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## Direct-to-Consumer Advertising of Prescription Drugs

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# Direct-to-Consumer Advertising of Prescription Drugs

## Summary

The Direct-to-Consumer (DTC) advertising of prescription drugs by pharmaceutical companies has been described as any promotional effort with respect to these drugs that targets the general public through the lay media. Spending by the drug industry on DTC advertising grew from \$791 million in 1996 to \$3.2 billion in 2003, mostly for promotion of 50 brand-name drugs. There is a growing consensus among health professionals and others that DTC advertising may have exacerbated recent problems with drug safety (e.g., Vioxx) and that it may contribute to the rising cost of health care.

Drug manufacturers claim that DTC advertising reminds patients to visit their doctors and be tested for health problems earlier, to take their medicines as prescribed, and to become more involved in their own treatment. Some physicians acknowledge that DTC advertising serves as an effective tool for conveying health information to their patients. Others, however, mistrust DTC advertising because, in their opinion, the information provided by the ads can sometimes be misleading. From their perspective, DTC ads rarely, if ever, discuss non-drug forms of treatment, such as weight control and other beneficial lifestyle changes.

In 1962, Congress gave the Food and Drug Administration (FDA) the authority to regulate prescription drug advertising, which, at the time, consisted primarily of ads in medical journals directed mostly toward physicians. The law prohibited FDA from issuing regulations that would require prior approval of the content of drug advertising. Published regulations require that all drug ads include a “brief summary” statement that discloses all the drug’s known risks. Because most commercial advertising is limited in length or duration, drug makers found compliance with these regulations difficult, particularly in television and radio advertising. Until 1997, FDA had given no guidance to the drug industry on how the “brief summary” requirements for broadcast advertising could be met. It then issued a draft guidance, finalized in 1999, clarifying that it would treat broadcast advertising differently than print advertising. It stipulated that broadcast ads had to include the advertised product’s most important risks (called a “major statement” by FDA) in the audio portion of the advertisement. FDA’s guidance provided that the DTC ads should give sources where more complete risk information about a drug would be available (i.e., on Internet sites, toll-free telephone numbers, referral to health care providers, and large-circulation print sources).

Some Members of Congress are asking whether FDA’s current policies on DTC ads give consumers information that appropriately balances risks and benefits or whether ads misrepresent important information patients need prior to purchasing or consuming the drug. This report examines legislative concerns and options on risk and health information as they relate to advertising of drugs. It also discusses activities that could be undertaken with current legislative authority to address concerns about DTC advertising; and examines options for new statutory authority on DTC advertising.

This report will be updated periodically.

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# Direct-to-Consumer Advertising of Prescription Drugs

## Introduction

Direct-to-Consumer (DTC) advertising is usually described as any promotional effort by pharmaceutical companies to present prescription drug information to the general public through the lay media.<sup>1</sup> DTC advertising shows up in magazines, newspapers, non-medical journals, pharmacy brochures, and direct-mail letters, and on television, radio, videos, and Internet websites. Anyone who watches television or listens to the radio today has likely seen or heard some sort of DTC advertisement for prescription drugs. The ads usually fall into one of three categories:<sup>2</sup>

- “Product-claim” ads that include a product’s name and a therapeutic claim about the product.
- “Help-seeking” ads that discuss a particular disease or health condition, and advise the consumer to “see your doctor” but do not mention the product’s name.
- “Reminder” ads that call attention to the product’s name but make no reference to the health condition the drug is used to treat.

Of these three categories of advertisements, the Food and Drug Administration (FDA) has the authority to directly regulate only product-claim ads. The regulations require that therapeutic claims not be false or misleading. The agency regulations differentiate between print and broadcast DTC product-claim ads. Print ads must contain all the risk information described in the drug’s FDA-approved label, including major side effects, contraindications, and precautions. Broadcast advertisements, however, must directly state only major risk information and must direct viewers and listeners to other sources from which they can access the complete risk information.

Help-seeking ads also are directed toward consumers but make no health claims. Reminder ads also make no health claims but are primarily directed toward doctors and health care professionals, who are more likely than consumers to know about the advertised product and its use. They also serve to acquaint consumers with brand names of products. Although the agency monitors these two types of ads, to ensure

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<sup>1</sup> R.G. Frank et al., *Prescription Drug Policy Issues in California*, report prepared for the California HealthCare Foundation, Apr. 1999, in Michael S. Wilkes, Robert A. Bell, and Richard L. Kravitz, “Direct to Consumer Prescription Drug Advertising: Trends, Impact, and Implications,” *Health Affairs*, Mar./Apr. 2000. (Hereafter cited as Frank et al., *Prescription Drug Policy Issues*.)

<sup>2</sup> [<http://www.fda.gov/cder/handbook/adverdef.htm>].

there is no implication of a product claim, it has issued only draft guidance on them because it does not have the authority to regulate these ads.

This report focuses on the impact of product claim ads and the regulatory requirements for these ads. This report also discusses FDA's funding, enforcement authority and initiatives, "commercial speech" court rulings, previous legislation, and other relevant agency activities.

## Growth in Spending on DTC Prescription Drug Advertising

Promotion and prescription drug DTC spending has reached significant levels in recent years. **Table 1** shows annual spending since 1996 on DTC advertising, along with spending on other types of promotional activities by pharmaceutical companies.

**Table 1. Total U.S. Promotional Spending  
on Prescription Drugs, 1996-2003**  
(millions of dollars)

Type	1996	1997	1998	1999	2000	2001	2002	2003
<b>Promotion to consumers</b>								
DTC <sup>a</sup>	791	1,069	1,317	1,848	2,467	2,679	2,638	3,235
<b>Other industry identified promotional activities</b>								
Office <sup>b</sup>	2,258	2,785	3,386	3,607	4,038	4,789	5,327	4,455
Hospital <sup>c</sup>	552	579	671	713	765	702	873	819
Journal ads <sup>d</sup>	459	510	498	470	484	425	437	448
Retail value of samples <sup>e</sup>	4,904	6,047	6,602	7,230	7,954	10,454	11,909	16,373
<b>Total</b>	<b>9,164</b>	<b>10,991</b>	<b>12,474</b>	<b>13,868</b>	<b>15,708</b>	<b>19,059</b>	<b>21,184</b>	<b>25,330</b>

**Source:** IMS Health, Integrated Promotional Services TM and CMR, 6/2004

- a. DTC promotion represents the expenditures for direct-to-consumer pharmaceutical advertising for prescription products on television, magazines and newspapers, on radio and outdoors.
- b. Office promotion includes costs associated with sales activities of pharmaceutical representatives that are directed to office-based physicians (often referred to as "detailing.")
- c. Hospital promotion captures the costs associated with sales activities of pharmaceutical representatives that are directed to hospital-based physicians and directors of pharmacies.
- d. Journal advertising reflects advertising expenditures for prescription products appearing in medical journals.
- e. The retail value of the product sampling activities of pharmaceutical representatives are those directed to office-based physicians, as reported by members of their front office staff.

According to **Table 1**, spending on DTC advertising of prescription drugs grew more than quadrupled between 1996 and 2003, rising from \$791 million in 1996 to \$3.2 billion in 2003. In 2003, spending on DTC ads constituted approximately 13% of all promotional spending for pharmaceuticals; when the retail value of samples is subtracted from the total amount, DTC advertising made up 36% of promotional spending, second only to the cost of pharmaceutical representatives' physician-office sales activities ("detailing").

One critic claims, however, that the drug companies use many different marketing methods to influence prescribing decisions of physicians, not all of which are included in the reported promotional spending (as seen in **Table 2**) of the drug industry.<sup>3</sup> These activities, she asserts, include educational meetings and luncheons that the industry provides to doctors, hospitals, and medical schools.<sup>4</sup>

## Effectiveness of Spending on DTC Ads

Studies differ in how advertising effectiveness is measured. According to IMS Health,<sup>5</sup> promotional spending has yielded increased sales for at least 49 brand-name drugs. IMS Health found in its study of "return on investment" in DTC advertising that at least 90% of the brands demonstrated positive returns; 70% of the brands had returns in excess of \$1.50 for each dollar invested; and 35% were in excess of \$2.50. The best-performing brand yielded a return of \$6.50 per dollar invested.<sup>6</sup> The study found that 10 of the leading 12 brands had sales of over \$1 billion. For these brands, return on investment was \$3.66 per dollar spent compared with slightly more than one dollar for every dollar spent on brands with sales below \$200 million. Other research has also found a good return for DTC ads. This research suggests "a yield of an additional \$4.20 in sales for every dollar spent on DTC advertising."<sup>7</sup>

Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association representing the major drug manufacturers, believes that advertising,

<sup>3</sup> Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (New York, Random House, 2004).

