Pharmaceutical Marketing & Promotion

PhRMA

Tough Questions, Straight Answers

contents

introduction

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Tough Questions, Straight Answers

In recent years, pharmaceutical marketing and promotion have been the subject of debate, with critics questioning the value of these efforts.

Less frequently discussed are the benefits of the wide variety of promotional efforts, such as free samples and physician education programs—all of which offer important benefits to both patients and physicians.

With strict government regulation and rigorous internal scrutiny, pharmaceutical marketing and promotion have emerged as valuable sources of information for consumers and beneficial additions to physician/patient communication.

This booklet, one in a series of *Tough Questions, Straight Answers* publications by the Pharmaceutical Research and Manufacturers of America (PhRMA), offers a concise collection of the latest facts about pharmaceutical marketing and promotion and dispels many common misconceptions.

This booklet makes clear marketing and promotion's proven track record in getting patients to discuss a range of health issues with their physicians, resulting in patients receiving needed treatment. And it highlights marketing and promotion's contributions to speeding the dissemination of valuable improvements in medical care.

PhRMA member companies hope that the information contained in this booklet will enhance dialogue surrounding pharmaceutical marketing and promotion. We look forward to further exploration of how best to get patients with conditions such as diabetes, asthma, hypertension, and high cholesterol into needed treatment, and how to more rapidly disseminate valuable medical technology.

We believe that through analysis of facts, as well as exploration of new ideas, better health care for all Americans can be achieved.

spending

Q: "Don't pharmaceutical companies spend more on marketing and promotion than they do on research and development (R&D)?"

A: *No. Spending on R&D by pharmaceutical companies far exceeds spending on pharmaceutical marketing and promotion.*

In 2003, PhRMA member companies alone spent much more on R&D—an estimated $33 billion—than the entire industry spent on all combined drug promotional activities, $25.3 billion.[1,2] Of this amount, pharmaceutical companies distributed over $16 billion worth of free samples to office-based physicians. Free samples offer patients and physicians a number of valuable options. For instance, free samples may get patients started on therapy right away, or help physicians optimize dosing or choice of drug before committing to a particular course of treatment. According to the *Journal of Family Practice,* free samples are also an important part of the health care safety net for low-income and uninsured patients.[3]

The entire industry's direct-to-consumer (DTC) advertising accounts for just $3.3 billion of total promotion, or 10 percent of R&D spending by PhRMA members alone—a percentage consistent with the spending levels of other major industries.

The remaining $5.7 billion the pharmaceutical industry expended on marketing and promotion in 2003 was spent on office promotion, hospital promotion, and journal advertising. [Figure 1]

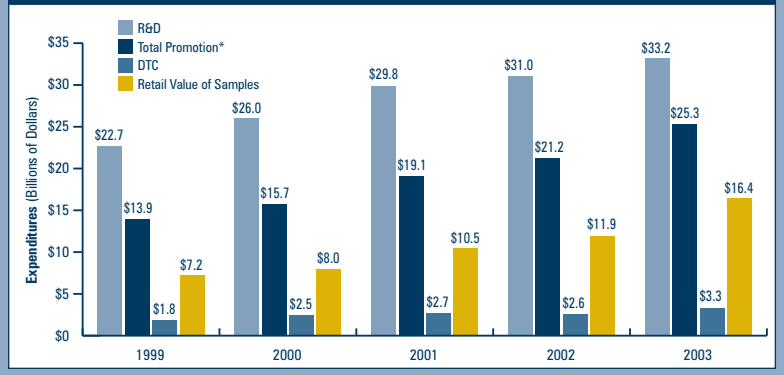
KEY FACT

"The largest part of the marketing costs in the U.S. are free samples of drugs, which enable patients to find out if a drug works for them without having to pay for it...a good way to help patients learn about drugs cheaply."[5]

Mark B. McClellan, M.D., Ph.D.

