use to any single factor; nevertheless, they conclude that "multifaceted state tobacco control programs are effective in reducing tobacco use"(p. 4). In a review focusing more specifically on the effectiveness of these new statewide tobacco control programs on teenage smoking, Wakefield and Chaloupka (1999) conclude that "There is consistent evidence the programs are associated with a decline in adult smoking prevalence"(p. 6), but they are somewhat more cautious about the impact of these programs on youth smoking. Nevertheless, they do conclude that "Notwithstanding these cautions, we find that the weight of evidence falls in favor of comprehensive tobacco control programs being able to reduce teenage tobacco use" (p. 6).

In the consideration of the emerging data from these statewide tobacco control programs, it is important to note that many programmatic elements of the comprehensive tobacco control program framework are still being refined and evaluated. Thus, no current statewide program serves an ideal or model program. Wakefield and Chaloupka (1999) conducted a careful review of the various elements of the statewide

programs in Arizona, California, Florida, Massachusetts, and Oregon. They placed special attention on the strengths of the "inputs"—"namely, what was actually implemented as part of the programs." Additionally, they assessed how "actual implementation of program strategies may differ substantially from intended implementation" and noted that "the extent of disparity may vary over time and between programs." Much more evaluation research is needed in order to sort out the efficacy of individual components of these evolving comprehensive programs and to refine the comprehensive program structure.

Finally, although the data from these statewide tobacco control programs are encouraging, these results need to be considered in the perspective of the less favorable results from the community trials. The conceptual framework for the comprehensive tobacco control programs shares many elements with the theoretical models used to develop the community trial interventions. However, as Wakefield and Chaloupka (1999) noted, the programs actually implemented may differ substantially from the intended implementation. There has been some effort to analyze how the program components within the emerging statewide tobacco control programs may differ from interventions tested within the community trials (Green and Richard 1993; Schmid et al. 1995), but much more work is needed in this area. As the IOM (2000) and Wakefield and Chaloupka (1999) concluded, the results from the statewide tobacco control programs are favorable. However, both reviews emphasize the importance of continued surveillance and evaluation efforts to monitor program performance, to provide accountability for the use of public funds, and to improve program efforts.

Conclusions

- 1. The large-scale interventions conducted in community trials have not demonstrated a conclusive impact on preventing and reducing tobacco use.
- 2. Statewide programs have emerged as the new laboratory for developing and evaluating comprehensive plans to reduce tobacco use.
- 3. Initial results from the statewide tobacco control programs are favorable, especially regarding declines in per capita consumption of tobacco products.
- 4. Results of statewide tobacco control programs suggest that youth behaviors regarding tobacco use are more difficult to change than adult ones, but initial results of these programs are generally favorable.

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Introduction

Tobacco use, particularly cigarette smoking, remains the leading cause of preventable illness and death in the United States (McGinnis and Foege 1993). A major challenge to our nation's public health leaders in the new millennium is to make this disturbing observation a thing of the past. Such a goal is no millennial dream. This Surgeon General's report provides evidence that tobacco use in this nation can be reduced through existing modalities of interventions.

The substantial body of literature reviewed in this report indicates that each of the modalities—educational, clinical, regulatory, economic, and social—provides evidence of effectiveness. The six major conclusions of this report provide the framework for the development of a coherent, long-term tobacco policy for this nation. Thus, although our knowledge about tobacco control remains imperfect, we know more than enough to act now. Widespread dissemination of the approaches and methods shown to be effective in each modality and especially in combination would substantially

- Reduce the number of young people who will become addicted to tobacco.
- Increase the success rate of young people and adults trying to quit using tobacco.
- Decrease the level of exposure of nonsmokers to environmental tobacco smoke (ETS).

- Reduce the disparities related to tobacco use and its health effects among different population groups.
- Decrease the future health burden of tobaccorelated disease and death in this country.

These achievable improvements parallel the health objectives set forth in *Healthy People 2010*, the national action plan for improving the health of all people living in the United States for the first decade of the 21st century (U.S. Department of Health and Human Services [USDHHS] 2000). Twenty-one specific national health objectives related to tobacco use are listed in *Healthy People 2010*, including reducing the rates among young people and adults to less than half of the current rate of use. Attaining all of these tobacco-related objectives will almost certainly require significant national commitment to the various successful approaches described in this report.