<sup>4</sup> Ibid. See also comments made by Janet Woodcock, FDA's Acting Deputy Commissioner for Operations, that drug companies continue to offer physicians free cruises and stays in exotic resorts. U.S. Congress, Senate Committee on Health, Education, Labor and Pensions, *Ensuring Drug Safety: Where Do We Go from Here?* hearings, 109<sup>th</sup> Cong., 1<sup>st</sup> sess., Mar. 3, 2005. Comments discussed in Gardiner Harris, "Drug Makers Are Still Giving Gifts to Doctors, F.D.A. Official Says," *New York Times*, Mar. 4, 2005.

<sup>5</sup> IMS is a for-profit source for pharmaceutical market intelligence, with operations in more than 100 countries, employing 6,000 professionals, and with an annual revenue of \$1.4 billion. See [<http://www.imshealth.com>].

<sup>6</sup> IMS Management Consulting [David Gascoigne], "DTC at the Crossroads: A 'Direct' Hit...or Miss?" *IMS Issues and Insights*, Sept. 23, 2004, at [[http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_5266\\_58193110,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_5266_58193110,00.html)].

<sup>7</sup> Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Arnold M. Epstein, and Richard G. Frank, *Demand Effects of Recent Changes in Prescription Drug Promotion* (Menlo Park, CA: The Kaiser Family Foundation, June 2003), pp. 18-19.

particularly DTC advertising, fosters competition among products which could lead to lower prices for consumers.<sup>8</sup> Other researchers observe, however, that it is unclear how DTC advertising would lead to lower prices because the point of the ads is to build consumer loyalty to a specific product whatever its price.<sup>9</sup> Decisions on how pharmaceutical manufacturers set prices and whether they pass the costs of DTC advertising on to consumers are proprietary.

## R & D Spending Versus Promotional Spending

The total amount spent on prescription drug advertising has raised a number of concerns with some Members of Congress. One such concern is that the drug industry could be spending more on marketing and promotion than on research and development, which some see as unacceptable. The drug industry association disputes that assertion, reporting that R&D spending exceeded promotional spending every year for the last five years (See **Table 2**).

**Table 2. Drug Companies' Spending on R&D, Promotional Activities, and DTC Advertising**  
(billions of dollars)

Type	1999	2000	2001	2002	2003
Research and development	22.7	26.0	29.8	31.0	33.2
Promotional spending	13.9	15.7	19.1	21.2	25.3
Direct-to-Consumer advertising	1.8	2.5	2.7	2.6	3.2
DTC advertising as a % of R&D spending	8%	10%	9%	8%	10%

**Source:** PhRMA, Pharmaceutical Marketing and Promotion, *Tough Questions, Straight Answers*, Nov. 2004, [<http://www.phrma.org/publications/policy/2004-11-10.1095.pdf>].

## Impact of DTC Advertising

Federal agencies, consumers, physicians, health care organizations, and industry groups hold a variety of opinions on the effect of DTC advertising. Hearings in the fall of 2004 raised questions about the role of DTC advertising in evaluating drug safety. In November 2004, FDA finalized analysis of three surveys of patients and physicians (a patient survey in 1999, and two surveys in 2002, one with patients and the other with physicians). Survey results are discussed below and are summarized in **Tables 3 and 4**. FDA found that DTC advertising affects information seeking,

<sup>8</sup> Testimony of Gregory J. Glover, representing the Pharmaceutical Research and Manufacturers of America before the U.S. Congress, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, *Prescription Drug Issues*, hearings, 107<sup>th</sup> Cong., 1<sup>st</sup> sess., July 24, 2001. (Hereafter cited as Glover, *Senate Commerce Committee Testimony*, 2001.)

<sup>9</sup> Frank et al., *Prescription Drug Policy Issues*, p. 110.



healthcare visits, questions and/or requests of physicians and ultimately the public health.

Most DTC advertising targets individuals with chronic health conditions, such as allergies, stomach ulcers, depression, high blood pressure, and high cholesterol. Some advertisements target caregivers and family members of those with chronic conditions, or those who may be at risk of a given disease.<sup>10</sup> Ads for osteoporosis medications, for example, are said to be targeted towards women in their 40s and 50s who may have some genetic predisposition for the disease. Such ads attempt to educate patients about different health conditions, and attempt to create a demand for the drug, in part by increasing interaction between patients and their doctors.

The criteria and discussions leading to company decisions on which medications to advertise are proprietary. Most of the top selling brand-name products are extensively advertised, and the advertising increases public awareness of these drugs.<sup>11</sup>

## Impact on Number of Adverse Events

Recent events have brought FDA's policies on DTC advertisements into focus for Congress.<sup>12</sup> Some Members have expressed concern about post market problems with the safety of certain drugs and the potential of causing harm to consumers. The perceived connection with DTC is that drug companies often use DTC ads to promote newly approved medications. Although judged safe by FDA with evidence from clinical trials, these approved drugs had been tested only on a certain number of patients (5,000 or fewer) and compared almost always with a placebo. With large

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<sup>10</sup> Ed Slaughter, Corporate Director, Advertising and Trends Research, Rodale, Inc., "Seventh Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines," *Prevention Magazine*, 2004, pp. 1-7.

<sup>11</sup> *Ibid.*

<sup>12</sup> Hearings in the fall of 2004 looked at whether certain antidepressants heighten suicidal thoughts and behaviors among children. U.S. Congress, House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *FDA's Role in Protecting the Public Health: Examining FDA's Review of Safety and Efficacy Concerns in Antidepressant Use by Children*, hearings, 108<sup>th</sup> Cong., 2<sup>nd</sup> sess., Sept. 9, 2004. In September 2004, Merck & Co. withdrew its anti-inflammatory medication Vioxx from the market because studies had shown an elevated heart-attack and stroke risk with prolonged use. Questions were raised at a November 2004 Senate Finance Committee hearing about whether earlier studies by the company and others had suggested this risk in Vioxx. See U.S. Congress, Senate Committee on Finance, *FDA, Merck and Vioxx: Putting Patient Safety First?* hearing, 108<sup>th</sup> Cong., 2<sup>nd</sup> sess., Nov. 18, 2004. At an FDA advisory panel meeting, February 16-18, 2005, the members voted for continuing marketing of Vioxx, Celebrex and Bextra but with stern warnings on the labels of these drugs, severely limited DTC advertising, and requirements that drug makers provide patients with information outlining the drugs' risks. FDA has pledged to consider the advisory panel recommendations in any regulatory actions the agency may take. However, some groups, notably Public Citizen, are arguing that all COX-2 drugs (class of drugs to which Vioxx, Celebrex and Bextra belong) should be removed from the market.

DTC advertising campaigns, many thousands and sometimes millions of people begin to take the drug.

With this large-scale use, a drug with serious side effects and risks that went undetected in pre-market trials may cause injury before the problem is recognized. FDA's adverse event reporting system, MedWatch, is intended to identify problems encountered as drugs are used in the wider population and to report this information back to physicians and medical care personnel. It is, however, a passive surveillance system, gathering anecdotal and often incomplete information from physicians and consumers.<sup>13</sup> Some in Congress, therefore, are wondering whether the MedWatch system is doing its job as well as it might. In addition some question whether the system for dispersing information on problems is reaching the medical professions in a timely manner.<sup>14</sup>

Others are concerned that DTC ads minimize the risks of certain medications while promoting the benefits. Critics say that some patients, taking these DTC heavily promoted drugs, could use other medications with fewer side effects for which there are more established health track records.<sup>15</sup> But drug industry representatives claim that prior to FDA's approval the drugs have been studied and proven safe with clinical trials and that they are safe under the labeled conditions of use.

On December 17, 2004, FDA asked Pfizer, Inc. to voluntarily suspend DTC advertising on Celebrex (one of a class of anti-inflammatory drugs potentially linked to heart disease) while the agency obtains and evaluates new and conflicting scientific data on adverse events associated with the drug.<sup>16</sup> Pfizer agreed to stop its advertising. FDA also requested that the company change the information provided to physicians to reflect the recommendations FDA made encouraging physicians to consider alternative therapies as they evaluate their individual patients' needs.

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<sup>13</sup> Because the MedWatch system provides a count of events without giving the total number of users, it is difficult to obtain systematic assessments of experience with prescription drugs following trials and FDA approval.