> According to a *Wall Street Journal* article, "If you're open to switching prescriptions, ask your doctor for samples. . . . Not only will you stave off having to pay, but doctors advise trying various medicines because they differ. Samples are 'an important way of trying to find out which ones work' for patients, says Anthony Montanaro, chairman of the Asthma and Allergy Foundation's Medical-Scientific Council."[4]
> —*The Wall Street Journal*

Figure 1: Pharmaceutical Research Companies' R&D Spending Exceeds Promotional Dollars



*Total Promotion refers to IMS Health data defined as: DTC, Retail Value of Samples, Office Promotion, Hospital Promotion, and Journal Advertising.

Sources: R&D Spending: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey* (Washington, DC: PhRMA, 2004). Promotional Data: IMS Health, *Integrated Promotional Services*™ and CMR, 6/2004.

marketing & drug prices

Q: "Doesn't pharmaceutical marketing increase the price of advertised drugs?"

A: *No. Experts have not found any relationship between drug marketing and drug price.*

According to reports and studies, there is no direct relationship between DTC advertising and the price growth of drugs. For example, December 2003 Federal Trade Commission (FTC) comments to the Food and Drug Administration (FDA) included a statement that "[DTC advertising] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better informed decisions about their treatment options. . . . Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices."[6]

The FTC comments continue, "DTC advertising accounts for a relatively small proportion of the total cost of drugs, which reinforces the view that such advertising would have a limited, if any, effect on price."[7]

Likewise, a recent study conducted by Harvard University and the Massachusetts Institute of Technology and published by the Kaiser Family Foundation found that DTC advertising accounts for less than 2 percent of the total U.S. spending for prescription medicines.[8]

KEY FACT

"Currently available empirical evidence does not support the allegations that DTC advertising increases inappropriate prescription of, or prices for, pharmaceutical products."[10]

Federal Trade Commission and Department of Justice,
Improving Health Care: A Dose of Competition

It is also important to remember that spending on pharmaceuticals remains a very small portion of the health care dollar. Of every health care dollar spent in the United States, only about 10.5 cents is spent on prescription drugs, including brand medicines, generic drugs, and pharmacy.[9] [Figure 2]

Figure 2: Where the Health Care Dollar Goes: 2002

Source: Centers for Medicare & Medicaid Services, *National Health Expenditures*, 8 January 2004, http://www.cms.gov/statistics/nhe (accessed 9 January 2004).

underdiagnosis & undertreatment

Q: "Don't pharmaceutical marketing and promotion create an overuse of prescription drugs?"

A: *No. In fact, there is significant underdiagnosis and undertreatment of serious diseases and conditions that affect millions of Americans. Pharmaceutical marketing and promotion help address this problem.*

Recently published research shows that for the majority of conditions and diseases there is actually underuse of recommended health care services, including prescription medications that are DTC advertised.

A study conducted by RAND Health and published in *The New England Journal of Medicine* found that nearly half of all adults in the United States fail to receive recommended health care. The RAND study found underuse of prescription medications in seven of the nine conditions for which prescription medicines were the recommended treatment. Conditions for which underuse was found include asthma, cerebrovascular disease, congestive heart failure, diabetes, hip fracture, hyperlipidemia, and hypertension.[11] Of the seven conditions for which RAND found underuse of recommended prescription medications, five are DTC advertised.

Pharmaceutical marketing and promotion get patients talking to their doctors about conditions that may otherwise have gone undiagnosed or undertreated. [Figure 3] According to a recent Harvard University/Massachusetts General Hospital and Harris Interactive Survey on health care experiences associated with DTC advertising of prescription drugs, one-quarter of adult patients who visited their physician after seeing a DTC ad received a new diagnosis of a condition.[12] Some of the most common new diagnoses that were discovered as a result of these visits—high cholesterol, hypertension, diabetes, and depression—are often underdiagnosed and undertreated in the general population.