The report's major conclusions are not formal policy recommendations. Rather, they offer a summary of the scientific literature about what works. In short, this report is intended to offer policymakers, public health professionals, professional and advocacy organizations, researchers, and, most important, the American people guidance on how to ensure that efforts to prevent and control tobacco use are commensurate with the harm it causes.

Continuing to Build the Scientific Base

Beginning with the 1964 Surgeon General's report, *Smoking and Health* (U.S. Department of Health, Education, and Welfare 1964), tobacco control policy in this nation has been built on a foundation of scientific knowledge. Each of the subsequent 24 reports of the Surgeon General on tobacco use has documented a vast and growing body of scientific literature. The substantial research reviewed in this report focuses on a key segment of the literature—what has been tried in the decades-old effort to reduce tobacco use. In turn, this focus clarifies which efforts work best. Certainly more research is needed so that these efforts can be

more efficient and effective; the key conclusion from this report, however, is that we know more than enough to take actions now to decrease the future health burden of tobacco-related disease and death in this country.

In the process of applying our current state of knowledge about preventing and controlling tobacco use, accountability and evaluation of the public health effort will be critical. However, because of the wide array of educational, clinical, regulatory, economic, and social influences that have been and will need to be brought to bear on the tobacco use problem, the direct

impact of a specific maneuver on a specific outcome becomes less meaningful as the combined effects become more substantial. Investigators tend to work on small, manageable aspects of the tobacco use problem, but the synergistic influence of multiple factors over time will likely extend far beyond the outcomes predicted from these smaller research undertakings. For example, as this report demonstrates, the most efficacious educational programs are those that take place in a larger community context, one that engenders and supports an environment of nonsmoking. Similarly, although clinical interventions to manage tobacco addiction clearly have some specific power to help smokers quit, primarily through pharmacological means, the social environment remains a major determinant of whether these new former smokers maintain their abstinence from nicotine addiction. Regulatory efforts, on the other hand, raise a host of social and economic issues and can produce broad societal changes—issues and changes, however, that are difficult to isolate, document, and evaluate. Economic strategies also have a great potential, but being fundamentally political in nature, they require public consensus and changes in social norms before they can be attempted. Finally, the public health advocacy involved in social program modalities is virtually impossible to assess in a prospective or controlled research design.

The research and evaluation tools of public health must expand to meet these complex issues. Comprehensive, multifactorial approaches to tobacco control appear to offer the most promise. However, the penalty for comprehensive approaches is a loss of statistical power to attribute outcomes to specific activities. Within each of the modalities, appropriate evaluation methodologies are being used (see Table 1.1). However, many of these methodologies involve retrospective case study, time trend, econometric, and surveillance approaches to evaluate the "natural experiment" as it evolves in the changing social environment. Thus, the traditional biomedical and epidemiologic research methods that have worked so well in defining the health consequences of tobacco use are not well suited to evaluating the potentially most efficacious methods to reduce tobacco use.

The Changing Tobacco Industry

This report documents that this country's efforts to prevent the onset or continuance of tobacco use have faced the pervasive, countervailing influences of tobacco promotion by the tobacco industry. Despite the overwhelming and continually growing body of evidence of adverse health consequences of tobacco use, the norm of social acceptance of tobacco use in this nation has receded more slowly than might be expected, in part because of such continued promotion.

Litigation and legal settlements have produced notable changes in the tobacco industry's public positions on health risks, nicotine addiction, and advertising and promotion limits. Additionally, individual manufacturing companies have become more directly involved in efforts to limit the access of underage persons to tobacco products and to prevent young people from initiating tobacco use. In this rapidly changing social and legal environment, it is difficult to project the nature and scope of future changes by the industry or their impact on the national effort to reduce tobacco use. Nevertheless, any analysis of changes in patterns of

tobacco use must consider the influence of these industry changes.

One of the major arenas of potential change will be in the tobacco product itself. The manufactured cigarette that is widely marketed in the developed world was noted to be changing dramatically when this issue was first considered by the Surgeon General in 1981, in *The Changing Cigarette* (USDHHS 1981). Recent public statements by the tobacco industry suggest that the pace of changes in the manufactured cigarette could be accelerating in the future. The public health implications of changes in manufactured cigarettes and other tobacco-containing products will require careful and significant attention from both public health researchers and policymakers.