<sup>14</sup> CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by Susan Thaul.

<sup>15</sup> “[O]verall harm from a new pharmaceutical may be increased when rapid expansion of prescribing occurs prior to the development of definitive data on safety. With new drugs whose safety profile is not well characterized, greater regulatory efforts to limit the use of the drug to the clinical population in which an unambiguous outcome benefit exists may minimize the potential for overall public harm,” Carolanne Dai, Randall S. Stafford, and G. Caleb Alexander, “National Trends in Cyclooxygenase-2 Inhibitor Use Since Market Release: Nonselective Diffusion of a Selectively Cost-effective Innovation,” *Archives of Internal Medicine*, vol. 165 (2005), pp. 171-177, at [<http://archinte.ama-assn.org/current.dtl>].

<sup>16</sup> “[T]he impact of marketing and promotional efforts must also be considered. COX-2 inhibitors have been heavily promoted both through direct-to-consumer advertising as well as to physicians.” Ibid. See also Food and Drug Administration, “FDA Statement on Celebrex DTC Promotion,” Dec. 20, 2004, at [<http://www.fda.gov/bbs/topics/news/2004/new01147.html>].

## Impact on Behavior

Two government agencies have stated that competition gives drug companies an incentive to deliver truthful and accurate information to consumers. Their studies confirm that DTC advertising is a powerful tool communicating health and wellness information to consumers that can change people's behavior. They claim, "good information is a necessary building block for both consumer empowerment and enhanced health."<sup>17</sup> However, one critic claims that it is impossible to separate what is the educational component of an advertisement from the marketing component because it is all marketing.<sup>18</sup> The title of a *New England Journal of Medicine* perspectives piece — "To Inform or Persuade?" — describes the dilemma.<sup>19</sup>

**Consumer View.** FDA conducted two national patient telephone surveys (one in 1999 and the other in 2002) to find out what patients thought of DTC advertising.<sup>20</sup> The results are summarized in **Table 3**. Most patients (81%) were aware of ads and that the ads contained both benefit and risk information. The ads prompted 43% of respondents to look for more information about a drug or medical condition. Almost 89% sought the information from their physicians, about 51% from their pharmacists, about 40% from reference books and 38% from friends, relatives, and neighbors. The survey indicated that fewer people in 2002 (18%) asked their physician about previously untreated conditions than in 1999 (27%). In the 2002 survey, fewer consumers held positive views of DTC ads than they had in 1999.

The results of FDA's surveys showed that the proliferation of DTC advertising has led many patients to become aware of newly available medical treatments for certain health conditions, and that patients are motivated to ask better questions of the healthcare provider. Some pharmaceutical companies call their messages "educational" and claim that DTC ads encourage patients to seek medical advice for conditions that sometimes go untreated.<sup>21</sup> For example, urinary incontinence and erectile dysfunction advertising brought these two apparently under-diagnosed and under-treated conditions to consumer attention. As such, these ads can lead to better

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<sup>17</sup> The Federal Trade Commission regulates the advertising of all consumer products other than prescription drugs. U.S. Department of Justice and the Federal Trade Commission, *Improving Health Care: A Dose of Competition*, July 2004, p. 20, at [[http://www.usdoj.gov/atr/public/health\\_care/204694.htm](http://www.usdoj.gov/atr/public/health_care/204694.htm)].

<sup>18</sup> Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (New York, Random House, 2004).

<sup>19</sup> Ernst R. Berndt, "To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs," *New England Journal of Medicine*, vol. 352, no. 4 (Jan. 27, 2005), pp. 325-328.

<sup>20</sup> For the 1999 survey, the response rate out of 960 patients was 65%. For the 2002 survey, the response rate for 944 people was 53%.

<sup>21</sup> IMS Management Consulting [David Gascoigne], "DTC at the Crossroads: A 'Direct' Hit...or Miss?" *IMS Issues and Insights*, Sept. 23, 2004, p. 2.

patient-physician discussions, leading to, for example, life-style changes that could be beneficial to their health (e.g., losing weight), independent of new drug use.<sup>22</sup>

The patient survey data provided limited evidence of increased visits to physicians as a result of DTC advertising.<sup>23</sup> Most people reported that health reasons prompted their visits to physicians. DTC ads can improve patient compliance with physician advice, the surveys found, particularly if physicians remind patients to take the medication as prescribed. These ads also have spurred patients to seek information about a given disease from sources other than their physicians.

FDA's patient surveys also showed patients had some negative reactions to DTC advertising. Patients felt that the ads can overstate drug efficacy and do not present a balance of benefit and risk information. Patients gave only modest ratings to the information that was meant to provide a more complete picture of the drug product's risk. In the 2002 survey versus the 1999 survey, fewer found DTC ads useful in conversations with their physicians and with healthcare decision making.

However, some ads also may encourage consumers to believe a common health problem can easily be fixed by a prescription drug. In fact, FDA's Center for Drug Evaluation and Research (CDER) Director has discussed what she calls the "medicalizing of health" by saying that some believe, due to DTC advertising, that "all aches should be treated with some pill."<sup>24</sup> The concern is that some people who have managed a small health problem with over-the-counter medications, for instance, are now pressing physicians to provide prescription drugs. The process may expose some people to harmful side effects of drugs that may not necessarily be needed. Other findings are summarized in **Table 3**.

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<sup>22</sup> Wendy Borow, "The AMA Explains Its About-face on Direct-to-Consumer Advertising," *Medical and Marketing & Media*, Sept. 1993, p. 68-74.

<sup>23</sup> Kathryn J. Aikin, John L. Swasy, and Amie C. Braman, "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results," Final Report, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Nov. 19, 2004.

<sup>24</sup> Comments made by Janet Woodcock, Director of the Center for Drug Evaluation and Research, at a public meeting titled "Research on Consumer Directed Advertising," given by the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Sept. 22-23, 2003.

**Table 3. FDA Findings on Patients' Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs**

Category of information	1999 survey results <sup>a</sup>	2002 survey results
Visits to healthcare provider	Not asked.	4% of patients surveyed who had visited their doctor had done so because of an ad.
Generation of questions	About 33% of patients said DTC had generated questions for their physician; 33% said friends and family generated questions; and 20% reported reference books sparked questions.	
Expectations about receiving Rx	42% of patients expected a prescription at the most recent doctor's visit; of these, 63% expected a refill, 17% were sick, and 6% had seen a television ad and 5% had seen a magazine ad that kindled the expectation.	
Asking behaviors	32% of patients asked if any drug were available. Of these, 39% asked about a specific brand. Over 90% reported that their physicians welcomed questions.	
Prescribing response	50% of patients reported getting a prescription for drug asked about. 33% got a different drug and 41% were told to change behavior or diet. Patients who asked for a specific named drug were more likely to get a prescription for that drug than patients who did not ask about a specific drug.	
Patient opinions about DTC advertising	86% of patients agree that ads increase awareness of new drugs; 70% felt ads provide enough information to discuss with physician; 60% say ads do not provide enough risk information and 44% say ads lack benefit information.	77% of patients agree that ads increase awareness of new drugs; 58% felt ads provide enough information to decide whether to discuss with physician; 39% thought ads encourage patients to seek more information about potentially serious medical conditions. As in 1999, 60% say ads do not provide enough risk information and 44% say ads lack adequate benefit information.
Influence on relationship with healthcare provider	62% of patients felt ads led to better discussions with doctor; 7% of patients were reluctant to discuss advertised drug for fear of implying mistrust of doctor.	73% of patients agreed that ads do not minimize physicians' role in product decisions; 43% said ads helped in discussions with physicians; 10% of patients were reluctant to discuss advertised drug for fear of implying mistrust of the physician.
Overstatement of benefits	Not asked.	58% of patients said ads portray products as better than they are; 42% felt ads make it seem that the product would work for everyone.
Effects on own health	47% of patients felt ads help them make better health decisions. No other questions were asked.	32% of patients felt ads help them make better health decisions; 18% said ads reminded them to take medicines; 17% said ads caused anxiety about health.
General attitudes	52% of patients reported they liked seeing DTC ads.	32% of patients reported they liked seeing DTC ads.
Understanding the Brief Summary risk information	Not asked.	78% of those interested read all or most of the main ad; 45% of patients read most or all of the risk details in the Brief Summary when interested in the drug; 50% of those who read some of the Brief Summary said it was difficult to read.
Cost issues	40% of patient respondents never discuss the cost of drugs with their doctors; 16% discuss it frequently. Most likely to discuss cost with their physicians were female patients in poor health taking prescription drugs and lacking drug insurance.	

