Public Policy Issues in Direct-to-consumer Advertising of Prescription Drugs

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July 8, 2002

I wish to thank Ed Slaughter of *Prevention Magazine* for providing data and comments on earlier, related drafts, and Randolph Stempski for data analysis. I benefitted greatly from comments by Pauline Ippolito and two anonymous reviewers. I also gratefully acknowledge partial financial support from the Coalition for Health Care Communication, whose members are the American Association of Advertising Agencies, the American Advertising Federation, the American Medical Publishers Association, the Association of Medical Publications, the Association of National Advertisers, the Healthcare Businesswomen's Association, the Healthcare Marketing & Communications Council, the Medical Marketing Association, the Midwest Healthcare Marketing Association, and the Public Relations Society of America.

Abstract

In August 1997, the Food and Drug Administration announced a reinterpretation of its rules on DTC advertising, the effect of which was to permit branded broadcast ads and therefore to increase the volume of DTC advertising several-fold. A substantial body of research, consisting primarily of consumer surveys, provides the basis for a preliminary assessment of the effects of DTC ads. The FDA's own assessment, that DTC ads can provide substantial benefits and do not appear to cause substantial harm, is consistent with survey and other data. DTC ads appear to provide valuable information (including risk information), induce information-seeking (mainly from physicians), prompt patients to discuss conditions not previously discussed, and generate significant positive externalities including the possibility of improved patient compliance with drug therapy. The effects of DTC ads on drug consumption and on health care have yet to be assessed. The author suggests that a further relaxation of FDA rules would accelerate the dissemination of valuable information, with favorable consequences for drug development and consumer health.

Introduction and Background

The 1962 amendments to the Food, Drug, and Cosmetic Act, which charged the Food and Drug Administration (FDA) with regulating pharmaceutical effectiveness in addition to regulating safety, also transferred responsibility for prescription drug advertising from the Federal Trade Commission (which still regulates advertising for over-the-counter drugs) to the FDA. In the early 1980s, a few pharmaceutical manufacturers experimented with prescription drug ads directed at consumers.[1] In September 1982, having previously announced that direct-to-consumer (DTC) advertising was not inherently in violation of FDA law and regulations, the FDA declared a "moratorium" on DTC advertising, with which the industry complied.

In 1985, the FDA lifted its moratorium but emphasized that DTC ads must meet the same standards as those aimed at professionals. Print ads would have to include a detailed "brief summary" of risk and other information. Broadcast ads would have to include a much shorter but nonetheless lengthy "major statement" of risks, while also making "adequate provision" for viewers to obtain full FDA-approved prescribing information. Because meeting the broadcast requirements was impractical, advertisements were forced to take one of two very different approaches. "Help-seeking" ads could discuss the fact that a treatment existed for a condition, but could neither mention a drug by name nor make suggestions and representations about drug treatments. "Reminder" ads could emphasize drug brands but could not mention what conditions the drugs could treat. Under these constraints, DTC advertising gradually increased from $12 million in 1989 to $55 million in 1991, $164 million in 1993, $340 million in 1995, and $579 million in 1996 (Pines 1999).

In August 1997, the FDA issued a preliminary "Guidance for Industry" that reinterpreted FDA regulations without actually changing any regulations

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[1] See Pines, 1999, upon which much of this history in this section draws.

(FDA 1997). Reiterating traditional requirements, the Guidance stated that in addition to being nondeceptive, prescription drug advertising must:

(1) Present a fair balance between information about effectiveness and information about risk.

(2) Include a thorough, major statement conveying all of the product's most important risk information in consumer-friendly language.

(3) Communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.

The new interpretation made clear, however, that the "major statement" in radio and TV ads could be far simpler than what had previously been required. "Adequate provision" of required information could be achieved by including a very concise summary of risks and related information (often via voice-over), while identifying sources for more complete information: an 800 number; an Internet website address; either concurrent print ads or information about specific, publicly accessible locations such as pharmacies; plus a statement that information is available from all physicians and pharmacists. The FDA stated that it would review its policy after 2 years, and invited interested parties to provide information and research on the effects of DTC ads.

In 1999, the FDA commissioned a consumer survey on DTC ads, which is discussed below. In August 1999, with preliminary survey results in hand, the FDA issued a final Guidance on DTC advertising (FDA 1999a, b). The requirements remained essentially unchanged from August 1997. The FDA also stated that it had not seen compelling evidence that DTC advertising had tended to cause any of the harms of which it had been accused. Reiterating its 1997 plan, the FDA planned to evaluate the effects of DTC advertising during the next two years (FDA 1999b). In March 2001, the FDA announced plans for another consumer survey plus a survey of physicians, and it invited comments on survey design and on the effects of DTC advertising (FDA 2001a). Partial results from the consumer survey (the results of which have not been completely released) are

discussed below. The physician survey has gone more slowly due to low response rates.

In the wake of the August 1997 policy change, DTC advertising continued to accelerate, reaching $1.3 billion in 1998, $1.9 billion in 1999, $2.5 billion in 2000, and $2.7 billion in 2001 (Petersen 2002 for years 1998-2000, IMS Health 2002 for year 2001). A pharmaceutical firm (Pfizer) was *Advertising Age Magazine*'s choice as 2001 marketer of the year, and was the ninth-largest advertiser during the first three quarters of 2001 (Goetzl 2001).

These events have been accompanied by vigorous debate on the effects of DTC ads. Before considering that debate, however, it will be useful to review the context in which DTC advertising occurs.

The Market Context of DTC Advertising

DTC advertising of prescription drugs differs from almost all other advertising in two respects. One is the requirement for consumers to obtain a physician's prescription before purchase, a requirement that (significantly for an understanding of FDA regulation) was not originally dictated by legislation.[2] This requirement has several effects. One is to alter consumer costs, in partially offsetting ways. The necessity of visiting or communicating with a physician increases costs in terms of time, inconvenience, and out-of-pocket expenditures for a visit. Marginal costs are minimal, however, when a prescription is obtained in an appointment that would have occurred anyway (as is almost always the case according to surveys discussed below). Out-of-pocket drug expenditures, on the other hand, are reduced by the fact that health insurance typically covers most of the cost of prescription drugs (but not over-the-counter, or OTC, drugs): the proportion of out-patient prescription drug costs paid by third-parties has

[2] On the obscure origins of the prescription requirement, see Temin 1979 and Marks 1995.

increased from 31% to 68% between 1980 and 2000 (Berndt 2001; USDHHS 2002a). The prescription requirement also insures (with very few exceptions) that the buyer receives the benefit of a physician's expert knowledge of the product, often with the addition of explicit information on product risks as well as benefits.[3] Finally, the prescription requirement delays the effects of advertising. In some cases, the delay can be substantial. An example, discussed below, is advertising for the statin class of cholesterol-reducing drugs, a drug category in which a prescription (if any) is typically written only after laboratory testing followed by an attempt at life-style changes.

A second unique aspect of DTC advertising is its regulatory environment. FDA regulation of prescription drug advertising is exceptionally stringent.[4] FDA staff do not always review ads before publication (but they often accede to manufacturers' requests to do so), but the most important advertising claims are essentially subject to pre-clearance because FDA regulations prohibit therapeutic claims that have not been approved for listing in drug labeling. That labeling is usually extremely detailed, specifying such matters as the precise illness or condition to be treated (certain outdoor allergies, for example, but not indoor allergies), dosage, even relationships with other or prior therapy. Hence the bulk of FDA advertising regulation has traditionally consisted of comparing ad claims to label contents (Fisherow 1987; Kessler and Pines 1990). The FDA also routinely challenges implied claims, and it systematically reviews advertising

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[3] A contrast with medical device marketing is worth noting. DTC advertising for devices is regulated by the FTC, not the FDA, and typically includes far less risk information. Most devices also require a physician's prescription, but that requirement is often subordinate to the simple fact that a physician's oversight is necessary to administer treatment using the device.

[4] The FTC and FDA actually share responsibility for prescription drug advertising directed at consumers, but the more expansive FTC approach to advertising regulation insures that FDA regulations are usually the constraining ones. The FDA does not have responsibility for regulating medical device advertising, even for such sophisticated devices as MRIs, where a physician's intervention is required. The FTC regulates device advertising, albeit with obvious deference to the views of the FDA.

materials either when voluntarily submitted beforehand or after they become public (Ostrove 1991; Adams 2002).

Perhaps the most important aspect of FDA advertising regulation is the fact that it is essentially never challenged in court by pharmaceutical firms, which (often after negotiation with FDA staff) invariably accede to FDA demands to modify or drop challenged claims and ads. As a member of the FDA advertising regulation staff noted in a 1987 journal article (Fisherow 1987, p. 230), "This capacity to resolve difficulties to its satisfaction before they reach the courts has delivered what FDA wants most, the prompt cessation or transformation of a questioned advertising claim or campaign, with a relatively modest expenditure of resources." This extraordinary level of cooperation arises from the fact that manufacturers know that in addition to regulating their advertising, the FDA approves all their new products, their manufacturing methods and facilities, and other essential operations including clinical trials. Firms therefore feel it is strongly to their interest to maintain amicable relations with the FDA staff (Hutt 1993; Calfee 1996). These forces were clearly described in Fisherow's article (p. 231-232; notes eliminated):

> One may speculate about why the Agency has been so successful. It may be that it is always correct in its analysis and persuasive enough in its communication to deter an advertiser from continuing to disseminate a questioned message. The more likely case is that the Agency is not always right, but that it succeeds anyway because of the nature of its relationship with pharmaceutical advertisers.

The author continues (p. 231-232; notes eliminated), comparing this situation with that surrounding FTC regulation:

> . . . the FDA licenses the prescription drug products subject to its regulation and approves labeling which effectively sets the limits on what may be communicated about product performance. This pervasive involvement in the industry's current and future business means that a corporate decisionmaker needs to consider more than just the merits of the company's position in the particular advertising dispute at hand. The executive must also weigh how much disagreement with the FDA staff in a current matter might

> affect future treatment. No such continuing relationship exists between the FTC and any industry.