The litigation environment has demonstrated the importance of tobacco industry documents in analyzing the industry's influence. Legal and public health analyses are just beginning to sift through the millions of pages of documents made public as part of the various legal actions undertaken over the last decade. As this process continues, public health researchers may develop better methods to define and evaluate the industry's past activities that may have contributed to the character, pace, or direction of changes in tobacco use patterns in this country or around the world.

The Need for a Comprehensive Approach

The evidence of effectiveness summarized in this report emphasizes that public health success in reducing tobacco use requires activity using multiple modalities. A comprehensive approach—one that optimizes synergy from applying a mix of educational, clinical, regulatory, economic, and social strategies has emerged as the guiding principle for future efforts to reduce tobacco use. The public health goals of such comprehensive programs are to reduce disease, disability, and death related to tobacco use through prevention and cessation, as well as through protection of the nonsmoker from ETS.

The emerging body of data on statewide tobacco control efforts is coming from programs broadly focused on prevention, cessation, and protection of the nonsmoker from ETS (Chapter 7). Preventing initiation among young people is a primary goal of any tobacco control effort. However, young people will perceive contradictory or inconsistent messages in our prevention efforts if programs do not also address the smoking behavior of millions of parents and other adult role models and the public health risks of ETS.

The Centers for Disease Control and Prevention (CDC) recently released Best Practices for Comprehensive Tobacco Control Programs (CDC 1999), which recommends that states establish tobacco control programs that are comprehensive, sustainable, and accountable. This document draws upon "best practices" determined by evidence-based conclusions from research and evaluation of such comprehensive programs at the state level. In the review of evidence from these states, it was evident that reducing the broad cultural acceptability of tobacco use necessitates changing many facets of the social environment. Nine specific elements of a comprehensive program are defined in the guidance document. Although the importance of each of the elements is highlighted, the document stresses that these individual components must work together to produce the synergistic effects of a comprehensive program.

A medical analogy might be helpful to understand the practical implications of the current state of knowledge about these best practices of tobacco control. If we found a combination of nine therapy elements that effectively treated an almost incurable disease (e.g., advanced lung cancer), we would study the combined therapy in many ways to learn more about how it worked and which aspects of this combination therapy were most effective. However, while we were doing this research, we would give every patient with the disease the full combination of the nine therapy elements.

In the same way, with the nine components of Best Practices, we need to continue evaluating ongoing comprehensive programs to gain more knowledge about how the components work individually and in combination. But while this research continues, states should be applying all nine components.

Best Practices thus provides effective guidance for state-level efforts; a comprehensive national tobacco control effort, however, requires strategies that go beyond this guidance to states. As documented in earlier chapters of this report, a comprehensive national effort should involve the application of a mix of educational, clinical, regulatory, economic, and social strategies. In each of these modalities, some of the program and policy changes that are needed can be addressed most effectively at the national level.

Identifying and Eliminating Disparities

The elimination of health disparities related to tobacco use poses a great national challenge. Although this issue was not a main aspect of the current report, two other recent USDHHS publications have taken this focus. The 1998 Surgeon General's report *Tobacco* Use Among U.S. Racial/Ethnic Minority Groups was the first to address the diverse tobacco control needs of the four major U.S. racial/ethnic minority groups— African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics (USDHHS 1998). Similarly, Healthy People 2010, released in January 2000, has two overarching goals: increase quality and years of healthy life and eliminate health disparities among different segments of the U.S. population (USDHHS 2000). Both publications not only highlight the significant disparities in health that exist in the United States but also stress the critical need for a greater focus on this issue, both in research and in public health action.

Cultural, ethnic, religious, and social differences are clearly important in understanding patterns of tobacco use, but little research has been completed on the relative effectiveness of interventions for prevention and treatment in some of the population groups or communities. Reaching the national goal of eliminating health disparities related to tobacco use will necessitate improved collection and use of standardized data to correctly identify disparities in both health outcomes and efficacy of prevention programs among various population groups. Broader historical, societal, and community characteristics can have a significant influence on the manner in which prevention and control strategies that work overall for the population as a whole may impact diverse groups. Many of these broader variables do not lend themselves to traditional measurement methods, nor are they easily assessed at the individual level through the use of traditional epidemiologic methods.