**Source:** Kathryn J. Aikin, John L. Swasy, and Amie C. Braman, “Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results,” Final Report, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Nov. 19, 2004.

- a. Where percentages stayed relatively the same in both the 1999 and 2002 surveys, results are presented as one.

Several other surveys added other perspectives to the issue. For example, a survey by the magazine *Prevention* found that even with the pervasiveness of DTC advertising in magazines and on television and with the tremendous increase in spending on DTC ads, patients’ requests of their physicians for or about advertised drugs has remained stable at about 8%. The author concludes that the ads “can’t overcome Americans’ desire to avoid taking prescription drugs.”<sup>25</sup> However, this survey also showed that about 7% of people surveyed asked for and received a prescription drug because of DTC advertising and 7% stopped taking a drug after seeing it advertised. It also established that a positive public health response to the advertising was that patients seek information about health conditions for themselves or for people in their care. This same survey states that “consumers are three times more likely to search for information about medicines family members or friends are already taking, than they are to ask their doctors for medicines for themselves.”<sup>26</sup>

Another study conducted by several Harvard professors found a portion of patients visits that were spurred by DTC ads were for clinically important conditions that resulted in a new diagnosis.<sup>27</sup> Their study did not detect widespread adverse effects of DTC ads on people’s health. This study also found that consumers can gain extra benefits not limited to the advertised drug because they get supplementary information about their health.

**Physician View.** Some physicians believe that DTC advertising serves as an effective tool for providing health information to consumers. Some believe that DTC advertising is one reason patients are visiting their doctors more, undergoing tests to catch health problems earlier, taking their medicines regularly, and getting more involved in their own treatment. However, some physicians mistrust DTC advertising because, in their opinion, the ads often promote a view of medicine that is misleading. Some say that the information presented in DTC ads obscures information about a drug’s risks.<sup>28</sup> Less expensive drugs can often work as well as

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<sup>25</sup> Ed Slaughter, Corporate Director, Advertising and Trends Research, Rodale, Inc., “Seventh Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines,” *Prevention Magazine*, 2004, p. 7.

<sup>26</sup> *Ibid.*, p. 60.

<sup>27</sup> Joel S. Weissman, David Blumenthal, Alvin J. Silk, Kinga Zapert, Michael Newman, and Robert Leitman, “Consumers’ Reports on the Health Effects of Direct-to-Consumer Drug Advertising,” *Health Affairs — Web Exclusive*, Feb. 26, 2003, p. W3-82 to W3-95.

<sup>28</sup> Council on Ethical and Judicial Affairs of the American Medical Association, “Direct-to-Consumer Advertisements of Prescription Drugs,” *Food and Drug Law Journal*, vol. 55, 2000, p. 121.

the advertised drugs,<sup>29</sup> and some claim that DTC advertising can give the false impression to consumers that prescription drugs are just like any other commercial product — soap, cars, cereal, snacks — and that patients only need a specific pill to fix whatever ails them.<sup>30</sup> This attitude, some say, could contribute to an unwillingness on the part of the patient to make needed lifestyle changes. DTC ads rarely, if ever, discuss non-drug forms of treatment.

In 2002, FDA questioned office-based physicians about the role of DTC in influencing their practices and relationships with their patients. **Table 4** summarizes the agency's presentation of the survey's findings. Out of a sample of 250 primary care physicians and 250 specialists chosen randomly from the American Medical Association (AMA) master file, 46% responded. Physicians, particularly primary care physicians, noted an increase in questions about prescription drug treatments with 85% saying patients asked often or all the time, and 62% reported patients asked frequently about generic drugs. They also described benefits and problems that arose. Most physicians reported being comfortable with denying medications particularly when the requested drug is not right for the patient. Ninety-three percent of physicians welcomed questions about specific drugs from patients, and between 74% and 77% of the doctors prescribed the requested drug when a specific drug was requested.<sup>31</sup>

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<sup>29</sup> National Institute for Health Care Management (NIHCM) Foundation. *Factors Affecting the Growth of Prescription Drug Expenditures*. Prepared by Barents Group LLC, July 9, 1999, p. 14.

<sup>30</sup> *Ibid.*, p. 7.

<sup>31</sup> Kathryn J. Aikin, John L. Swasy, and Amie C. Braman, "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results," Final Report, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Nov. 19, 2004.

**Table 4. FDA Findings in 2002 on Physicians' Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs**

Category of information	2002 survey responses
Benefits and problems of patient DTC exposure	41% of physicians thought exposure was beneficial, leading to better discussions, greater awareness of treatments, and that DTC was a source for informing patients. 18% said exposure led to problems such as misconceptions, requiring physician correction, requests for unnecessary drugs, and requests for one medication when another treatment was effective. 73% said patients asked thoughtful questions because of DTC exposure. 41% of physicians said patients were confused about drugs effectiveness because of the DTC ad.
Patient drug requesting behavior	The survey distinguished between patients asking if there were a drug to treat a specific problem and those asking for a specific drug. 86% of physicians recalled patients asking about a drug and 88% of them said that the patient had the condition the drug treats. 77% of primary care physicians prescribed the requested drug whereas 74% of specialists did.
Denial of requests	Most frequent reason given by physicians for denial was that the drug was not right for the patient and another drug was more appropriate. Primary care physicians denied prescriptions for a variety of reasons: because there was a less expensive drug available, no prescription was required, or patient could engage in behavioral or diet changes. Specialists declined prescriptions because a different drug was appropriate, a drug was not right for patient, or the drug had side effects unknown to the patient.
Pressure to prescribe	50% of physicians reported no pressure, and 91% reported a patient did not try to influence treatment that would have been harmful to patient. 22% of primary care physicians felt "somewhat" or "very pressured" to prescribe; 13% of specialists felt that way. 73% of primary care physicians reported patients came to the appointment expecting a prescription versus 63% of specialists. Primary care physicians were more likely to say this influenced their prescribing.
General opinions about patient understanding of DTC advertising	Physicians thought that 75% of patients understood that drugs are available only with a prescription, 82% knew that only a physician could make the decision about appropriateness, and 78% understood the drug's benefits. Between 40%-50% believed patients understood the risks and possible negative effects of drugs, 30% understood the limits of drug efficacy, and 25% were the type of person who should avoid drugs.
Opinions about problems	65% of physicians felt patients confuse the relative risks and benefits of DTC advertised drugs and 75% felt that ads led patients to overestimate the efficacy of the drugs. 38% believed DTC ads caused patients to question their diagnoses, and 28% said that ads led to tension in the doctor-patient relationship.



Category of information	2002 survey responses
Opinions about benefits	72% of the physicians think DTC ads increase awareness of possible treatments, 44% believe that ads facilitate earlier awareness of health conditions. About 33% think DTC ads increase the likelihood of proper medication usage, and 33% believe ads help patients maintain treatment.
Overall impressions of influence of DTC advertising on patients and practice	33% of physicians said that DTC ads had positive effect; 33% said ads had a negative effect; and 33% said the ads had no effect at all. 38% of primary care and 27% of specialists rated DTC advertising as having a somewhat or very negative effect on their patients and practice.

**Source:** Kathryn J. Aikin, John L. Swasy, and Amie C. Braman, "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results," Final Report, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Nov. 19, 2004.

**Industry View.** Drug companies rely on DTC advertising to stimulate demand and to increase sales for pharmaceuticals.<sup>32</sup> The drug industry claims that DTC ads have increased consumer awareness that all prescription drugs have risks and side effects; that non-drug approaches exist to improve health; and that advertisements remind and motivate consumers to comply better with drug therapy regimes.<sup>33</sup> According to the pharmaceutical industry, the increase in prescription drug use and spending appears to be the result of several different factors, and not necessarily attributable to DTC advertising: a significantly greater number of prescriptions being written for an aging population to restore and/or maintain health; a shift in prescriptions to newer higher cost drugs; new standards of medical practice encouraging greater use of drugs; more treatment of previously untreated patients; and a greater attention to preventing and managing disease resulting in net savings at times compared with spending in hospitals.<sup>34</sup> In addition, if more people take a specific drug or the same number of people are using the drug but more frequently (staying compliant), the total amount of what is spent on the drug will also increase.<sup>35</sup>

As discussed earlier, economists have stated that recent growth in DTC advertising has increased the demand for well-publicized drugs because, as people learn of alternative therapies, consumers may request newer, higher-priced drugs in

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<sup>32</sup> Glover, *Senate Commerce Committee Testimony*, 2001, p. 5.