The willingness of FDA staff to link enforcement actions in one area, such as manufacturing facilities, with regulation in another area, such as new drug approvals, is well known and has been widely reported in the news media.[5] Firms have recently paid fines of as much as $500 million because of FDA dissatisfaction with manufacturing facilities even when neither the FDA nor the medical community has deemed any of the products from the factories in question to be unsafe or worthy of recall (Anand 2002)

Notwithstanding industry forbearance from challenging the FDA in court, the First Amendment's protections for commercial speech also play a role. The Washington Legal Foundation, an independent public interest group, has launched several First Amendment challenges to FDA regulation of advertising and promotion directed at physicians (W.L.F. 1994, 1995). Other litigation has challenged FDA regulations for the advertising of supplements (Pearson v. Shalala 1999). These cases have proceeded slowly but with considerable success, forcing the FDA to loosen its policies about manufacturers' dissemination of "off-label" information (i.e., information not listed in the FDA-approved materials about a prescription drug; see Oliphant 2000).

Even critics who vigorously advocate even stronger FDA regulation have stated that nondeceptive DTC ads (the only kind that FDA regulations permit) are protected by the First Amendment (Wolfe 2002). A return to the years before any DTC ads took place, or to the regulatory regime that existed before 1997, would be Constitutionally suspect. Reflecting these circumstances, the FDA recently published a Federal Register notice asking for public comments on how it can ensure that its regulatory activities conform to recent Supreme Court

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[5] In their article on current FDA effects to raise manufacturing standards through enforcement actions, Petersen and Abelson (2002) note, "The agency has also begun holding up approval of new drugs until the companies can convince it that they have fixed manufacturing problems -- an action that gets investor attention quickly and can send the price of a company's stock down."

rulings on First Amendment protections for commercial speech (FDA 2002a, which also briefly summarizes the related litigation).

The Debate over DTC Advertising

The United States and New Zealand are the only developed nations that permit DTC advertising of prescription drugs.[6] Canada and the European Union nations have seen a continuing debate over whether to follow the U.S.'s example.[7] The E.U. recently began a very limited experiment in which manufacturers would be permitted to provide consumers with information on treatments for three therapeutic categories (diabetes, AIDS and asthma) via pamphlets and other materials (but only in response to consumer requests), and in websites (European Commission 2001 and Meek 2001). There seems little reason, however, to expect Canada or the E.U. to substantially alter their policies in the near future (Meek 2001).

In the meantime, DTC advertising has prompted considerable discussion and analysis in the U.S.[8] Most of the criticism has come from the physician community (Hollon 1999), and health insurance organizations. A late 1997 poll of physicians found a strong majority desiring tighter regulation or a ban on DTC

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[6] The New Zealand experience is of obvious interest not just because DTC ads are permitted but also because they are regulated by the Advertising Standards Authority, a self-regulatory body. See Hoek and Gendall 2002a and 2002b, the latter to be published in this journal along with the present paper. The pharmaceutical industry view of DTC in New Zealand is provided in R.M.I.A.N.Z. (n.d.).

[7] Meek 2002 provides a thorough review of DTC regulatory issues in the E.U., New Zealand, and Canada. On the Canadian situation, also see Calfee 2001. A recent debate in the pages of the *British Medical Journal* consists of Mintzes 2002 and Bonaccorso and Sturchio 2002.

[8] Leading reviews are Wilkes, Bell, and Kravitz 2000; Lyles 2002; Rosenthal, et al. 2002; plus a May 2001 conference, complete with papers, convened by the office of the Assistant Secretary for Planning and Evaluation in HHS (see Bero and Lipton 2001; Frank, et al. 2001; Schommer and Hansen 2001). Other useful reviews include Meek 2001 and National Health Council 2002b.

advertising (IMS Health Dec. 2, 1997; McGinley 1999). Managed care organizations and large employers have complained that DTC advertising causes excess prescribing or shapes consumer preferences toward more expensive branded drugs (NICHM 2001; Blue Cross Blue Shield 2002; Burton 2002).

The medical community's opposition to DTC advertising has greatly moderated in the past few years. In 1998, *Lancet*, a leading British medical journal, published an unsigned editorial arguing that DTC advertising would benefit European consumers. Hoek and Gendall (2002b) note that both the New Zealand Medical Association and the Royal College of New Zealand General Practitioners have issued statements endorsing the continuation of DTC advertising in New Zealand under the current self-regulatory regime. In 2000, the American Medical Association (AMA) issued a statement that concluded, "If used appropriately, direct-to-consumer (DTC) advertising has the potential to increase patient awareness about treatment options and enhance patient-physician communication. Advertising directly to the public educates patients, enabling them to better understand and participate in medical care" (AMA 2000). The statement emphasized that this observation applied only to advertisements that "do not distort information and mislead patients."

Especially significant is a January 2002 report on DTC advertising, plus an accompanying statement, from the National Health Council, an organization of approximately 50 voluntary health associations (e.g., American Heart Association), 35 professional and membership organizations (including the American Medical Association and medical specialty associations, plus the main pharmaceutical trade association), other nonprofit associations (including AARP and the Rosalynn Carter Institute), and large businesses (mainly pharmaceutical firms). The National Health Council report was reviewed by all member organizations and approved unanimously. The accompanying statement concluded, "After completing a thorough review of Direct-to-Consumer (DTC) prescription drug advertising, the National Health Council believes that DTC advertising is an effective tool for educating consumers and patients about health

conditions and possible treatments" (N.H.C. 2002a, 2002b). At about the same time, the National Medical Association (an organization of African-American physicians) published the results of a member survey, in which attitudes toward DTC advertising were largely (but by no means universally) favorable, and also published a policy statement that noted the existence of an "educational benefit" in DTC advertising, sought an increase in DTC ads in African-American media, and urged physicians to be open to such ads as a communication device so long as ads are balanced.[9] This policy is consistent with research showing that African-Americans are disproportionately likely to have undetected and untreated elevated cholesterol, and with an earlier appeal by the Association of Black Cardiologists to the FDA to support petitions (which failed) from Merck and Bristol-Myers-Squibb to move the two oldest statin drugs (Mevachor and Pravachol) to OTC status. The same research reached the same conclusions about Hispanics, and the leading organization of Hispanic physicians also supported switching those two drugs to OTC status (Elliott 2000; Lueck 2000).

In July 2001, the FDA official in charge of DTC advertising regulation and research stated in Congressional hearings that "At present, FDA is not aware of any evidence that the risks of DTC promotion outweigh its benefits" (Ostrove 2001), a view that reinforced what the agency had said in 1999. Speaking at an April 2002 conference, former FDA Commissioner David Kessler, who had vigorously opposed opening up DTC advertising during his tenure from 1990 to 1997, said that he has changed his mind and now supports the expanded role of DTC advertising. The Federal Trade Commission (FTC), which shares jurisdiction with the FDA, argued in a 1996 comment to the FDA that DTC advertising can be valuable for consumers, and reiterated its support for DTC

[9] See Allison-Ottey, Ruffin, and Allison 2002, and National Medical Association 2002. The Department of Health and Human Services recently launched a campaign to encourage African-Americans to see physicians to learn of possible preventive care; see USDHHS 2002b.

advertising in a 2001 comment to the Office of Management and Budget (FTC 2001).

Nonetheless, debate continues, with both Congressional and state legislators considering legislation to restrict DTC advertising (Senate Commerce Committee Subcommittee hearings 2001; Pallarito 2001; Pear 2002). An overarching issue is the impact of DTC ads on total health care costs, on the financial costs of impaired health, and on consumer welfare including non-financial benefits. Assessing this impact would require extensive use of the medical and health economics literature to determine the net impact of increased drug usage, assuming that DTC advertising increases pharmaceutical demand. I will not deal with these topics beyond noting the following points. The literature yields clear evidence that for some therapeutic categories (but by no means all), increased pharmaceutical use is associated with reduced health care costs (AIDS treatments and anti-ulcer drugs being examples; see Neumann, et al. 2000). Reductions in workplace and personal costs have also been documented (Kleinke 2001; Lichtenberg 2001). Some analysts have concluded that pharmaceutical advances, like technological progress generally, tends to reduce overall health care costs (again see Kleinke 2001 and Lichtenberg 2001). Beyond the matter of health care costs lie the benefits realized primarily by consumers, as when heart disease drugs prolong life even though they increase the probability of eventually suffering other illnesses such as cancer, and antidepressants reduce the very large perceived degradations in quality of life caused by depression (see, e.g., Bennett, et al., on the disutility of depression).

Our concern, however, is with DTC as an advertising phenomenon. Obvious issues include DTC's impact on pharmaceutical prices and expenditures, its impact on consumer information, and the extent to which DTC advertising is deceptive. Also important are the questions of whether DTC advertising affects physician prescribing behavior and the patient-physician relationship. Finally, there is the question of whether DTC advertising confers positive externalities on the marketplace, such as by increasing drug therapy compliance and conveying

useful information about nonbranded drug therapy or lifestyle changes. One interesting topic not addressed here is the impact of DTC advertising on products liability litigation, where the New Jersey Supreme Court ruled that DTC advertising can abrogate the "learned intermediary" defense that normally requires patients to sue physicians, rather than manufacturers, in cases about prescription drug safety and appropriateness (cf. Berger 2000 and Gemperli 2000).

The Potential Role of DTC Advertising

A preponderance of research shows that advertising improves markets by providing consumers with essential information that they would otherwise ignore, fail to receive, or receive too late. The Federal Trade Commission, which regulates most advertising (but not prescription drug advertising), has emphasized that advertising plays an essential role in improving consumer information and otherwise improving markets (Calfee and Pappalardo 1989; Pitofsky 1996; Calfee 1997).