Improving the Dissemination of State-of-the-Art Interventions

One of the greatest challenges in tobacco control and public health in general continues to be overcoming the difficulty in getting advances in prevention and treatment strategies effectively disseminated, adopted, and implemented in their appropriate delivery systems. Simply stated, our recent lack of progress in tobacco control is attributable more to the failure to implement proven strategies than it is to a lack of knowledge about what to do. The result is that each year in this nation, more than 1 million young people continue to smoke, and more than 400,000 adults continue to die prematurely from tobacco-related diseases.

Within each of the modalities reviewed in this report, some specific research advances in tobacco prevention and control strategies have not been fully implemented. Studies are urgently needed to identify the social, institutional, and political barriers to the more rapid dissemination of these research advances. Understanding these barriers and determining how they could be overcome would benefit not only tobacco control but also public health efforts more broadly.

Tobacco Use in Developing Nations

Analyses by the World Health Organization (WHO) have concluded that by 2030, current smoking patterns will produce about 500 million premature deaths from tobacco-related disease among people alive today (World Health Organization 1999). WHO further estimates that by 2030, tobacco is expected to be the single greatest cause of death worldwide, accounting for an estimated 10 million deaths per year. Although the impact of tobacco-related disease and death has been until recently a problem primarily for the developed countries of this world, WHO now estimates that by 2020, 7 of every 10 tobacco-related deaths will be in the developing world.

This report addresses research on strategies to reduce tobacco use within our nation's social, legal, and cultural environment. Nevertheless, findings from this report may have broad utility in the planning of tobacco control efforts around the world. As Chapter 2 documents, the public health response in this country to the scientific findings about the health consequences of tobacco products has taken more than four decades to emerge. In many parts of the developing world, the problems of tobacco use are similar to those in this country in the 1950s and 1960s. Hence, a key public health question for this millennium may be the following: can the time interval be significantly shortened between when the health risks of tobacco for a developing country are recognized and when a comprehensive national response is begun?

WHO, the World Bank, and the United Nations Foundation, with technical assistance from the CDC, have undertaken major new initiatives to address this problem. The WHO Tobacco Free Initiative is developing an international tobacco control infrastructure, which includes a global tobacco surveillance system, intervention tool kits, and regional technical assistance workshops. The World Bank has published Curbing the Epidemic: Governments and the Economics of Tobacco Control (Jha and Chaloupka 1999). This document provides an economic analysis that supports a multipronged approach to tobacco control, involving raising excise taxes, promoting policy changes related to the sales and promotion of tobacco products as well as to restrictions on smoking in public places, and widening access to smoking cessation therapies. The scientific findings in this report are consistent with the programmatic recommendations of both the WHO Tobacco Free Initiative and the World Bank document.

A momentous undertaking of WHO and member states, including the United States, is the development and negotiation of the Framework Convention on Tobacco Control. If brought to its intended ratification in the next few years, this agreement would provide a framework within which countries could develop more specific bilateral and multilateral protocols for cooperation on containing the spread of the tobacco epidemic. The framework would enable countries to start from a common understanding of the issues, priorities, and strategies necessary to harmonize tobacco control efforts between themselves so that some countries do not benefit at the expense of others. This is the spirit of the other activities of U.S. governmental and nongovernmental agencies in their effort to collaborate with WHO and with other countries in their development of surveillance, cessation, prevention, mass media, regulatory, economic, and social approaches to global tobacco control.

In the near future, emphasis must be placed on the development of surveillance systems so that countries can know the extent, distribution, and trends of the tobacco consumption problems in their populations. These systems will also track—for international comparison and monitoring of progress—the emergence of new forms of tobacco promotion, as well as new legislation, regulations, and programs for countering tobacco use. In the longer term, the gaps must be filled in each country's defenses against the incursions of tobacco use on their young people and other vulnerable populations. In particular, there will be a continuing need to ensure that the rapidly expanding knowledge about the efficacy of various tobacco control modalities be made available to the developing world.

The challenge to the world is to prevent tobacco use, particularly smoking, from ever becoming the leading cause of preventable illness and death in the world. Dr. Gro Harlem Brundtland, the current directorgeneral of WHO, clearly defined this challenge when she stated, "If we do not act decisively, a hundred years from now our grandchildren and their children will look back and seriously question how people claiming to be committed to public health and social justice allowed the tobacco epidemic to unfold unchecked" (Asma et al., in press).