<sup>33</sup> Testimony of Senior Assistant General Counsel Marjorie E. Powell, Pharmaceutical Research and Manufacturers of America before the U.S. Congress, Senate Special Committee on Aging, *Direct to Consumer Advertising: What are the Consequences?*, hearings, 108<sup>th</sup> Cong., 1<sup>st</sup> sess., July 22, 2003.

<sup>34</sup> *Ibid.*, pp. 11-12.

<sup>35</sup> Geoffrey F. Joyce, Jose J. Escarce, Matthew D. Solomon, and Dana P. Goldman, "Employer Drug Benefit Plans and Spending on Prescription Drugs," *JAMA*, vol. 288, no. 14 (Oct. 9, 2002), pp. 1733-1739. Increasing co-payments for prescription drugs and requiring mandatory generic substitution reduced overall drug spending among working age enrollees with employer-provided drug coverage.

place of less expensive ones, thereby increasing health care costs.<sup>36</sup> Whether that substitution is medically necessary is another issue. However, one physician testifying before the Senate Special Committee on Aging concluded that DTC advertising can drive the spending on pharmaceuticals but is responsible for only a small share of the total growth in spending on drugs, referring instead to other factors mentioned above.<sup>37</sup>

Studies sponsored by both industry and academic researchers suggest that the ads can lead to cost-effective treatments in some circumstances.<sup>38</sup> For example, many experts find that although “statin” drugs lower blood cholesterol levels and are relatively cost-effective as secondary prevention in persons with existing heart disease, they are much less cost-effective than primary prevention such as weight control and exercise.<sup>39</sup>

A spokesman for the pharmaceutical industry in testimony before Congress stated that medicines are the “most cost effective form of health care” because they can keep patients out of hospitals and nursing homes and avoid surgery.<sup>40</sup> He quoted a National Institutes of Health study which found that clot-busting drugs used to treat stroke patients save, on average, \$4,300 a year per patient by reducing the need for hospitalization, rehabilitation, and nursing-home care.<sup>41</sup> However, others, who have researched cost-effectiveness of pharmaceuticals, say that the question of whether drugs are cost effective “depends critically on the context in which the drug is used and the intervention to which it is being compared.”<sup>42</sup>

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<sup>36</sup> Stephen Heffler, Katherine Levit, Sheila Smith, Cynthia Smith, Cathy Cowan, Helen Lazenby, and Mark Freeland, “Health Spending Growth Up in 1999; Faster Growth Expected in the Future,” *Health Affairs*, vol. 20, no. 2 (Mar./Apr. 2001), p. 198.

<sup>37</sup> Testimony of Meredith B. Rosenthal in U.S. Congress, Senate Special Committee on Aging, *Direct to Consumer Advertising: What are the Consequences?* hearing, 108<sup>th</sup> Cong., 1<sup>st</sup> sess., July 22, 2003.

<sup>38</sup> Frank Lichtenberg, Benefits and Costs of Newer Drugs: An Update, *Working Paper 8996*. National Bureau of Economic Research, June 2002 at [<http://www.nber.org/papers/w8996>].

<sup>39</sup> Peter J. Neumann, Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman, “Are Pharmaceuticals Cost-Effective? A Review of the Evidence,” *Health Affairs*, vol. 19, no. 2 (Mar./Apr. 2000), pp. 97 and 99 (Hereafter cited as Neumann et al., “Are Pharmaceuticals Cost-Effective?”) Cited examples of successful interventions that produce health benefits for relatively little cost or save money for the health care system are: warfarin therapy to prevent stroke in patients with atrial fibrillation, immunosuppressive drugs for those with kidney transplants, and treatment with mood-altering drugs for some people with depression.

<sup>40</sup> Glover, *Senate Commerce Committee Testimony*, 2001

<sup>41</sup> S.C. Fagan, L.B. Morgenstern, A. Petitta, R.E. Ward, B.C. Tilley, J.R. Marler, S.R. Levine, J.P. Broderick, T.G. Kwiatkowski, M. Frankel, T.G. Brott, M.D. Walker, and the NINDS rt-PA Stroke Study Group, “Cost-Effectiveness of Tissue Plasminogen Activator for Acute Ischemic Stroke,” *Neurology*, vol. 50 (Apr. 1998), pp. 883-890.

<sup>42</sup> Neumann et al., “Are Pharmaceuticals Cost-Effective?” p. 104.

Other critics claim that there is no scientific evidence that DTC ads educate the public about illnesses or new medicines, or that they encourage physician visits. Rather, some observers, such as Arnold S. Relman, emeritus editor-in-chief of the *New England Journal of Medicine*, say that those assertions are made by salespeople whose sales have increased due to these ads.<sup>43</sup> One research group has looked at how consumers and physicians report DTC advertising's effect. It reported that patient visits to physicians promoted by DTC ads did not necessarily result in a prescription for the advertised drug.<sup>44</sup> The authors commented that consumers benefit when they visit physicians about a particular drug because many visits resulted in new diagnoses such as "high cholesterol, hypertension, diabetes, and depression, health conditions often underdiagnosed and undertreated in the general population."<sup>45</sup> The authors note, however, as did Dr. Relman in testimony before the Senate Special Committee on Aging, that these interview studies were not designed to determine whether ads were misleading, caused patients to receive more expensive drugs than necessary, or increased the cost of health care. Neither could these studies determine whether other sources of public information could achieve the educational benefits of DTC at lower cost.

## **FDA's Existing Authority to Regulate DTC Advertising**

The following sections describe the statutory basis for current regulation of DTC advertisements, recent FDA actions and funding.

### **Federal Food, Drug, and Cosmetic Act (FFDCA)**

The FFDCA sets forth the statutory requirements that pharmaceuticals must meet before they can be approved for marketing in the United States. Since 1938, Section 201 of the Act gives the FDA broad authority to consider drugs misbranded if their labeling or advertising is false or misleading in any way. At the time, advertising was primarily printed material directed towards physicians. In 1962, Congress added Section 502(n) to the Act, to give the FDA the authority to regulate prescription drug promotional labeling and advertising, including DTC advertisements.<sup>46</sup> In the same section, Congress prohibited FDA from issuing any regulations that would require prior approval of the content of any advertisement.

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<sup>43</sup> Testimony of Arnold S. Relman, in U.S. Congress, Senate Special Committee on Aging, *Direct to Consumer Advertising: What Are the Consequences?* hearing, 108<sup>th</sup> Cong., 1<sup>st</sup> sess., July 22, 2003.

<sup>44</sup> Joel S. Weissman, David Blumenthal, Alvin J. Silk, Michael Newman, Kinga Zapert, Robert Leitman, and Sandra Feibelmann, "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs — Web Exclusive*, Apr. 28, 2004, p. W4-226.

<sup>45</sup> Joel S. Weissman, David Blumenthal, Alvin J. Silk, Kinga Zapert, Michael Newman, and Robert Leitman, "Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising," *Health Affairs — Web Exclusive*, Feb. 26, 2003, pp. W3-82 to W3-95.

<sup>46</sup> 21 U.S.C. § 502 (n).

## Regulations

In 1969, FDA issued final regulations governing drug advertising at 21 C.F.R. § 202.1.<sup>47</sup> Under these regulations, advertisements must have four basic attributes: (1) they cannot be false or misleading; (2) they must present a “fair balance” of information about the risks and benefits of using the drug; (3) they must contain “facts” that are “material” to the product’s advertised uses; and (4) in general, the advertisement’s “brief summary” of the drug must include every risk from the

product’s approved labeling. The regulations require that companies submit promotional materials to FDA at the same time they make them available to the public.<sup>48</sup> The promotion within these materials must be supported by scientific evidence and be consistent with FDA-approved product labeling. The ads can be the approved labeling or other promotional materials, but must not recommend or suggest any use of a drug that is not listed in the approved drug’s labeling. (See text box.) Only uses approved by FDA can be listed on the label or in advertising.

### Differences between labeling and advertising

FDA considers promotional material and advertising to be different from approved product labeling. FDA must approve the wording of a drug’s approved product labeling before the product can be marketed. Labeling generally includes the drug’s known significant side effects (both those serious and those not serious but frequently occurring). It uses technical language since the information it conveys is mostly targeted at health care professionals. While FDA does have authority for approving labeling, it does not, as noted, have authority to require the *pre-approval* of any promotional materials or advertising, including DTC advertising.