There are compelling reasons to expect similar effects from DTC advertising for the prescription drug market. Recent decades have seen a rapidly expanding role for drug therapy in medical practice (Altman and Parks-Thomas 2002). These years have also seen a powerful trend toward greater consumer involvement in health care. FDA policy reflects these trends. In the past 2 decades, the FDA has moved more than 600 drugs from prescription to over-the-counter (OTC) status, including such potent drugs as nicotine patches, the anti-inflammatory drug Naproxen, and treatments for vaginal yeast infections (FDA 1999d; Lueck 2000). The FDA has also stated that "It [DTC advertising] is consistent with the whole trend toward consumer empowerment. We believe there is a certain public health benefit associated with letting people know what's available" (Stolberg 2000).

The medical literature provides strong evidence that some of the most important pharmaceutical information -- especially relatively new information -- often fails to reach physicians or patients in a timely manner. This situation is reflected in the proliferation of practice guidelines for physicians, and also in published findings that medical practice often falls well short of what can be achieved by following even the least controversial aspects of consensus guidelines (e.g., Kane and Garrard 1994; Felch and Scanlon 1997; Ayanian and Quinn 2001).

Consumers and patients, of course, tend to be even less well informed than their doctors. Many of the most valuable new drugs involve conditions or illnesses that require consumers to take the initiative in seeking medical advice for dealing with depression, for example, or to learn whether one is at risk for heart disease, and if so, what can be done to reduce that risk. A number of studies and consensus statements from the medical community have documented the existence of large numbers of underdiagnosed and undertreated consumers who suffer from serious, yet treatable, medical conditions, a few of which are depression, AIDS, diabetes, and osteoporosis.[10]

A 2001 report from the National Cholesterol Education Program at the National Institutes of Health illustrates these trends. That report concluded that elevated cholesterol should be treated much more aggressively than in the past, even as earlier studies have found that most persons who should have been treated under the previous guidelines were in fact not treated and, often, not even identified (NIH 2001; also see Cleeman and Lenfant 1998). Recent research has also found that African-Americans and Mexican-Americans are less likely than others to undergo cholesterol screening, or to be treated after being identified as requiring medication (Nelson, Norris, and Mangione 2002).

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[10] On depression, see Glick, et al., 2001, and the 1999 Surgeon General's report. See Fleming, et al., 2002 on AIDS; Leape 1995 on diabetes; and Allen 1999 on osteoporosis (describing the findings of the National Osteoporosis Risk Assessment study).

These circumstances dictate that patients and consumers must play an active role in their own health care. In particular, consumers need to acquire information about medical therapies, talk to their physicians about medical symptoms and conditions, and decide with their doctors how to deal with illnesses and conditions. The FTC and FDA statements cited above are consistent with this view.

DTC advertising can confer substantial benefits because it provides firms with incentives to attach missing information to their brands, and to disseminate that information in order to increase brand demand. The consumer benefits would come partly from consumption of the advertised brand (yielding consumer surplus in the economic sense), and partly through positive externalities or spillover, such as providing information that can lead to improved health without using the advertised brand.

It is worth noting here that the increasing role of pharmaceutical marketing extends well beyond the escalation of DTC advertising, and even beyond the continuing importance of promotion to physicians (through detailers, sponsored seminars, and other techniques). Drug research and development has become more marketing-driven in recent years, sometimes with clinical trials being designed with an eye toward specific marketing claims. A striking example from the early 1990s was the launching of large clinical trials on statin cholesterol-reducing drugs for preventing heart attacks in persons with only moderately elevated cholesterol and no history of heart disease. This research, which was undertaken in search of superior marketing claims, provided the first persuasive scientific evidence that reducing cholesterol would prevent heart attacks. The blend of marketing with pharmaceutical research and development continues to evolve.[11]

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[11] See the discussion in Calfee 2000a, p. 30-31, which relies partly on Langreth 1998. For more recent developments, see Kranhold 1999 (on the acquisition of a clinical trials research firm by an advertising group), Harris 2001 (on the growing role of marketing executives in drug development at Merck), and O'Connell 2002 ("'What you're seeing is an emerging convergence between the clinical development and the

Empirical Research on the Effects of DTC Advertising

Empirical research on the effects of DTC advertising is scarce (at least in the public domain), befitting a phenomenon that became of obvious interest to the public policy community only in 1997. Thus a May 2001 conference convened by the Department of Health and Human Services to examine DTC advertising focused almost exclusively on how to perform research on DTC advertising, rather than on the results of prior research (Bero and Lipton 2001; Frank, et al. 2001; Schommer and Hansen 2001; USDHHS 2001).

Most research to date has consisted of consumer surveys. In this section, I address the few topics in which research not based on surveys has been of value, and then briefly describe the most important consumer survey work. Succeeding sections address major topics for which surveys have been essentially the sole research tool.

DTC Advertising and Drug Prices

Expenditures for out-patient prescription drugs have been increasing at about 15% annually (Berndt 2000; NIHCM 2002). Several studies have found that about three-fourths of these increases have been caused by expanded usage and switching to newer and more effective drugs, while price increases have accounted for only about one-fourth.[12] Even this modest role for price increases is overstated, because standard measures of pharmaceutical prices fail to take into

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commercialization of drugs,' says Thomas Harrison, chief executive officer of the Diversified Agency Services division of Omnicom Group Inc.") On the importance of conceptual connections between pharmaceutical R&D and marketing considerations, see Calfee 2000b, 2001c, and 2002, and Galambos 2002.

[12] The most rigorous study is Dubois, Chalwa, et al. 2000. A useful wide-ranging survey of the factors causing expenditure increases in the past two decades is Berndt 2001. NIHCM 2002 finds that price increases accounted for 37% of expenditure increases in 2001. That study, however, uses Scott-Levin price data that do not reflect individual drug discounts or rebates to pharmaceutical benefit managers or managed care, and that ignore dosage size and prescription length (30- vs 90-day).

account improvements in the quality and value of new drugs or drugs that have found expanded uses (Triplett 1999).

These facts suggest that even if DTC advertising increases prices, such an effect has been quite limited simply because overall price increases have been small, and the amount of DTC advertising is only about 2% of total pharmaceutical expenditures.[13] Research has generally found that advertising tends to reduce prices, rather than increase them, primarily because advertising makes markets more competitive (Calfee 1997, p. 10-11, and citations therein).

One could imagine scenarios in which pharmaceutical advertising would be an exception, however. For pharmaceuticals, whose value lies exclusively in information about a relatively simple product and in broad dissemination of that information, it is possible for advertising to be positively associated with prices. Firms sometimes conduct expensive research on a drug after it has been approved for marketing. For example, clinical trials and more fundamental research on the statin class of cholesterol-reducing drugs has been exploring several topics, including the benefits of treating lower cholesterol levels and the prevention or cure of osteoporosis, stroke, and Alzheimers, at a cost of hundreds of millions of dollars so far.[14] This is typical of research on the closely targeted drugs developed using modern pharmaceutical research methods, because the targeted proteins and other entities often turn out to be important for other illnesses. Another example is research on cox-2 inhibitors (Celebrex, Vioxx, and emerging competitors), which appear promising in treating colon cancer (Chau and Cunningham 2001). A logical consequence of this kind of research could be both higher prices and additional marketing to inform the market of the new information. There seems little evidence of this actually taking place, however.

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[13] Total out-patient pharmaceutical expenditures were $122 billion in 2000, and predicted to be $142 billion in 2001 (USDHHS 2002a). As noted, DTC advertising in 2001 was $2.7 billion.

[14] See Sandercock 2001 on strokes, Elliott 2002 on osteoporosis, Langreth 1998 on statin drugs, and *American Medical News*, June 18, 2001, on Alzheimers and other illnesses. More examples are available in Wertheimer, O'Connor, and Levy 2001.

I am not aware of any econometric research on DTC advertising and prices. Considerable data suggest, however, that there is little relationship between DTC advertising and prescription drug prices. Manning and Keith (2001, Fig. 7) re-examined the NIHCM 2001 data and noted that a rank ordering of brands according to DTC spending bore essentially no relationship with percentage increases in cost per prescription. Detailed data are available for the statin class of cholesterol-reducing drugs such as Pravachol, Zocor, and Lipitor. Total expenditures for statin drugs have increased rapidly, making this one of the three largest therapeutic categories in terms of total sales.[15] Statin drugs have also been among the leaders in DTC advertising (NIHCM 2001). Yet average statin drug prices increased only 7% in real terms between 1995 and 2000.[16] The fact that the original statin drug, Mevachor, has gone off-patent and competes with generics, will exert new downward pressure on statin drug prices.

DTC Advertising and Pharmaceutical Consumption

Very little research seems to have been performed on the effects of DTC advertising on pharmaceutical consumption. This is hardly surprising for such a new phenomenon, given that such research is rare even in long-established markets (the obvious exceptions being markets for controversial products such as tobacco and alcohol).

Findlay (2002, drawing on NIHCM 2001) and others have described an association between rapidly growing therapeutic categories and DTC advertising. Neither Findlay (2002) nor the NIHCM (2001) report attempted to assess causality, however, nor did they take into account confounding variables in a

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[15] NIHCM 2002, Table 1, shows "cholesterol reducer" as the third-ranking therapeutic category in 2001. The bulk of those sales are for statin drugs, which are the dominant cholesterol-reducing therapies and were still on patent in 2001, in contrast to older cholesterol-reducing drugs. Two of the three best-selling brands were statin drugs.

[16] Proprietary price data were provided by IMS Health and are summarized in Calfee, Winston, and Stempski 2002. The IMS price series takes into account discounts but not rebates.

systematic way, and the NIHCM report authors concluded that their calculations ". . . add to the growing circumstantial evidence that such ads are one element -- and perhaps an increasingly important one -- in the recent trend to the expanded use of newer prescription drugs and the resultant increased overall spending on pharmaceuticals." Nonetheless, some observers have assumed that the tables presented in NIHCM (2000) amount to a demonstration of causation (USGAO 2002, p. 6; Families USA 2002, p. 15).