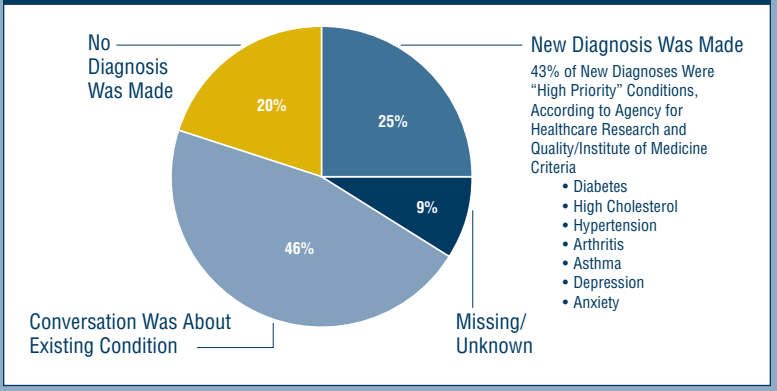
> "Especially noteworthy is the role of DTC ads in prompting consumers to consult their physicians for a previously undiagnosed condition."[14]
> —Federal Trade Commission

KEY FACT

One-quarter of adult patients who visited their physician after seeing a DTC ad received a new diagnosis of a condition.[13]

Harvard University/Massachusetts General Hospital and Harris Interactive Survey published in *Health Affairs*

Figure 3: Diagnoses Resulting from DTC-Inspired Visits



Source: J. S. Weissman et al., "Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising," *Health Affairs Web Exclusive,* 26 February 2003, http://www.healthaffairs.org (accessed 27 February 2003).

patient education

Q: "Do patients benefit from pharmaceutical advertising?"

A: *Yes. DTC advertising creates awareness of diseases and treatment options, helps get patients into needed treatment, and empowers patients with information.*

DTC advertising's overarching purpose is to inform and educate consumers about treatable conditions, the symptoms that may help them identify diseases, and available therapies. Research demonstrates that DTC advertising helps educate patients about medical conditions and treatment options by encouraging dialogue with their physicians.

On April 18, 2002, the FDA released the results of their patient survey on DTC advertising. The telephone survey of 943 people who had been to the doctor within the past three months revealed that DTC advertising empowers patients to become more active in their own health care. Consider the following:

- Nearly one in five patients reported speaking to a physician about a condition for the first time because of a DTC ad.[15]
- Thirty-two percent of patients reported that DTC ads helped them have better discussions about their health with their doctor.[16]
- Forty-three percent of patients said an ad for a prescription drug caused them to look for more information about the drug or about their health.[17]

In July 2004, the FTC and the Department of Justice (DOJ) released a joint report entitled *Improving Health Care: A Dose of Competition*.[18] According to the report, "[DTC] advertising provides a powerful tool to communicate information about health and wellness to consumers—and the information can change people's behavior. Thus, good information is a necessary building block both for consumer empowerment and enhanced health."

> "It [DTC advertising] is consistent with the whole trend toward consumer empowerment. We believe that there is a certain public health benefit associated with letting people know what's available."[20]
> —Food and Drug Administration (FDA)

> "...[DTC] advertising increases consumer and physician awareness of the potential benefits of pharmaceuticals and helps close the information gaps among pharmaceutical manufacturers, doctors, and consumers."[21]
> —Federal Trade Commission and Department of Justice

KEY FACT

"It [DTC advertising] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better-informed decisions about their treatment options."[19]

Federal Trade Commission comments before the FDA

patient compliance

Q: "Doesn't pharmaceutical marketing adversely affect patient behavior?"

A: *No. Patients who are more informed about and involved in their treatment due to DTC advertising better adhere to their physicians' directions.*

Another benefit of DTC advertising is its ability to encourage compliance with physician-prescribed treatment regimens. Lack of compliance is a critical problem in achieving efficacious medical care. The World Health Organization states, "Poor adherence to long-term therapies severely compromises the effectiveness of treatment making this a critical issue in population health both from the perspective of quality of life and of health economics."[22]

According to the July 2004 FTC and DOJ report, ". . . DTC advertising can increase compliance with pharmaceutical usage regimes and can assist in educating patients and health professionals about the risks, diagnosis, and treatment of a particular medical condition."[23]

Survey data also demonstrate that pharmaceutical promotion encourages patients to comply with their physicians' prescribed treatment regimen. For example, a June 2001 study by Pfizer and RxRemedy[24] found that patients who involve themselves in their health care by asking their doctor about a prescription drug they saw in a DTC advertisement are more likely to take their medication than those who do not.