## FDA Use of Current Authority

Monitoring compliance and enforcement of DTC advertising regulations is the responsibility of FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC), a division within the Center for Drug Evaluation and Research. Most drug manufacturers voluntarily submit draft materials to FDA for review and comment prior to some of their ads being aired on TV and radio.<sup>49</sup> In fact, some drug manufacturers ask for comments at all stages of their broadcast ad’s preparation. The agency pays particular attention to final broadcast videotapes

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<sup>47</sup> Jane E. Henney, “Challenges in Regulating Direct-to-Consumer Advertising,” *MSJAMA Report*, vol. 284 (Nov. 1, 2000), p. 2242.

<sup>48</sup> 21 C.F.R. § 314.81(b)(3)(i) states: “The applicant shall submit specimens of mailing pieces and any other labeling at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product.”

<sup>49</sup> See 21 C.F.R. § 314.81(b)(3)(i). According to an FDA official, pharmaceutical companies often voluntarily ask for agency comments on their proposed ads to ensure that, prior to airing, the ads will meet FDA’s requirements, because of the expense of these ads. If it needs to, the agency can take enforcement actions but only after an ad is made public.

because these ads can make or imply inappropriate claims just by their non-verbal and visual presentations.

## Guidance for Broadcast Ads

With respect to TV and radio ads, until 1997, it was unclear how to comply with the law for, if a product-claim print advertisement mentioned the name of the prescription drug and its intended medical indications, it had to include **all** the information about side effects, contraindications, and precautions from the product's approved labeling.<sup>50</sup> For the most part, conveying all of a product's risk information in print advertising is not difficult. However, because commercial broadcast advertisements are often of limited length (30 to 60 seconds), to include this kind of detailed information in television and/or radio advertising was thought by the drug industry to be too cumbersome and expensive.<sup>51</sup> Although the regulations allowed for an alternative to presenting every risk in a broadcast advertisement, prior to 1997, FDA had not issued any interpretation of how broadcast advertisements could fulfill the "adequate provision" regulation which is an alternative to presenting all the risk information in the brief summary.<sup>52</sup> The industry reportedly assumed that FDA expected broadcast DTC advertising to meet the same requirements as ads in print.<sup>53</sup>

In August 1997, FDA issued draft guidance on how pharmaceutical companies fulfill the existing regulatory requirements for advertising prescription drugs on radio and television. The draft guidance was finalized, without major change, in August 1999.<sup>54</sup> The guidance provided that DTC broadcast advertisements had to include the advertised product's most important risks (called a "major statement" by FDA). The major statement was required to be in the audio portion of the advertisement, but could be in the video portion as well. The agency explained that the regulations had always allowed for broadcast advertisements to **either** include all the drug's risks **or** ensure that consumers would have "adequate provision" of an advertised product's approved labeling. The guidance provides one way to ensure that consumers with different information-seeking needs and capabilities have adequate access to the product labeling by disclosing four different sources of this information. These sources,<sup>55</sup> which were to be broadly disseminated to the general public, must include:

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<sup>50</sup> See [<http://www.fda.gov/cder/guidance/index.htm>].

<sup>51</sup> Pharmaceutical Research and Manufacturers Association, *Direct-to-Consumer Advertising: Backgrounders and Facts* (2000).

<sup>52</sup> 21 C.F.R. § 202.1(e)1.

<sup>53</sup> Wayne L. Pines, "A History and Perspective on Direct-to-Consumer Promotion," *Food and Drug Law Journal*, vol. 54, no. 4 (1999), pp. 489-518.

<sup>54</sup> The only significant change in the final guidance was the clarification of FDA's thinking that its guidance on broadcast DTC advertising could also be used for telephone advertisements. 64 *Federal Register* 43197 (Aug. 9, 1999), at [<http://www.fda.gov/cder/guidance/1804fnl.pdf>].

<sup>55</sup> FDA, Center for Drug Evaluation and Research, Intra-Agency Group on Advertising and Promotion. *Questions and Answers on the Consumer-Directed Broadcast Advertisements Guidance*, June 8, 2000, [<http://www.fda.gov/cder/guidance/1804q&a.htm>].

Internet sites,<sup>56</sup> toll-free telephone numbers, referral to health care providers, and other print sources with large circulations.<sup>57</sup>

## Draft Guidance for Print Ads

In January 2004, FDA issued three draft guidances: *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (brief summary guidance), *“Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* (disease awareness guidance), and a third on medical device advertising (which will not be discussed here).<sup>58</sup> All the guidances attempt to improve the information that consumers and health care practitioners receive in advertising about prescription drugs and devices. They also require drug and medical device firms to disseminate truthful, non-misleading, scientifically accurate information on medical products and health conditions to consumers and health care practitioners.

**Brief Summary Guidance.** FDA requires that any prescription drug advertisement contain “information in brief summary relating to the side effects, contraindications, and effectiveness” of the drug.<sup>59</sup> The information on the risks of the product (known as the brief summary) must disclose all the risk-related information in the drug’s package labeling. So ads in print often include the entire section of the approved professional labeling with its side-effects and warnings. FDA has been concerned that the technical language and volume of material presented discourage consumers from using the information. The agency has now proposed in its 2004 draft guidance<sup>60</sup> that manufacturers choose among three options (other than printing the entire professional labeling) to satisfy the brief summary requirement for DTC print ads. All would require that the manufacturer print all contraindications; all warnings; the major precautions, including any that describe serious adverse drug experiences or steps to be taken to avoid such experiences; and the three to five most common nonserious adverse reactions most likely to affect the patient’s quality of life or compliance with drug therapy.<sup>61</sup> What would vary is how the manufacturer could present that information. The first option would be to reprint

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<sup>56</sup> Alex Frangos, Special Report: E-Commerce; Prescription for Change, *Wall Street Journal*, Apr. 23, 2001. Web-based sites, whether third-party or proprietary, usually contain a link to a site that advertises one company’s product. Experts suggest that the line between information and promotion has been blurred.

<sup>57</sup> 64 *Federal Register* 43197 (Aug. 9, 1999); see also Council on Ethical and Judicial Affairs of the American Medical Association, “Direct-to-Consumer Advertisements of Prescription Drugs,” *Food and Drug Law Journal*, vol. 55 (2000), p. 120.

<sup>58</sup> Draft Device Broadcast Advertising Guidance would apply the same, less burdensome, brief summary requirement to DTC broadcast ads for restricted medical devices.

<sup>59</sup> 21 U.S.C. § 352(n).

<sup>60</sup> FDA, “[DRAFT] Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, Division of Drug Marketing, Advertising, and Communications,” CDER, Jan. 2004, at [<http://www.fda.gov/cder/guidance/5669dft.pdf>].

<sup>61</sup> *Ibid.*

the FDA-approved *patient* labeling in full.<sup>62</sup> For the second option, the manufacturer could print a portion of the patient labeling, including the risk information but omitting, for example, directions for use. The third option relates to a proposed “highlights” section of the professional labeling.<sup>63</sup> But because this highlights section would be written for medical professionals, FDA recommends in the brief summary guidance draft that it be rewritten to be understandable to consumers.

The agency has asked drug firms to consider the costs and benefits of each of these options and decide which option is best. Supporters say that less type and lower information volume will mean lower advertising costs, and consumer oriented risk information will mean that the information is more useful. Critics argue that this approach may be appropriate for only a small subset of products. They also argue that FDA should be going further in developing guidelines for the kind of risk disclosures that actually allow patients to use them as a basis for further discussion with a health professional.<sup>64</sup> After reviewing the three January 2004 draft guidance documents at FDA’s request, Federal Trade Commission staff agreed that presenting risk information in more accessible language would be better than reprinting the brief summary. The FTC report recommended, however, that FDA conduct consumer research to assess the various types of risk presentation, the influence on industry’s advertising incentives, and other costs and benefits of the proposed formats and others to “determine ... the most effective means of providing drug risk information in DTC print ads.”<sup>65</sup>

**Disease-Awareness Guidance.** The agency clarifies in this guidance when it does and does not have jurisdiction over help-seeking ads that encourage consumers to seek treatment for a medical condition.<sup>66</sup> The draft “Disease

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<sup>62</sup> This could be the Patient Package Insert (PPI), special patient materials that FDA approves that are used to instruct patients about the safe use of the prescription product in simple, easily understood language. These materials may be given to patients by their health care provider or pharmacist and are part of FDA-regulated product labeling. They are based on the approved labeling of the drug.