Again, Manning and Keith (2001, Fig. 6) re-examined the NIHCM 2001 data. They showed that a rank ordering of brands according to DTC spending bore no discernible relationship with percentage increases in sales. One unpublished paper has examined DTC advertising for a single therapeutic category, the statin class of cholesterol-reducing drugs (Lipitor, Zocor, Pravachol, and competitors). Using data for 1995-2000, and exploring numerous dependent variables and lagged structures, Calfee, Winston, and Stempski (2002) found no relationship between DTC advertising and either prescriptions or sales. In fact, statin prescriptions increased at a very steady rate both before and after the August 1997 change in FDA policy toward DTC advertising.

This very limited body of research is of course inconclusive. An obvious problem in this line of research is the length and complexity of the relationship between DTC advertising and the consumption of pharmaceuticals for chronic conditions. In the case of the statin drugs, one reason for the apparent lack of a short-term connection between advertising and prescriptions is the fact that several steps of varying length must take place between the time when a consumer reacts to an ad and when that consumer receives a prescription (initial physician visit, cholesterol test, advice for life-style changes, etc.), if in fact a prescription is written at all.

Given the inexperience of pharmaceutical firms in the art of broadcast advertising (the dominant DTC media), it is possible if not likely that major DTC advertisers have sometimes met with disappointment. Economic intuition suggests, however, that DTC advertising, on average, helps the brand being

advertised. That does not imply that DTC advertising in aggregate increases overall pharmaceutical demand (cf. the discussion of the "fallacy of composition" in Calfee 2000c). Nonetheless, I believe it very likely that DTC advertising, which is a new tool for promoting products that are themselves quite new and are also strongly dependent on the dissemination of information, tends or will tend to increase consumption of the therapeutic categories being promoted.

The extent of consumption increases induced by DTC advertising must be very small, however, at least so far. Pharmaceutical consumption has been increasing rapidly in all developed economies, in some cases achieving much greater per capita usage than in the United States (Calfee 2000a, p. 6-7), and price controls in European nations and Canada are probably the main reason pharmaceutical expenditures in those nations have increased less rapidly than in the U.S. DTC advertising in the U.S. equals only about 2% of outpatient pharmaceutical expenditures (noted earlier), and advertising expenditures in 2001 increased only slightly over those of the year before. This is contrary to what one would expect if firms had discovered that very large consumption increases followed upon increases in advertising for major therapeutic categories. Experience has shown, moreover, that formerly advertised brands rapidly lose market share in the face of new generic competition; Prozac, an extremely well-known brand that went off-patent in 2001, lost most of its market share to generics within a few months because of the aggressive actions of pharmaceutical benefit managers determined to reduce costs (Mantz 2001).

DTC Advertising and Inappropriate Prescribing

Beyond the matter of whether DTC advertising increases usage lies the question of whether it induces inappropriate prescribing. The proposition that newer drugs tend to be medically inferior or just expensive variants on older drugs is difficult to defend. Scholarly reviews of drug therapy (the "drug therapy" series in the *New England Journal of Medicine*, for example) typically

focus on newer drugs and their superiority to older treatments.[17] So do major consensus reports on treating such important chronic conditions as depression, osteoporosis, diabetes, and elevated cholesterol (see earlier citations). Rare side-effects from new drugs tend to appear more rapidly than in earlier decades because of the growth of managed care and other changes in health care that accelerate the dissemination of newer treatments. This trend does not support a finding that newer drugs are more dangerous, however (Friedman, et al. 1999). Thus little direct evidence seems to have emerged that recent increases in drug expenditures have disproportionately involved medically unwise prescriptions,[18] or that DTC advertising in particular has caused medically inappropriate prescribing.[19] More targeted research supports the same conclusion. A forthcoming study of the rapidly growing and heavily advertised statin drugs found no tendency toward less appropriate prescribing (Dubois, Alexander, et al., 2001). Calfee, Winston, and Stempski (2002) similarly found no significant decline in the initial cholesterol levels of patients receiving new statin prescriptions in recent years, even though the medical literature and federal government recommendations have urged more aggressive treatment of elevated cholesterol.

Increases in drug utilization seem to be driven primarily by the fact that health care organizations, physicians, and patients find many of the newer drugs

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[17] Three examples are Knopp 1999 on cholesterol, Kohlmeier 1999 on osteoporosis, and Yanovski and Yanovski 2002 on obesity.

[18] An interesting exchange is Lasser, et al. (2002) and Temple and Himmel (2002) in the same issue of the *Journal of the American Medical Association*. Lasser, et al., argue that recently approved drugs have proved unusually dangerous, and that physicians should be reluctant to prescribe them. The opposing view, an editorial, is from two members of the FDA division responsible for approving new drugs.

[19] Mintzes, et al. 2002, reported the results of a survey of 78 physicians (38 in Sacramento, CA, the rest in Vancouver, Canada). Physicians felt "ambivalent" about granting a patient's request for a prescription for an advertised drug more often (50%) than they did when acceding to a request for a non-advertised drug (39%), but the difference was not statistically significant. No other information on the appropriateness of these prescriptions was provided.

to be extremely valuable. We have seen that a large body of evidence indicates that many of the most effective drugs are underused, rather than overused. Hence the intense public debate over prescription costs for Medicare patients has focused almost exclusively on how to pay for broader and more aggressive drug therapy, rather than on how to curtail the inappropriate use of pharmaceuticals.[20]

Nonetheless, anecdotal evidence suggests that DTC may drive consumption away from generics toward expensive branded antihistamines, anti-ulcer treatments, and arthritis analgesics, for example. For the first two categories, at least, this has not raised safety or efficacy problems, as the leading brands have received the endorsement of FDA expert panels to move to OTC status as patents for those brands expire and low-cost generics emerge.[21] Whether these and other popular branded prescription drugs are inappropriate from an economic standpoint is largely a matter of whether third-party payments for prescription drugs undermines reasonable consumer diligence in balancing costs and benefits. On the whole, the FDA seems satisfied that DTC ads are not the cause of substantial *medically* inappropriate prescribing. This is evident from the July 24, 2001 Senate testimony of FDA official Nancy Ostrove, who mentioned the possibility that DTC advertising could cause inappropriate prescribing and concluded (regarding that and other issues), "At present, FDA is not aware of any evidence that the risks of DTC promotion outweigh its benefits."

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[20] A recent advertising campaign by AARP has focused on encouraging the use of generics rather than brand names, but AARP has apparently not argued that a significant proportion of pharmaceutical prescribing is medically inappropriate as opposed to be unnecessarily expensive (Greene 2002). The organization strongly advocates comprehensive drug coverage for Medicare patients.

[21] Thus the battle between older generics and the newer generation of branded allergy and anti-ulcer drugs is becoming moot. Claritin, the leading nonsedating antihistamine, is losing patent protection in late 2002 or 2003, and is likely to be converted to OTC status. The same is true of Prilosec, the pioneering proton pump inhibitor for gastric distress, which in 2001 was the second best-selling brand in the in the U.S. at $4.0 billion. Generic Prilosec will probably also greatly reduce sales of Prevacid, another proton pump inhibitor, which ranked third in 2001 with $3.2 billion in sales (NIHCM 2002, table 3).

Consumer Surveys

The bulk of research on DTC advertising consists of several nationally representative consumer surveys. The most notable examples include two surveys commissioned by the FDA itself (FDA 1999b, 1999c, 2002), a series of surveys commissioned by *Prevention Magazine* (1999, 2000), and an unusual online web-TV survey by the Kaiser Family Foundation (K.F.F. 2001). The 2002 FDA project includes both consumer and physician surveys, fielded in early 2002. The consumer survey was completed by early April, when FDA staff began presenting partial results in public meetings (Aikin 2002; FDA 2002b, c). The FDA and *Prevention* surveys were large nationally representative telephone surveys using random digit dialing. The K.F.F. survey involved drawing random sample from a nationally representative panel (subject to the usual constraints on the representativeness of panels), and having each respondent view three different advertisements via web-TV. Respondents were randomized into two groups, one of which saw no DTC ads while the other group saw one of three different DTC ads.

Other more limited, but nonetheless useful research includes national consumer surveys by AARP,[22] the National Consumers League (1998), and NewsHour with Jim Lehrer (2000, with the Kaiser Family Foundation and the Harvard School of Public Health). A more limited survey of only California consumers (Bell, Kravitz, and Wilkes 1999) and two content analyses of individual DTC ads (Bell, Wilkes, and Kravitz 2000a, 2000b; Woloshin 2001)) are not considered here.[23]

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[22] The 2000 AARP survey is available on the AARP website (accessed September 28, 2000). Executive summary: /research.aarp.org/health/2000_04_advertising_1.html. A link to the full report (pdf file) is: research.aarp.org/health/2000_04_advertising.html. A search for "direct-to-consumer" should find these links.

[23] The California survey, in addition to being smaller and restricted to California residents, was not nearly as comprehensive as the FDA or *Prevention Magazine* surveys. The content analyses were used to support the argument that DTC ads fail to provide some useful information, such as mechanism of action, success rate, supportive

These surveys shed light on many of the central topics in public policy toward DTC advertising. I focus on the FDA and *Prevention Magazine* surveys, with citation to K.F.F. and others where they are of interest.

Advertising and Information

Awareness of DTC Advertising

All the surveys found very high levels of awareness of DTC ads. Eighty-one percent of 2002 FDA respondents (up from 72% in 1999) recalled seeing a prescription drug ad in the past 3 months (mostly on television), and most recalled seeing several ads. This is comparable to the 85% recall level in the 2001 *Prevention* survey, which represents a modest increase from previous years: 63%, 70%, 81%, and 80% in 1997 through 2000, respectively. In the *Prevention* survey, follow-up questions about individual brands revealed virtually universal aided recall levels. Other surveys, all asking for unaided recall of DTC ads, also found very high awareness levels: 91% in the PBS NewsHour-Kaiser-Harvard, 80% in the National Consumers League, and 65% in the AARP survey (which was restricted to print ads).