- **Arthritis** patients who have seen a DTC ad are **75 percent** more likely to stay on their medication.
- **Allergy** patients who have seen a DTC ad are **twice** as likely to stay on their medication.
- **Diabetes** patients who have seen a DTC ad are **10 percent** more likely to stay on their medication.
- **High cholesterol** patients who have seen a DTC ad are **16 percent** more likely to stay on their medication.
- **Depression** patients who have seen a DTC ad are **37 percent** more likely to stay on their medication.

Source: Pfizer Inc and RxRemedy, Inc., *Impact of DTC Advertising Relative to Patient Compliance*, June 2001, http://www.pfizer.com/are/about_public/mn_about_dtcadsdoc. html (accessed 11 August 2004).

> "DTC advertising increases compliance with prescribed treatments. Studies show that compliance with medication regimens also increases. Enhanced patient compliance actually reduces utilization rates of other, more expensive, healthcare services, including surgical procedures and inpatient care."[25]
> —Pfizer Inc

KEY FACT

In 2001, 12 percent of consumers said DTC advertisements made them "more likely" to refill their prescription.[26]

Prevention Magazine

physician attitudes

Q: "Doesn't DTC advertising interfere with the physician/patient relationship?"

A: *No. Many physicians and patients report that DTC advertising actually enhances their communication.*

Far from interfering with the physician/patient relationship, pharmaceutical advertising has a positive impact on the physician/patient relationship and increases communication between the physician and the patient, according to the FDA Patient Survey. A vast majority (93 percent) of patients who asked about a drug reported that their physician "welcomed the question."[27]

Of patients who asked about a drug, 77 percent reported that their relationship with their doctor remained unchanged as a result of the office visit, and 20 percent reported that their relationship improved.[28]

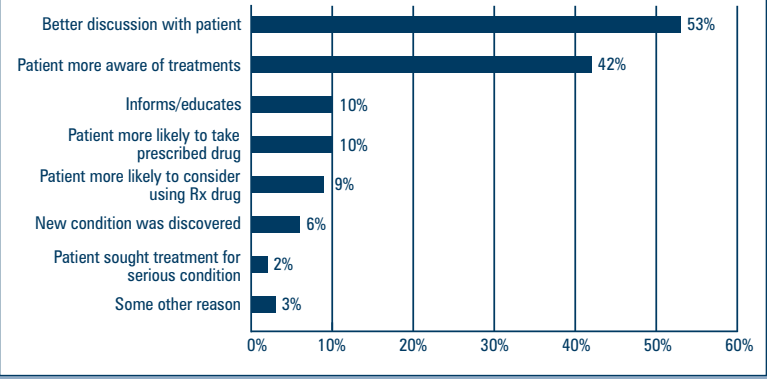
KEY FACT

According to Lucille Perez, M.D., President of the National Medical Association, "Doctors are finding that these ads are helping patients talk to us about medical conditions they're at risk for. When you consider the majority of drugs advertised can treat the diseases that disproportionately affect the African-American community, there is incredible potential. . . . Further, we must view them [DTC ads] as one of the several tools that are potentially beneficial to the physician-patient dyad."[30]

National Medical Association, "African American Doctors Say DTC Ads Raise Disease Awareness, Bolster Doctor-Patient Ties"

The FDA's survey of physicians on DTC advertising was released on January 13, 2003, and found that 56 percent of physicians believed that DTC ads helped patients ask better questions (17 percent of physicians disagreed with this statement); 53 percent of physicians believed that they had better discussions with their patients about their health because of DTC ads (16 percent of physicians disagreed with this statement); and 45 percent believed that the usefulness of their time with the patient was increased by DTC ads (35 percent of physicians disagreed with this statement). [Figure 4] The survey was a random sample of 500 physicians from the American Medical Association's physician database.[29]

Figure 4: Beneficial Effects of DTC Advertising



Source: K. Aikin, *Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results*, 13 January 2003, http://www.fda.gov/cder/ddmac/globalsummit2003/index.htm (accessed 13 January 2003).

Q: "Doesn't advertising pressure physicians to prescribe advertised medicines?"