<sup>63</sup> FDA, “[DRAFT] Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics,” May 2000, at [<http://www.fda.gov/cder/guidance/1888dft.pdf>].

<sup>64</sup> Rosemary C. Harold and John F. Kamp, “Grounding Regulations in Behavior Science: Strengthening FDA’s Approach to DTC Risk Disclosures,” *Update, Food and Drug Law, Regulation, and Education*, no. 6 (Nov./Dec. 2004), pp. 8-12.

<sup>65</sup> Federal Trade Commission, “In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion,” Docket No. 2004D-0042, May 10, 2004, at [<http://www.ftc.gov/os/2004/05/040512dtdrugscomment.pdf>]; and FTC, “FTC Staff Provides Comments to FDA on Direct-to-Consumer Drug and Device Ads,” *FTC: For the Consumer*, May 12, 2004, at [<http://www.ftc.gov/opa/2004/05/dtdrugs.htm>].

<sup>66</sup> The Federal Trade Commission has jurisdiction over these types of communications and could investigate and challenge ads if they appeared to be “unfair or deceptive acts or practices” (15 U.S.C. § 45, in general; 15 U.S.C. § 52, specific application to drugs and devices).

Awareness Guidance”<sup>67</sup> provides recommendations on how to make these ads perceptually distinctive from product advertising. Both FDA and FTC officials are watchful when marketers of the only product in a therapeutic category have a commercial interest in funding a disease awareness ad.<sup>68</sup>

## FDA’s Enforcement Activities

While the law and regulations do not give FDA prior approval authority for prescription drug advertising, the law does give FDA authority to review the accuracy of claims in a prescription drug’s promotion. In 2003, FDA received approximately 38,000 ads (known as submissions to the agency) from drug sponsors.<sup>69</sup> These submissions include all types of promotional materials, both broadcast and print advertisements, and promotional labeling for new products, directed at all audiences including consumers and health care professionals. In 2003, the agency reviewed 161 broadcast and 221 print DTC ads that had been voluntarily submitted by the manufacturers to the agency for review prior to release to the public. These voluntary submissions give FDA an opportunity to object to ads that either omit or minimize risks, promote unapproved uses of the drug or make unsubstantiated claims about how effective and safe the drugs are or how effective the advertised drugs are relative to competitive products.<sup>70</sup> In addition, the agency has found that some ads obscure the warning information that is required.

If the FDA feels that an advertisement for a drug that is before the public does not contain the required information or is false or misleading, it can respond through a variety of enforcement actions.<sup>71</sup> In most cases, the agency asks the company to withdraw voluntarily the violative ad. It can send a letter to the company (called an “untitled letter” by the agency) warning that the advertisement violates the FFDCA. Often, the letter states that the ad is “misleading” because it overstates or guarantees the product’s effectiveness, expands the population approved for treatment, or minimizes the risks of the product. The letter asks that the ad be stopped immediately. Another letter that FDA can send is a “Warning Letter” directed at more serious violations.

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<sup>67</sup> Food and Drug Administration, “Draft Guidance for Industry: ‘Help-Seeking’ and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms,” Jan. 2004, available at [<http://www.fda.gov/cder/guidance/6019dft.doc>].

<sup>68</sup> “Disease Awareness Ad Guidance Stresses Need for ‘Distinct’ Messages,” *The Pink Sheet*, [F-D-C Reports, Inc., Chevy Chase, MD], Feb. 9, 2004, p. 6.

<sup>69</sup> The total submission number was split between 32,000 pieces of promotional materials directed to health care professionals (such as pens, pins, and labeling) and 6,000 pieces of promotional material directed at consumers such as booklets, brochures and videos (author’s conversation with FDA officials).

<sup>70</sup> Thomas W. Abrams, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration, “DDMAC Update-Regulation of Prescription Drug Promotion,” Feb. 26, 2004. Slide presentation found at [<http://www.fda.gov/cder/ddmac/Presentations/DIA/DIA%20022604%20Slides.ppt>].

<sup>71</sup> Between 1999 and April 2002, FDA reviewed the content of 706 broadcast advertisements for 76 different pharmaceuticals. Forty-six broadcast ads, about 6.5%, warranted some type of regulatory notice.



In 2004, the agency sent 23 letters concerning violative promotional labeling, broadcast ads, or print ads that did not comply with regulations. In one case, on December 21, 2004, FDA issued an “untitled letter” stating that a “patient safety” print ad made false or misleading safety claims that minimize the risks associated with Crestor (See text box).<sup>72</sup> The company had placed that ad in several newspapers defending its brand drug in response to recent congressional testimony from an FDA safety official who had named Crestor among five marketed drugs that, he said, present significant safety risks.<sup>73</sup>

#### A Recent “Untitled Letter”

On December 21, 2004, FDA sent an “untitled letter” to AstraZeneca stating that the firm’s ads run in large national papers on November 23 and 24, 2004 made “false and misleading safety claims that minimize the risks associated with Crestor.” FDA claimed that the ad suggests that Crestor is safer than was demonstrated by substantial evidence and clinical experience. The letter stated that the company had agreed to a risk management plan whereby patients in three clinical trials taking a 40 mg dose of Crestor would be given regular renal monitoring. The 40 mg dose was also to be given only to patients with severe hypercholesterolemia who did not respond to other treatments. According to FDA’s letter, the ad headlined the sentence, “*You can be assured that at AstraZeneca, patient safety is our number one priority.*” The untitled letter also said that it appeared to the agency that the Company was seeking to assure readers that Crestor is “*more effective and just as safe as the leading medications in its class.*” [emphasis added] The untitled letter stated that FDA is not aware of evidence or experience demonstrating that all doses of Crestor are “just as safe” as other statins. Similarly, FDA expressed concern about the section of the ad that stated: “*The FDA has confidence in the safety and efficacy of CRESTOR. ... The scientists at the FDA who are responsible for the approval and ongoing review of CRESTOR have, as recently as last Friday, publicly confirmed that CRESTOR is safe and effective; and that the concerns that have been raised have no medical or scientific basis.*” FDA states that the ad misleadingly suggests that the Agency does not believe that Crestor poses safety concerns. For this claim, the AstraZeneca ad cites “*www.fda.gov accessed on 11/19/04.*” In its letter, FDA notes that there is no statement on the website by FDA concluding that the concerns about Crestor have no medical or scientific basis. The letter further states that recent reported statements made by the Agency contradict that conclusion, referring to an article entitled “Campaign Waged Against Crestor” appearing the previous week (on November 18, 2004) in the *Washington Post*. In describing the safety concerns raised by the consumer advocacy group Public Citizen about Crestor, the article quotes Dr. Steven Galson, Acting Director of the FDA’s Center for Drug Evaluation and Research, as saying: “[the Agency] has been very concerned about Crestor since the day it was approved, and we’ve been watching it very carefully” and that the Agency is “concerned about the same issues with Crestor as Public Citizen.” FDA’s December 21, 2004 untitled letter therefore requested AstraZeneca to immediately cease the dissemination of violative promotional materials for Crestor. The FDA sent another untitled letter to AstraZeneca on March 8, 2005 concerning another Crestor ad. In both letters, FDA requested that the company’s reply, due in 10 business days, include its plan for discontinuing use of such materials.

**Source:** See [<http://www.fda.gov/cder/warn/warn2004.htm>] and [<http://www.fda.gov/cder/warn/warn2005.htm>].

<sup>72</sup> 21 U.S.C. § 352n; 21 C.F.R. §202.1(e)(6)(i).

<sup>73</sup> U.S. Congress, Senate Committee on Finance, *FDA, Merck and Vioxx: Putting Patient Safety First?*, hearing, 108<sup>th</sup> Cong., 2<sup>nd</sup> sess., Nov. 18, 2004, available at [<http://finance.senate.gov/sitepages/hearing111804.htm>].

Of the 23, 12 were actual Warning Letters for violative broadcast ads concerning print materials that did not comply with the regulations.<sup>74</sup> Warning Letters state that, in addition to stopping the violative activity, the company must take corrective steps by disseminating corrective information to the audience of the violative promotional materials such as physicians, pharmacists, and patients. At times, companies must run ads in the same media to correct the misleading impressions. Usually, the companies respond immediately to the Letter.

If Warning Letters fail to rectify the situation, FDA can work with the Department of Justice to seek injunctions against companies, or criminally prosecute firms, or FDA can seize products deemed to be misbranded by intentional and/or serious misstatements, or can withdraw the drug's approval. For example, in 1995, a prominent company pleaded guilty to having promoted its acne treatment drug for use in treating sun-wrinkled or "photoaged" skin. The company paid a \$5 million fine and \$2.5 million for the costs of the investigation. In fact, however, very few cases have been brought to court for resolution.