Information-Seeking Triggered by DTC Advertising

Half of the 1999 FDA respondents who recalled seeing DTC ads said ads had sometimes caused them to seek additional information. They sought information from a variety of sources, including books, friends, the Internet, and the news media, but the most common sources were physicians (81% talked to their own doctor and 22% talked to another doctor), followed by pharmacists (52%) (adding to more than 100% because respondents could indicate more than one source).

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behaviors, and alternatives to the brand being advertised.

In the 2002 FDA survey, 18% of those recalling ads said DTC ads had at some time caused them to talk to their doctor about a specific medical condition or illness for the first time. This is a remarkable result, suggesting that approximately one-sixth of the adult population who have seen doctors in the past three months have been motivated by advertising to discuss a new topic. (The number in the 1999 survey was higher, 27%, whereas the 1999 *Prevention* survey, which unlike the FDA survey did not oversample persons who had recently seen a doctor, found 14%.) The 1999 FDA survey also asked whether respondents were likely to ask their doctor about a drug that was advertised to treat a condition that was "bothering you." A very large proportion (80%) said they were somewhat or very likely to ask.

Risk Information

The FDA survey addressed readership of the detailed risk information in print ads. Forty percent said they read half or more of that information, and another 26% said they read a little of it. I suspect this reflects at least a modest degree of socially responsible yea-saying by respondents. More significant, however, is that fact that 85% said they would read all or almost all of the information if they were especially interested in the drug; see Table 1.

Table 1: Readership of Print Risk Information

	Question 11: ". . . How much, if any, of the small-print information would you say you usually read? . . ."	Question 12: ". . . If you were especially interested in the advertised drug for some reason, how much, if any, of the small print information would you read? . . ."
All	15%	73%
Almost all	11%	12%
About half	14%	8%
Only a little	26%	3%
None	30%	4%
Did not notice fine print	3%	
Have never seen newspaper/magazine ads	1%	
Don't know/refused	1%	0.2%
Sample size	688	682

Adapted from FDA 1999c.

The 2000 *Prevention Magazine* surveys also found high readership of risk information. Of those recalling print ads, 54% recalled that the ads contained technical information, 37% recalled either skimming the brief summary, looking for key information, or reading most of the summary. Several questions explored this topic further, revealing that readership of the fine print was higher for those taking a prescription drug, and highest for those taking the advertised drug. Only 35% thought the technical information was "very clear," however, documenting a long-standing situation of which the FDA is well aware (Pines 1999). Finally, 86% of those who at least skimmed the fine print said it provided sufficient information for them to ask their doctors about risks associated with the drug. Of special interest is the fact that those who gave higher ratings to the adequacy of risk information in ads were more likely to have discussed an advertised drug with their doctor, and the same relationship held for those who had brought up a new medical condition with the physician (based on cross-tabulations).

These results are of great interest because a considerable body of research shows that patients receive surprisingly little risk information from either physicians or pharmacists, and often tend to ignore the information they do receive (Lyles 2002, p. 82-83). The 2000 *Prevention* survey asked how often physicians provided various kinds of risk information about the drugs they prescribed (a topic not addressed in the FDA survey.) Patients who had spoken with their doctor about an advertised drug were more likely to receive information about side effects (64% vs 54% for serious side effects; 56% vs 47% for annoying, nonserious side effects).

The AARP also asked a series of questions about receiving risk-benefit information from physicians. Fifty-four percent said their doctor "usually" talks to them about the risks and potential side effects of drugs being prescribed, while 18% said doctors "sometimes" did this, 18% "rarely," and 9% "never." Physicians talked less frequently about alternative prescription drugs (43% usually and 27% rarely or never) and about nonprescription drugs (35% usually, 35% rarely/never).

A Note on Advertising Deception

Section 502(n) of the Food, Drug, and Cosmetic Act requires drug advertisements to include the drug's name and ingredients, plus "such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations . . ." to be issued by the FDA. Those regulations, set forth in the Code of Federal Regulations (at 21 CFR 202.1), contain numerous requirements that advertisements must meet in order not to be judged "misleading." The FDA's focus on the concept of "misleading" is parallel to the FTC's mandate to policy "deceptive" acts or practices. Hence the benefits of DTC ads depend partly on whether the FDA has established reasonable standards for deception.

Clearly, it is possible to set standards too high. Advertising regulation involves a trade-off because regulators cannot be certain which claims will turn out to be deceptive and which will prove truthful and nonmisleading (Calfee and Pappalardo 1989 and 1991). If the rules are too tight, the loss to consumers from the suppression of useful information will exceed the gains from eliminating deceptive information. The attempt to strike a reasonable balance provides the conceptual foundations for FTC regulation of deceptive advertising (FTC 1983, Ford and Calfee 1986, Craswell 1991).

Two factors strongly suggest that FDA advertising regulation is almost certainly far too strict. One concerns regulatory incentives. The problem is most easily seen by looking not at advertising regulation but at new drug approvals. FDA regulators face pressure to avoid making "Type I" errors, permitting harmful new drugs into the market, in favor of making "Type II" errors, prohibiting or delaying useful new drugs. This is because Type I errors are severely penalized, as they arouse adverse publicity and provoke criticism of the FDA approval authorities. A recent example is the awarding of a Pulitzer Prize for a series of newspaper stories on the FDA approval process for several drugs that encountered safety problems.[24] In contrast, relatively few people are aware of the potential value of drugs that have been kept from the market. The tendency for these distorted incentives to unduly delay new drug approvals is well documented.[25]

Similar forces apply to the regulation of advertising, i.e., to decisions about what advertising claims to permit. While the FDA deserves credit for

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[24] The recipient was David Willman of the Los Angeles Times [http;//www.pulitzer.org/year/2001/investigative-reporting]. Also see Lasser, et al., 2002, for an article in the *Journal of the American Medical Association* critical of the FDA's safety standards in new drug approval.

[25] This reasoning gave rise to a rich, empirically robust literature, beginning with Peltzman's 1973 analysis of the drug approval slowdown in the wake of the 1962 amendments to the Food, Drug, and Cosmetic Act. Subsequent analyses include Wardell and Lasagna 1975, DiMasi 1996, and Tabarrock 2000 (who reviews much of the drug lag literature).

expanding DTC advertising to broadcasting in 1997, it still faces powerful incentives to tightly circumscribe the content of advertising claims. DTC advertising has been much criticized (and little praised) in the medical and popular press since the FDA's 1997 initiative, and much of that criticism has been directed at the FDA either directly or by implication (because most advertising passes unchallenged by the FDA). On the other hand, criticism of the FDA's near-ban on broadcast DTC advertising before 1997 emanated from a narrow group of academics and industry spokesmen, and it attracted little public attention. In fact, the FDA's bias against making Type I errors -- i.e., possibly allowing claims that turn out to be deceptive -- at the expense of Type II errors (suppressing truthful claims) may be even stronger than its bias against taking risks in approving new drugs. This is because manufacturers usually have a bigger stake in new drug approvals than in advertising claims; hence they will fight harder behind the scenes to overcome regulatory resistance to new drug approvals than they will for innovative advertising claims. In addition, patient groups sometimes exert pressure for new drugs, but they seldom press for new advertising claims.

Worth noting in this context is the change in regulatory incentives that occur after a new product has been approved. Once a group of grateful users has been created, the FDA may face pressure to keep a useful drug on the market even if it encounters problems. An example is the recent reintroduction of Latronex, which the FDA had pulled from the market in the wake of intense popular criticism of the approval process, only to be met with criticism from patients who wanted to regain access to the drug.[26] Again, parallel forces apply to DTC advertising, whose popularity with consumers may help preserve its existence even as the FDA faces pressure to curtail it.

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[26] See Aoki 2002 for an insightful view of the entire process from approval to withdrawal to reapproval. Latronex was one of the drugs analyzed in the Los Angeles Times' Pulitzer Prize-winning stories. See Willman 2001.

Reinforcing the incentives to avoid public attacks and blame is a second factor, the lack of recourse by manufacturers to the courts. Here, the contrast between how the FTC and the FDA deal with advertising deception is illuminating. Both agencies enforce a vague mandate against false or misleading advertising. The FTC, however, has for decades been forced to articulate predictable, empirically based standards that can withstand scrutiny in the courts, including First Amendment challenges (cf. FTC 1983, 1984; Ford and Calfee 1986). The FDA, on the other hand, has never had to defend its policies in court.

This leaves the FDA free to establish broad *per se* standards for advertising content. These standards are not based upon empirical findings on how physicians or consumers perceive or act upon specific advertising claims.[27] A salient example is the FDA's prohibition on off-label therapeutic claims. FDA policy assumes that even a very sophisticated audience (physicians) requires protection against all therapeutic claims that have not been formally approved by the agency. This is almost certainly unnecessary. For decades, a steady flow of off-label therapeutic information has been widely accepted and fruitfully used by the medical community, which often finds off-label information to be essential to good practice (USGAO 1991; Calfee 1996; Thakkar 1997, summarizing Calfee and McGinniss 1997; Tabarrock 2000; Yanovski and Yanovski 2002). In fact, off-label information (such as practice guidelines) has been disseminated by authoritative sources including agencies other than the FDA within the Department of Health and Human Services, such as the National Cancer Institute and the National Cholesterol Education Program. Yet the FDA prohibits

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[27] I am unaware of empirical research underpinning the FDA's assertions of what advertising claims are likely to mislead either consumers or physicians. Wazana 2000 reviews the research literature on the extent to which physician prescribing is influenced by pharmaceutical promotion (mainly detailing rather than advertising). As Lexchin and Mintzes point out in this issue of the *Journal of Public Policy and Marketing*, much of this research is critical of the influence of physician detailing. That research appears not to address deception directly, however. On the other hand, a recent survey of physicians (Kaiser Family Foundation 2002) found that 74% thought the information they received from industry detailers were very or somewhat useful, and 81% thought the information was very or somewhat accurate.

manufacturers from disseminating that same information, even if its off-label status is explicitly noted.