A: *No. A majority of physicians actually report* not *prescribing requested medications.*

Just asking a physician about a drug doesn't guarantee a prescription. According to a General Accounting Office report, of the 61.1 million people (33 percent of adults) who had discussions with their physician as a result of a DTC advertisement in 2001, only about 8.5 million (5 percent of adults) actually received a prescription for the product, a small percentage of the total volume of prescriptions dispensed.[31]

According to Jack E. Calfee, Ph.D., Resident Scholar at the American Enterprise Institute for Public Policy Research, "The evidence suggests that prescribing decisions are dominated by the physician's advice, which may involve non-drug therapy, a generic prescription, or an over-the-counter drug recommendation, as alternatives to prescribing the advertised brand."[32]

The FDA survey of physicians showed that the vast majority of physicians do *not* feel pressured to prescribe prescription drugs when requested by their patients as a result of seeing a DTC ad.

KEY FACT

Nancy M. Ostrove, Ph.D., Deputy Director, Division of Drug Marketing, Advertising and Communications at the FDA, testified in July 2001 before a congressional committee that there is no evidence that DTC advertising is increasing inappropriate prescribing.[38]

Nancy M. Ostrove, Ph.D., congressional testimony before the Senate Committee on Commerce, Science and Transportation

prescribing practices

- The vast majority of physicians (91 percent) said the patient did not try to influence the course of treatment in a way that would have been harmful.[33]
- Seventy-two percent of physicians, when asked for a prescription for a specific brand name drug, felt little or no pressure to prescribe a medicine.[34]
- Seventy-one percent of physicians said they did not prescribe the requested medicine because they felt that an alternative medicine was more appropriate.[35]
- Of the physicians reporting a negative effect from DTC advertising, only 5 percent listed "pressure to prescribe" as one of the reasons.[36]
- Of the eighty-six percent of physicians that reported that their patient asked about a specific brand name drug, 88 percent reported that the patient did indeed have the condition the drug treats.[37]

> "It's one thing to talk to the doctor *about* an advertised medicine, and another thing to ask the doctor *for* it. Of the 62.4 million consumers who have talked to their doctors about advertised drugs, only 26 percent—approximately 16.2 million people—have taken the additional step of requesting that medicine from their doctors."[39]
> —*Prevention Magazine*

provider education

Q: "Do pharmaceutical marketing and promotion provide any benefit to physicians and other health care providers?"

A: *Yes. Pharmaceutical marketing and promotion provide physicians and other health care providers with the latest information on new treatments and medical advances that give them another means of providing patients with the newest and highest quality of care.*

In January 2003, the Institute of Medicine issued *Priority Areas for National Action: Transforming Health Care Quality.*[40] The report states that "the United States has the know-how and technology to deliver world-class health care to the public, but often fails to translate such expertise into everyday clinical practice." Pharmaceutical education of health care providers, often referred to as "detailing," provides health care professionals with the latest, most accurate FDA-regulated information available regarding prescription medicines, and helps bridge this gap in "translating research findings into medical practice."[41]

Pharmaceutical education helps translate new technologies and therapies into practice by raising physician awareness of clinical practice guidelines and identifying untreated patients. For example, in May 2001, the National Institutes of Health updated their practice guidelines for the treatment of high cholesterol, increasing to 36 million the number of individuals who should be taking medicines to lower their cholesterol, up from 13 million just eight years before.[42]

KEY FACT

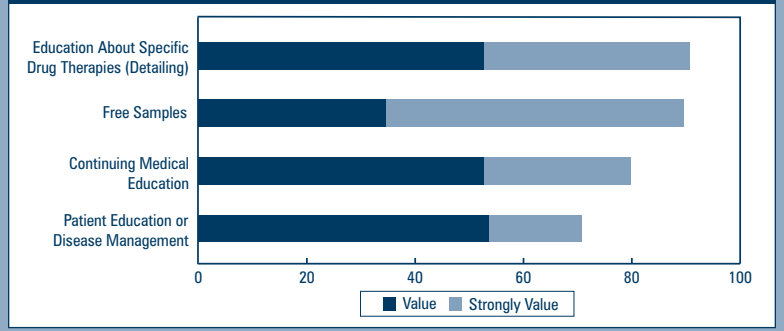
According to a recent physician survey, physicians said the education provided by pharmaceutical representatives about specific drug therapies was either "somewhat valuable" (53 percent) or "very valuable" (38 percent).[44]