Tobacco Control in the New Millennium

Tobacco use will remain the leading cause of preventable illness and death in this nation and a growing number of other countries until tobacco prevention and control efforts are commensurate with the harm caused by tobacco use. This report provides the composite review of the major methods—educational,

clinical, regulatory, economic, and social—that can guide the development of this expanded national effort. This report is, therefore, a prologue to the development of a coherent, long-term tobacco policy for this nation.

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Abbreviations

ABC	American Broadcasting Company	GASP	Group Against Smokers' Pollution, Inc.,
ACIR	Advisory Commission on Intergovernmental Relations	Alleviate Smoking in Public Places,	Group Against Smoking Pollution, Group to Alleviate Smoking in Public Places, Georgians Against Smokers' Pollution
ACS	American Cancer Society	GATT	General Agreement on Tariffs and Trade
ADA	Americans with Disabilities Act	GCP	German Cardiovascular Prevention Study
ADAMHA	Alcohol, Drug Abuse, and Mental Health	ICC	Interstate Commerce Commission
	Administration	IMPACT	Initiatives to Mobilize for the Prevention and
AEG	American Economic Group, Inc.	minci	Control of Tobacco Use
AHA	American Heart Association	INWAT	International Network of Women Against
AHRQ	Agency for Healthcare Research and Quality		Tobacco
AIDS	acquired immunodeficiency syndrome	IOM	Institute of Medicine
ALA	American Lung Association	IRS	Internal Revenue Service
ALERT	Adolescent Learning Experiences in Resistance Training	KYB	Know Your Body
AMA	American Medical Association	LST	Life Skills Training
ANR		MFN	most favored nation
ASSIST	Americans for Nonsmokers' Rights	MHHP	Minnesota Heart Health Program
	American Stop Smoking Intervention Study	MPP	Midwestern Prevention Project
AzTEPP	Arizona Tobacco Education and Prevention Program	NAAAPI	National Association of African Americans for Positive Imagery
BRFSS	Behavioral Risk Factor Surveillance System	NAFTA	North American Free Trade Agreement
BUGA-UP	Billboard Utilising Graffitists Against Unhealthy Promotions	NCI	National Cancer Institute
CAUC	Coalition Against Uptozwn Cigarettes	NELS	National Education Longitudinal Study
СВО	Congressional Budget Office	NHLBI	National Heart, Lung, and Blood Institute
CDC	Centers for Disease Control and Prevention	NSA	National Smokers Alliance
CHAD	Community Syndrome of Hypertension,	NSTEP	National Spit Tobacco Education Program
	Atherosclerosis and Diabetes	NTCP	National Tobacco Control Program
COMMIT	Community Intervention Trial for Smoking	OIG	Office of Inspector General
	Cessation	OR	odds ratio
CRS	Congressional Research Service	PSA	public service announcement
CSAP	Center for Substance Abuse and Prevention	RICO	Racketeer Influenced and Corrupt
CSH	Coalition on Smoking OR Health		Organizations Act
D.A.R.E.	Drug Abuse Resistance Education	SAMHSA	Substance Abuse and Mental Health Services
DOC	Doctors Ought to Care		Administration
EPA	Environmental Protection Agency	SCARC	Smoking Control Advocacy Resource Center
ETS	environmental tobacco smoke	SHOUT	Students Helping Others Understand Tobacco
FCC	Federal Communications Commission	SHPPS	School Health Policies and Programs Study
FDA	Food and Drug Administration	STAT	Stop Teenage Addiction to Tobacco
FDCA	Food, Drug, and Cosmetic Act	TNT	Towards No Tobacco Use
FTC	Federal Trade Commission	TPLR	Tobacco Products Litigation Reporter
GAO	General Accounting Office	11 21	Toonee I rounces Enganon Reporter

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TVSFP	Television, School, and Family Smoking Prevention and Cessation Project	VSMM	University of Vermont School and Mass Media Project
U.S.C.	United States Code	WCTU	National Woman's Christian Temperance
USDA	U.S. Department of Agriculture		Union
USDHEW	U.S. Department of Health, Education, and	WHO	World Health Organization
	Welfare	WSP	Waterloo Smoking Projects
USDHHS	U.S. Department of Health and Human Services	YRBS	Youth Risk Behavior Survey

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