The FDA has, of course, brought no litigation against DTC ads. Instead, it has issued a series of warning letters and other reprimands (summarized in Ostrove 2001 and Wolfe 2002). These have rapidly declined in frequency by more than half since 1998, when the industry was still discovering the contours of the FDA's new DTC policy. Given that pharmaceutical firms invariably accede to FDA requests to alter or halt advertising claims, the likelihood of sustained deception, even based on the FDA's own views of what is misleading, is very small. The remarkably even balance between risk and benefit information in DTC ads, reviewed in the next section, also indicates a lack of deception (although I shall argue later that a disproportionate emphasis on benefits would not necessarily be deceptive). In addition, the FDA has itself concluded that it is unaware of any evidence that DTC ads are harming public health through deception or other means.[28]

These circumstances, considered in combination, strongly suggest that deception in DTC advertising is almost certainly very rare. An important additional factor is the prescription requirement for obtaining advertised drugs. It provides a potent check on adverse consequences of consumer deception, if it should occur.

With this as background, we turn to what surveys have revealed about risk and benefit information and DTC advertising.

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[28] See FDA 1999a for an assessment of DTC advertising since it beginnings. Ostrove 2001 reviews the very limited FDA legal actions against DTC advertising in recent years.

The Balance of Risk and Benefit Information

Risk and Benefit Information

Of central importance, at least from the FDA's perspective, is evidence on the balance of risk and benefit information conveyed by DTC ads. Doubts about the ability of DTC ads to convey reasonably balanced risk and benefit information was arguably the chief reason for the FDA's DTC moratorium in the 1980s and its suppression of broadcast ads before 1997 (Morris and Millstein 1984; Morris, Ruffner, and Klimberg 1985; Pines 1999). The FDA surveys devoted considerable attention to risk and benefit information, as did the series of surveys by *Prevention Magazine*, and to a lesser extent, the 2001 K.F.F. survey.

The FDA was obviously interested in learning whether DTC ads tend to emphasize the benefits of prescription drugs while downplaying the risks. A series of detailed questions revealed a remarkably balanced assessment. Asked what kinds of information they saw in TV ads, 90% (87% in 1999) of respondents said, "the benefits of the drug," while 90% (82% in 1999) said, "risks or side effects," and 89% (81% in 1999) said, "who should not take the drug." (These high levels were not caused by yea-saying, as only 10% said they had seen information on overdosage, which is not covered in DTC ads). Respondents in the 1999 surveys were also asked what kinds of information the ads did not provide enough of: Fifty-nine percent said ads do not give enough information about risks and related matters, but 49% said ads do not give enough information on the benefits of drugs.

The FDA surveys asked several broad questions about the relationship between DTC advertising and the nature of prescription drugs. One question asked whether ads make drugs seem better than they really are, and 58% (in 1999) agreed that they did. In a sense, however, this is a rather low level of agreement. For decades, consumer surveys on advertising have found that roughly 70% of consumers expect advertisements to be strongly biased in favor of the product being advertised. Consumers are routinely skeptical of advertising

(Calfee and Ringold 1994). The FDA survey revealed that the nearly universal assumption that advertising exaggerates benefits applies to DTC ads, although with somewhat less force.

Relevant here is the fact that these ads are for products that can be obtained only after getting a physician's prescription. In one 1999 FDA question, 70% agreed that ads provided sufficient information for them to talk to their doctor about the drug (parallelling responses to similar questions in the 1999 *Prevention* survey). When asked in the same survey whether DTC ads "make it seem like a doctor is not needed to decide whether a drug is right for me," 70% disagreed. Finally, in responding to a question that is particularly relevant to debates over DTC advertising, just 29% agreed that ads are allowed only for the "safest" prescription drugs.

The *Prevention* surveys also addressed consumer perceptions of risk information in advertising. The most comprehensive question was asked in 1999:

> Does the information in these ads about the possible risks of taking the prescription medicine make you MORE confident or LESS confident about the overall safety of the medicine—or doesn't it make a difference in the way you feel about the overall safety of the medicine?

Thirty-six percent said the ads made them "less confident," as opposed to 24%, who said "more confident" and 34%, who found "no difference." This is a striking result, suggesting that in the course of providing a mix of positive and negative aspects of drugs, DTC ads raise awareness of risk even as they raise awareness of medical conditions and treatments. It is consistent with findings from consumer research conducted in the mid-1980s by the FDA, research that paved the way to the lifting of the FDA's moratorium on DTC advertising (Morris, et al., 1984, 1985, 1986).

Additional questions addressed more specific aspects of risk and benefit communication. Respondents in the 2001 survey thought that ads were moderately better at providing information about benefits (60% said excellent or

good) than they were at providing information about annoying side effects (50%) or serious warnings (51%). Significantly, these numbers were almost constant regardless of whether respondents were asked about TV or print ads (an example of how brief risk information can be as salient as detailed information, something that was also found in the FDA's research (Morris, et al., 1984, 1985, 1986). Large majorities in the 2001 survey thought that the information in ads on both risks and benefits was sufficient to prepare patients to ask a physician about risks and benefits (62% and 68%, respectively). In the 1999 survey, virtually all respondents (90%) remembered that TV ads included advice to see a physician, and 70% recalled that ads contained an 800 number for additional information.

The 2002 K.F.F. survey also provided information about consumer perceptions of risk information. The nature of the exercise generated primarily brand-level data. The most interesting information pertained to Lipitor (a statin-class cholesterol-reducing drug). Asked about side-effects, 70% of those who saw an ad for Lipitor said the side-effects were potentially very or somewhat serious. Between 74% and 83% of Lipitor ad viewers correctly said the drug should not be taken by persons in three specific categories, but viewers tended to exaggerate risks by agreeing to the mistaken statements that Lipitor should not be taken by those with high blood pressure (29%) or heart problems (34%).

Patient-Physician Discussions

In the 2001 *Prevention* survey, 32% of those recalling ads said that they had talked with a physician about an advertised drug as a result of seeing an ad. This figure has been amazingly stable: 31%, 33%, 31%, and 32% in 1997 through 2000, respectively. The great majority (84% in 2001; question 26) said they talked to their physicians during a regularly scheduled appointment. Among FDA 1999 survey respondents (all of them, not just those recalling ads), only 21% said they had seen or heard anything that made them want to ask a specific question in their last visit to a doctor. Among the sources that inspired questions,

ads (46%) ranked equally with news media (45%) and somewhat higher than friends (28%) and other doctors (23%).[29] In the 2002 survey, only 4% said their more recent physician visit was motivated by a prescription drug ad. Thus surveys provide little reason, so far, to believe that DTC ads play a major role in generating new appointments.

A number of 1999 FDA questions (again, asked of all respondents, not just those recalling ads) focused on what transpired in the doctor's office. Two-thirds of respondents were already on prescription medications. Of those, 54% expected no change in prescriptions, while most of the rest expected either to switch to another drug or to get a new drug for a different condition. Asked in several ways why they thought they might receive a new prescription, respondents generally ranked ads well below past prescription history, information from friends or relatives, and previous discussion with physicians. A substantial proportion were prepared to ask about a specific prescription drug. Of those who did not expect simply to continue their medication, about one-third said they asked their doctor whether there was a prescription drug for their condition. Thirteen percent asked about a specific brand (amounting to about 9% of the entire group who had seen physicians in the past 3 months), while 8% percent mentioned a specific ad, and 4% brought some kind of information with them (not necessarily an ad).

A crucial segment of the FDA surveys asked patients about physicians' reactions to their questions. Very large majorities said their doctor welcomed their questions (93%; 81% in 1999), reacted as if those questions were an ordinary part of a visit (83%; 71% in 1999), and proceeded to discuss the drugs with the patient (86%; 79% in 1999). Only 3% (4% in 1999) said their physician "seemed angry or upset." Asked whether their relationship with their physician had gotten better or worse in the visit in which they had asked about an

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[29] The combined totals for advertising and news media are not limited to 100% because respondents could choose more than one subcategory within both the advertising and news media categories.

advertised drug, 20% said it got better and only 2% said it got worse. In the 1999 survey, 85% of respondents were satisfied or very satisfied with their discussions with physicians about advertised drugs, with only 7% unsatisfied or very unsatisfied. Sixty-two percent agreed or strongly agreed that DTC ads helped them have better discussions with their physicians.

The 1998 National Consumers League survey provided results similar to those in the FDA surveys. Asked to choose among eight statements to describe the results of ad-motivated conversations with doctor, 30% of respondents said it "helped us talk about the drug/disease," and only 5% said either the conversation "caused tension" with the physician, or the doctor was unwilling to talk about the advertised drug, or the doctor "did not like the information I gave."

The FDA surveys did not ask whether a patient had requested a specific prescription. For those who had brought up a specific advertisement, however, or had asked "about" a specific brand, the FDA asked what the physician did. In both the 1999 and 2002, about half prescribed the brand the patient asked about, while about one-third prescribed a different brand. Roughly 15% recommended an OTC drug, and about the same recommended no drug therapy at all. Most important, approximately 40% recommended changes in lifestyle or behavior (it was 29% in 1999, when the survey asked only those who did not receive the prescription they asked about).

The *Prevention* survey asked whether those who had talked to physicians (or someone in the physician's office) had also asked their doctor to prescribe the advertised medicine. Seventy-two percent did not request a prescription. For the 26% who did, physicians prescribed the requested medicine 69% of the time, and did not prescribe any drug 19% of the time. The FDA survey, in which respondents said what happened when they asked *about* a drug, rather than for one, found physicians providing a prescription for the brand in question only 50% of the time.