Pfizer Inc, "Pharmaceutical Marketing and Promotion: Creating Access to Innovation"

According to an October 2002 article in *The American Journal of Managed Care*, "Concurrent public and private efforts aimed at physicians and consumers were related to increased diagnosis and treatment [of patients with high cholesterol]. Physician-directed initiatives have included pharmaceutical industry marketing, continuing medical education programs, and promotion of NCEP [National Cholesterol Education Program] guidelines. Consumer-directed initiatives have included direct-to-consumer advertisements sponsored by various pharmaceutical companies and patient education programs sponsored by many managed care organizations."[43]

In addition to helping translate new technologies and therapies into practice, pharmaceutical marketing and promotion are valuable sources of education for physicians and patients alike. [Figure 5]

Figure 5: How Physicians Value Interactions with Pharmaceutical Representatives



Source: Pfizer Inc, "Pharmaceutical Marketing and Promotion: Creating Access to Innovation," *Economic Realities in Health Care* 3, no. 1, http://www.pfizer.com/download/public_policy_pmp.pdf (accessed 9 February 2004).

government regulation

Q: "Don't pharmaceutical companies have free reign over their marketing activities?"

A: *No. Pharmaceutical marketing is closely regulated by the FDA to ensure that it is accurate, fairly balanced, and limited to information that has been approved by the FDA. In addition, many pharmaceutical companies have adopted a voluntary pharmaceutical industry code encouraging appropriate interaction between health care providers and industry representatives.*

Federal law strictly regulates promotional activities by pharmaceutical companies. Under the Federal Food, Drug, and Cosmetic Act, promotional materials must present accurate information and fairly represent both the benefits and the risks of the drugs promoted. Every print or electronic ad must not only be accurate and comply with a drug's FDA-approved labeling, but also be fairly balanced—that is, explain both the risks and benefits associated with the drug. Every print ad must contain a detailed description of risks. And every electronic ad must contain a statement about a drug's major risks and provide ways for consumers to obtain more information.

KEY FACT

"FDA has monitored DTC promotion, and especially broadcast promotion, very closely to help ensure that adequate contextual and risk information, presented in understandable language, is included to fulfill the requirement for fair balance and to help the consumer accurately assess promotional claims and presentations."[47]

Nancy M. Ostrove, Ph.D., congressional testimony before the Senate Committee on Commerce, Science and Transportation

The FDA's Division of Drug Marketing and Communication (DDMAC) is responsible for drug advertising oversight to ensure that DTC advertisements are in compliance with the FDA's rules and regulations. Although pharmaceutical companies are not required by law to submit their broadcast advertisements to DDMAC for prior review, many voluntarily do so.[45] If an advertisement is in violation of FDA rules or regulations, the FDA does have remedies. For example, the FDA can require that the violating promotion be stopped immediately. It can also require a remedial campaign to correct any misimpressions left by the advertisement.[46]

DDMAC also monitors prescription drug promotion to physicians in every venue, including audio conferences for physicians, pamphlets distributed at professional meetings, conversations between industry representatives and physicians at professional meetings, mailings to health care professionals, advertisements in professional journals, and the like.

In addition to drug advertising oversight being provided by the FDA, in 2002 the Pharmaceutical Research and Manufacturers of America's (PhRMA's) Board of Directors adopted the *PhRMA Code on Interactions with Healthcare Professionals*. According to the voluntary PhRMA Code, "Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing health care professionals about products, providing scientific and educational

information, and supporting medical research and education." The Code also notes that "ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines" is "critical to our mission of helping patients by developing and marketing new medicines."[48]

Finally, in May 2003, the Office of the Inspector General, Department of Health and Human Services, issued its final "Compliance Program Guidance for Pharmaceutical Manufacturers" (Final Guidance). The Final Guidance provides recommendations to the pharmaceutical industry for developing, implementing, and refining internal corporate programs, such as educational grants, research funding, and consulting agreements with physicians, to ensure compliance with applicable fraud and abuse laws. According to the Final Guidance, the PhRMA Code "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."[49]

endnotes

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Fall 2004