One should bear in mind the imprecision of both the FDA and *Prevention* questions. Those questions could comprehend a variety of circumstances.

Patients may start out asking about one brand, receive a prescription for a different brand after a friendly discussion, feel satisfied with the outcome, and then, when responding to a survey, recall the event as something other than a refusal by their doctors to prescribe what they had requested. Another possibility is that physicians had already made clear their own views of whether a particular drug was appropriate, and patients chose to make an explicit request mainly in situations where the physician had either encouraged the request or made clear that it was purely a matter of choice for the patient. These comments are consistent with the fact that 71% did not request a specific prescription, despite having discussed a drug because of an ad, and that both the *Prevention* and FDA surveys found very little evidence of any conflict or tension between patients and physicians in discussions about advertised drugs. Only 5% of respondents in the 1999 *Prevention* survey said that physicians were "not too willing" or "not willing at all" to talk to them about the drugs they had asked about.

Externalities from DTC Advertising

Economic theory, supported by empirical evidence, indicates that advertising can improve consumer markets by providing useful information beyond that strictly associated with the advertised brand. The best documented example is health claims for foods, which buttressed consumer information about diet and health, improved consumer diets, and motivated competitive improvements in products (Calfee 1997; Calfee and Pappalardo 1989 and 1991).

DTC advertising could impose harm as well as benefits. Frequent false or misleading claims could reduce the credibility of true claims or cause consumers to exaggerate the safety or appropriateness of drug therapy generally. I noted earlier, however, that there is little reason to expect substantial deception from DTC ads, and little, if any, evidence of deception. If new drugs cause more harm than good, DTC advertising could increase or accelerate those adverse effects,

but again, there is scant evidence that newer drugs in aggregate fail to provide large net benefits to patients.[30]

On the other hand, the consumer surveys described here strongly suggest that DTC ads have conferred substantial positive externalities or spillovers that have little to do with the specific brands being advertised. These externalities fall roughly into four categories.

Risk awareness: DTC ads apparently increase the salience of the fact that virtually all prescription drugs are risky and have side effects. The survey findings showing high awareness of risk information clearly apply to pharmaceuticals generally, rather than just to specific brands. This is unsurprising, given the prominence of the "brief summaries" in print ads and the staccato list of warnings in TV ad voice-overs. In addition, as noted previously, the 2000 *Prevention Magazine* survey found that physicians tend to provide more risk information to those patients who ask about advertised drugs.

The dynamics of competitive advertising are also relevant. Firms will sometimes emphasize safety in ways that call attention to, or spring from consumers' prior attention to, the riskiness or downsides of competing brands. Examples include advertising for cigarettes, food, insurance, politicians, and many other products even including cough drops containing heroin when it was legal around the turn of the 20th century.[31] FDA rules inhibit this strategy for prescription drugs by imposing extremely high standards for comparative claims. DTC ads often emphasize reduced side-effects, however, but do so without making direct comparisons with competing brands. This tends to call attention to the problem of side-effects generally.

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[30] A separate debate addresses a larger and more philosophical question, which is whether DTC advertising tends to "medicalize" conditions that should not be addressed through medical interventions at all (Mintzes 2002, Bonaccorso and Sturchio 2002).

[31] Calfee 1997, p. 46-57, which (drawing on Musto 1991) quotes from an ad for cough drops containing heroin. The ad claimed that the brand in question was less likely than other heroin products to be addictive.

Nondrug ways to improved health: Another spillover benefit from DTC ads involves calling consumers' attention to nondrug approaches to improved health. This appears to be inevitable. When DTC ads prompt consumers to talk to their doctors about obesity, diabetes, depression, and cholesterol levels, the patients almost certainly learn that behavioral and lifestyle changes are the first line of treatment. Many DTC ads (for cholesterol-reducing drugs, for example) begin by mentioning the value of dietary changes and exercise, thus focusing viewers' attention on alternatives to getting a prescription. In response to a 2000 *Prevention* survey question asked of respondents who said that ads had caused them to talk to their physician, 53% said their doctor had mentioned a nondrug therapy for their condition. The proportions were much higher for certain conditions: diabetes (77%), high cholesterol (92%), and obesity (84%) (*Prevention Magazine* 2000, p. 58).

Information on conditions not previously discussed with physicians: In both the FDA and *Prevention* surveys, substantial numbers of respondents said ads had caused them to ask physicians about problems they had not discussed previously. New discussions about elevated cholesterol, diabetes, obesity, and other chronic conditions do not invariably lead to prescriptions for the advertised drugs. On the contrary, when ads induced patients to talk to their doctor, most patients did not actually ask for or about the brand whose advertising sparked the discussion, and when they did, the result was either a prescription for the advertised drug, or a prescription for a competing drug, or recommendations for an OTC drug, and/or advice to change lifestyles or behavior. In general, ads can raise awareness of the possible need for a particular type of drug to treat a particular condition, but the benefits of that consciousness-raising may go to competitors rather than to the advertiser, as well as going to the patient.

Drug therapy compliance: Research has shown that inadequate compliance with physician instructions when taking prescription drugs is extremely common, often causing serious danger to patients and others (Reissman 1998; Ellickson, Stern, and Trajtenberg 1999). Because consumers tend to pay disproportionate

attention to advertising for brands they use, DTC ads could prove to be an excellent vehicle for inducing better compliance. In fact, the FDA and *Prevention* surveys found that consumers pay special attention to ads for drugs they are taking or in which they have a special interest.[32]

The *Prevention* surveys contained a highly relevant series of questions which produced very consistent results. Fifty percent of respondents were taking one or more drugs, up slightly from 46%, 47%, and 46% in the three preceding years. More than half (57%) of those taking drugs recalled seeing an ad for a drug they were using. Asked whether ads made them feel better or worse about the safety of their prescriptions, 34% said the ads made them feel better, and only 4% said the ads made them feel worse (in 1999 and 1998 it was 36%/3% and 46%/1%). A parallel question about benefits yielded similar responses: 40% felt better, and 1%, worse (52% vs 1% in 1999). In response to the question, "Do ads make you more or less likely to take your medicine regularly?", "more likely" outscored "less likely" by 17% to 2% (22% to 3% and 31% to 2% in 2000 and 1999, respectively). In addition, 33% in the 1999 survey said that prescription drug ads reminded them to have their prescriptions refilled.

There seems little reason to expect the reminder effects of DTC advertising to be restricted to the advertised brand. Although no research appears to have been done on the topic, these survey results strongly suggest that by reminding patients to take their medicine and refill their prescriptions, DTC ads tend to encourage patients to persist in their drug therapy. The 2002 National Health Council statement explicitly endorsed the ability of DTC ads to increase patient compliance (p. 6, citing the *Prevention* survey results presented above).

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[32] Worth noting is the fact that competitive forces tend to yield new drugs that have fewer side-effects or are easier to take, partly because new therapeutic regimens often involve fewer drugs or less frequent administration. See Simon 2001 on the history of antidepressants, and Knopp 1999 on the superiority of the modern generation of cholesterol-reducing drugs. Because compliance is adversely affected by side-effects, DTC ads tend to improve compliance when they induce switching to newer drugs. But this would usually not be an externality, as the benefits are typically captured by the advertised brand and the recipient patient.

Global Attitudes Toward DTC Advertising

Survey questions about global attitudes are of some value. Asked in the 1999 FDA survey whether they liked seeing DTC ads, those who did outnumbered those who did not by nearly two to one. Eighty-six percent said the ads "help make me aware of new drugs." Consumers did not react unthinkingly, but responded in ways that reflected the unique nature of prescription drugs and the necessity of making decisions in collaboration with their physicians. Thus, while only 47% agreed that ads help them make better decisions about their health, 62% said DTC ads help them have better discussions with their physician about their health. These percentages were higher for those who had asked their physicians about a new condition as a result of seeing ads: 59% said ads led to better decisions, and 75% said ads helped them have better discussions with their doctors.

The 1999 and 2001 *Prevention* surveys provided roughly similar results. Seventy-six percent in the 1999 survey thought that ads "allow people to be more involved with their health care." Comparable majorities agreed that DTC ads "help people make their own decisions about prescription medicines" (64% in 2001, 63% in 1999) and "educate people about the risks and benefits of prescription medicines" (72% in 1999). Much smaller proportions agreed with negative assessments, such as, ads "cause tension between patients and their doctors" (37% in 2001) and "make prescription medicines seem harmless" (49% in 2001). The entire series of questions may have induced yea-saying, however, partly because they asked for opinions about how advertising works for everyone rather than asking about respondents' own experience (unlike the FDA survey, which found very little tension between patients and physicians).

The National Consumers League survey asked two questions on global attitudes toward DTC ads. Seventy-six percent agreed that prescription drug ads "increase consumer knowledge about medicines," and 78% agreed that prescription drug ads "increase consumer knowledge about disease."

The PBS NewsHour-Kaiser-Harvard survey took a different approach, asking respondents about their level of trust in six sources of information about prescription drugs: their doctor, their pharmacist, family and friends, the FDA and other government agencies, advertising, and product packaging. Advertising was the least trusted, with only 48% saying they trusted ads "somewhat" or "a lot." Family and friends were the second lowest, at 61%. The others ranged between 80% (government agencies) and 95% (physicians). The low global ratings for advertising are hardly a surprise, because consumer surveys generally show that roughly 70% of consumers distrust advertising claims in general (Calfee and Ringold 1994). Those results do not apply, however, to attitudes toward advertisements at the brand level, which explains why consumers find advertising in general (Calfee and Ringold 1994), and DTC in particular, to be useful tools.

A Preliminary Assessment of DTC Advertising

In 1999, when the FDA reaffirmed its August 1997 policy of permitting broadcast DTC advertising, it stated, "FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising" (FDA 1999a). The available evidence supports that conclusion. On the whole, DTC advertising appears to be conveying substantial benefits with little obvious cost. This is very a much a preliminary assessment, however. Little is yet known about such basic matters as the effects of advertising on consumption. New evidence could either contradict or reinforce the conclusions offered here, or even illuminate new benefits yet to be identified.

I believe we can infer at least six tentative conclusions from the leading consumer surveys and other evidence on DTC advertising. In essentially every case, the survey results are very consistent from 1999 through 2001.

First, we can largely rule out the possibility that DTC advertising is causing systematic consumer deception, including the inappropriate downplaying of risks and side effects. FDA advertising regulation is inherently biased toward prohibiting nondeceptive claims rather than risk permitting possibly deceptive claims. Survey results bear this out. The FDA and *Prevention* surveys address the FDA's central concern -- the balance of risk and benefit information -- in many ways, and the surveys contained questions that could easily have revealed a strong tendency for DTC advertising to downplay the risks of prescription drugs. The results, however, strongly indicate the absence of a bias against risk information. It is very unlikely that widespread consumer deception has escaped detection by the FDA regulators.

Second, surveys supply direct and indirect evidence that DTC advertising provides valuable information to consumers, not just on obvious topics such as potential treatments and dosages, but also on risks and side effects. On the whole, DTC advertising appears to increase the salience of both risks and benefits from drug therapy. This provides a valuable addition to the market in view of the proven difficulties of communicating risk information to patients (reflected in AARP survey results) and the pervasive consumer information deficits about treatable medical conditions. The high levels of awareness about and attention to DTC ads also strongly suggest that consumers gained information about the core topics of those ads -- the symptoms of medical conditions, potential therapies, alternative dosages, and related topics -- as an by-product of competitive advertising.

Third, the information in DTC advertising motivates consumers to seek additional information from many sources, but especially from physicians and pharmacists. Many of these consumers ask about conditions they had not previously discussed with their doctors. They usually do so, however, in regularly scheduled appointments. Given the overwhelming numbers of consumers who are aware of DTC ads, it is notable that between 14% and 27% of them (in the 1999 *Prevention* and 1999 FDA surveys, with the 2002 FDA survey

at 18%) said DTC ads caused them to ask their doctors about a medical condition they had not previously discussed.

A fourth finding is that from the patient's perspective at least, DTC advertising is causing almost no tension in the doctor's office. A consistent finding is that very few respondents -- usually under 5% -- encountered resentment or resistance when they brought up what they had seen in advertising, or asked about specific drugs, while overwhelming majorities said their physicians treated their questions as an ordinary part of office discussions.

Fifth, consumers like DTC advertising. Large majorities (on the order of 60% to 80%) think DTC ads provide them with useful information and help them in talking to their doctors.

Sixth, DTC advertising appears to yield significant spillover benefits that go to consumers rather than to advertisers. Such benefits range from heightened awareness of the inherently risky nature of prescription drugs to better compliance with drug therapies and even motivation to pursue life-style and behavioral changes that may obviate the need to use pharmaceuticals. In particular, ads reminded consumers to take their medications and to refill their prescriptions. DTC ads also appear to make patients more comfortable with the risks and benefits of the medicines they take, and may improve compliance with drug therapy.

Overall, these survey results are strongly supportive of a situation in which consumers are motivated by advertising first to seek additional information -- especially from physicians, and particularly for previously untreated or inadequately treated conditions -- and then to work with their doctor to reach a decision about what, if any, prescription drug to use.

Policy Recommendations

The range of feasible policy options for DTC advertising appears narrow. An outright ban on DTC advertising, including broadcast advertising as conducted since August 1997, is probably ruled out by the First Amendment. The Supreme Court has long based its commercial free speech decisions on very practical matters. Faced with a growing body of evidence showing substantial benefits and modest costs, the Court would probably provide First Amendment protection to DTC ads. On the other hand, the comprehensive nature of the FDA's regulatory mandate (which as we have seen extends far beyond advertising and promotion) rules out a drastic relaxation of DTC advertising rules. This assumes, of course, that the FDA continues to have primary responsibility for regulating DTC ads, a topic taken up later.

Quite aside from First Amendment considerations, there is little reason for the FDA to roll back its expansion in the scope of DTC advertising in the late 1990s. Advertising deception and consequent medically inappropriate prescribing appear to be minimal, while the benefits of DTC ads appear substantial. The possibility that DTC advertising increases drug expenditures and usage is not a charge against the advertising itself. To use restrictions on DTC advertising as a method to improve physician prescribing would be to employ an extremely blunt tool with no assurance that the result would be to improve consumer health. Proposals to tighten regulation (mandatory pre-clearance, for example, as recommended by Lyles 2002, p. 81) are unlikely to increase consumer welfare, because they would tend to increase costs and reduce the scope of DTC advertising, and therefore limit its benefits.

On the other hand, the FDA should consider relaxing some of its rules. I noted that the context of FDA regulation virtually ensures that its advertising standards are too stringent, thus depriving the market of useful information. An obvious problem is the quantity of warning information required in broadcast ads. This information, which is already modulated according to risks, could be further

simplified and shortened, partly replaced by simpler advice to the effect that physicians will have something important to say about whether and how to use the drug. One effect would be greater relative prominence for strong warnings in ads for the few drugs for which dangers are substantial and consumer vigilance is especially useful. In addition, the FDA could accelerate (with help from manufacturers, of course) its ongoing effort to simplify consumer risk and dosage information, which would allow the substantial proportion of consumers who look at this material in ads to make more sense of it (see FDA 2001b).

More generally, the FDA should reconsider the notion that all DTC ads need to balance information about risks and benefits. Advertising works best as a dynamic medium, filling the most important relevant holes in consumer awareness and emphasizing different product features as dictated by circumstances. This makes information dissemination more efficient, an essential virtue in information-intensive markets such as pharmaceuticals. (Consumers, of course, assume that information in ads is biased in favor of the advertiser, and have recourse to more objective sources.) In addition, advertising is necessarily poorly targeted, with the vast majority of viewers unlikely to use the advertised product. It makes more sense for detailed risk information to be targeted precisely at users, which would be the natural result of focusing risk dissemination in physician offices and pharmacies. The ability of consumer advertising to work well in medical markets, despite the absence of detailed risk information in ads, is apparent for products such as hospitals, clinics, physicians, and dentists.

The FDA has shown considerable energy and courage in opening up DTC advertising, which is prohibited by all other advanced economies except New Zealand. It has also commissioned surveys that could easily have demonstrated harm from its DTC ad policy, a level of self-scrutiny that is rare among regulatory agencies. Nonetheless, there are reasons to think that the FDA is not the best agency for regulating direct-to-consumer advertising at all.

Congress should consider returning responsibility for prescription drug advertising (at least when directed to consumers) to the FTC, which had jurisdiction before the 1962 amendments to the Food, Drug, and Cosmetic Act (cf. Calfee 1996). This would permit regulation to focus on advertising and communication, unencumbered by pervasive regulatory linkages to other matters such as new drug approvals and manufacturing oversight. Regulation would also be conducted by an agency with superior experience and expertise in assessing advertising. Most important is the fact that the FTC must defend its actions in court against advertisers who are not afraid to challenge the agency and possibly offend its staff. This provides an essential system of checks and balances, which is the only way to ensure that the regulating agency strikes a reasonable balance between the dangers of deceptive advertising and the consumer benefits of free flow of commercial information. Fortunately, there is little reason to fear that FTC regulation would engender numerous damaging advertising claims for inherently risky products. This is clear from the FTC's record in regulating advertising for such diverse products as hospitals, clinics, physicians, medical devices, even automobiles and motorcycles. The FTC could easily augment its staff with a small group of pharmacology experts, and consult with outside experts, as it already does on other matters involving health and safety.

Finally, the United States should take advantage of the New Zealand experience, described in the article by Hoek and Gendall in this issue of the *Journal of Public Policy and Marketing.* New Zealand has demonstrated that self-regulation for DTC advertising can work well, providing substantial information to patients with little apparent harm, while also achieving support from the medical community. This is of great significance precisely because the New Zealand experience departs so strongly from both the American system and those in Europe and other developed nations. This experience strongly suggests that many of the protections in the tightly regulated pharmaceutical information regimes of Europe and Canada are both unnecessary and costly to consumers.

Toward New Research

We still know very little about the effects of DTC advertising, especially its impact on consumer behavior (as opposed to attitudes and knowledge) and, ultimately, on consumer health. We also lack even elementary knowledge of the nature of the market forces unleashed by the FDA in its August 1997 policy change. Experience in other markets, such as airlines, has shown that short-run effects of deregulation often differ strongly from longer run effects, which may be very different from those expected by both supporters and opponents of regulatory change (Morrison and Winston 1995). Second-order effects from DTC advertising, such as enhanced consumer participation in health care decisions, improved patient compliance, faster research and development, swifter development and adoption of new uses for older drugs, smaller distribution margins (a typical result of national brand advertising), even increased awareness of non-drug therapies, could dominate short-run effects.

The papers in the 2001 HHS conference (USDHHS 2001; Frank, et al. 2001; Schommer and Hansen 2001; Bero and Lipton 2001) provide useful suggestions, with considerable attention to consumer research methods. Econometric research is of course promising, although very little has been performed to date. Panel data may prove especially useful for both consumer research and econometric methods. Large sample sizes, rich demographic data, and the ability to employ longitudinal methods to assess the impact of waves of DTC advertising, with lagged effects, offer exceptional opportunities to test many hypotheses regarding compliance, for example, as well as physician visits and prescriptions.[33]

Finally, physician surveys, with all their expense and difficulty, could also be very useful. Two major efforts, one by the FDA and the other by a group at

[33] See Wosinska 2001 for a recent analysis of panel data to assess the brand-level effects of statin drug advertising.

Harvard School of Public Health (with industry funding), should be forthcoming soon.

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