The agency has had its authority to regulate DTC advertisements and other forms of prescription drug promotion examined in the courts. The rulings emphasized that the agency should not impose unnecessary restrictions on "commercial speech."<sup>75</sup> In reaction to these decisions, on May 16, 2002, FDA published in the *Federal Register* a notice requesting comment by July 30, 2002, on "commercial speech" issues under the First Amendment.<sup>76</sup> In the notice, FDA mentions an unfavorable court decision on its regulation of commercial speech.<sup>77</sup> The finding led the agency to question whether it continues to have legal credibility to sustain its authority to carry out its public health duties, and, in addition, whether its position on promotional speech about prescription drugs is valid.<sup>78</sup> The notice solicited public comments about FDA's legal basis for its regulations, guidances,

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<sup>74</sup> See [<http://www.fda.gov/cder/warn/warn2004.htm>].

<sup>75</sup> George W. Evans and Arnold I. Friede, "The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis," *Food and Drug Law Journal*, vol. 58, no. 3 (2003), pp. 365-437.

<sup>76</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Request for Comment on First Amendment Issues. 67 *Federal Register* 34942 (May 16, 2002). See CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

<sup>77</sup> *Thompson v. Western States Medical Center*, 535 U.S. 357 (April 29, 2002). In this case, the Supreme Court struck down a pharmacy-compounding provision in the FDA Modernization Act (FDAMA). Pharmacy compounding involves a pharmacist mixing a slightly altered version of a drug for an individual, such as removing a preservative for a patient who is allergic to that preservative. The FDAMA provision said that a drug could be compounded only if the physician or pharmacist does not advertise or promote the compounding of a particular drug, class, or type of drug. The Supreme Court ruled that the provision's advertising restrictions violate the First Amendment to the Constitution. *FDA Week*, June 21, 2002.

<sup>78</sup> "FDA Seeks Comment on Ad Regs: Can Rx Be More Regulated Than OTCs?" *The Pink Sheet*, vol. 64, no. 20 (May 20, 2002), p. 14.

policies, and practices to ensure the agency continues to comply with the law. It reads:

Is FDA's current position regarding direct-to-consumer and other advertisements consistent with empirical research on the effects of those advertisements, as well as with relevant legal authority? What are the positive and negative effects, if any, of industry's promotion of prescription drugs ...? Does the current regulatory approach and its implementation by industry lead to over-prescription of drugs? Do they increase physician visits or patient compliance with medication regimes? Do they cause patient visits that lead to treatment for under-diagnosed diseases? Does FDA's current approach and its implementation by industry lead to adequate treatment for under-diagnosed diseases? Do they lead to adequate patient understanding of the potential risks associated with use of drugs? Does FDA's current approach and its implementation by industry create any impediments to the ability of doctors to give optimal medical advice or prescribe optimal treatment?<sup>79</sup>

FDA extended the deadline for comments but has not published any formal response. In another section of the notice, FDA asked whether it should distinguish between labels and advertisements in the regulation of commercial speech and whether both should be subject to the same degree of regulation as they are currently.

The General Accounting Office (GAO — now called the Government Accountability Office) found in 2002 that FDA's oversight of DTC advertising is generally effective at halting the dissemination of ads that it reviews and identifies as misleading. However, GAO also stated that FDA's oversight has limitations in two areas. The agency cannot verify that it receives all newly disseminated ads from drug companies, nor does the agency have the ability to quickly issue regulatory letters after an violation is identified. FDA/DDMAC used to issue letters a few days after determining an ad was violative but because of a policy switch all letters must now go through FDA's Office of the Chief Counsel where the letters are reviewed for legal sufficiency and consistency with agency policy. This review can take between 13 and 78 days according to GAO.<sup>80</sup> According to FDA officials, DDMAC and the Office of Chief Counsel have now streamlined this process to five days for warning letters and 15 days for untitled letters.<sup>81</sup>

In addition, in his last speech as the outgoing Chief Counsel of FDA, Daniel Troy, in November 2004, claimed that the courts had reaffirmed the authority of FDA to regulate commercial free speech under the First Amendment with regard to DTC advertising. In the fall of 2004, he established an inter-center coordinating group to develop guidance documents that will bring transparency to FDA's regulation of

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<sup>79</sup> Food and Drug Administration, "Request for Comment on First Amendment Issues," 67 *Federal Register* 34943(May 16, 2002).

<sup>80</sup> U.S. General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177, Oct. 2002.

<sup>81</sup> "FDA Chief Counsel Warning Letter Review to Continue After Troy's Departure," *The Pink Sheet*, Nov. 22, 2004, p. 14.

promotional communication, and establish common standards for regulating commercial communications across all FDA's product areas.<sup>82</sup>

## Funding

Two offices within FDA handle the bulk of review and enforcement activities regarding drug promotion: the Division of Drug Marketing, Advertising, and Communications (DDMAC), and the Office of Drug Safety (ODS), both units within the Center for Drug Evaluation and Research (CDER). **Table 5** gives the total resources for DDMAC and for the review of DTC advertisements. It also shows that the resources used for review of DTC advertisements decreased not only as a percentage of the total division resources, but also in actual dollars between FY2003, and FY2005.

**Table 5. Appropriations for CDER's Division of Drug Marketing, Advertising, and Communications FY2003, FY2004 (actual), FY2005 (projected), and FY2006 (requested)**

	FY2003 (actual)	FY2004 (actual)	FY2005 (projected)	FY2006 (requested)
Total appropriation for Division of Drug Marketing, Advertising, and Communications (DDMAC)	\$4,167,242	\$3,615,357	\$3,870,979	\$4,255,979
Appropriation for the review of DTC advertisements	\$1,069,605	\$755,880	\$806,525	\$883,525
Percentage of DTC review appropriations as a percentage of DDMAC total appropriation	25.7%	20.9%	20.8%	20.8%

**Source:** FDA, Office of Budget and Program Analysis, Budget Formulation and Presentation Division.

Another source of funds for regulating DTC advertising could be fees collected under the Prescription Drug User Fee Act (PDUFA).<sup>83</sup> When the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) was enacted, it reauthorized PDUFA (known as PDUFA III) and *authorized* added funds for the DDMAC: an increase of \$2.5 million for FY2003, \$4 million for FY2004, \$5.5 million for FY2005, \$7.5 million for FY2006, and \$7.5 million for

<sup>82</sup> Ibid.

<sup>83</sup> The initial authorization in 1992 restricted FDA's use of PDUFA user fees to new drug reviews. PDUFA III, enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act [P.L. 107-188], expanded that authority to drug safety activities.

FY2007. The funds were to be used to hire additional staff to monitor broadcast and Internet ads more vigilantly to ensure that the messages conveyed do not mislead consumers. The authorization reflected Congress' general concern over drug safety.<sup>84</sup> However, these sums were not appropriated in FY2003, FY2004 or FY2005, nor were they requested for FY2006.

In the reauthorization process for PDUFA III, FDA committed to doubling (to almost 100) the number of staff assigned to monitor the side effects of drugs already on the market. Some of these new hires in FDA's Office of Drug Safety (ODS) will be used to increase agency efforts to provide consumers with the latest information about newly approved drugs.<sup>85</sup> **Table 6** gives the appropriations for ODS since FY1999. As is clear from the numbers, the infusion of PDUFA funding has allowed more reviewers to consider post-market issues.

**Table 6. Funding for the CDER's Office of Drug Safety and Full-Time Equivalent (FTE) Positions**  
(millions of dollars)

Fiscal years	Budget authority	PDUFA (user fees)	Total	FTEs
FY1999	\$10.8	N/A <sup>a</sup>	\$10.8	60
FY2000	\$17.2	N/A	\$17.2	69
FY2001	\$13.5	N/A	\$13.5	76
FY2002	\$15.4	N/A	\$15.4	77
FY2003	\$13.4	\$6.8	\$20.2	90
FY2004	\$15.8	\$8.0	\$23.8	94
FY2005 est.	\$17.9	\$9.0	\$26.9	109
FY2006 req.	\$22.9	\$10.5	\$33.4	134

**Source:** Food and Drug Administration, Office of Budget and Program Analysis, Budget Formulation and Presentation Division. The additional 25 new requested FTE's for FY2006 came from comments of FDA's Chief Financial Officer Kathleen Heuer as reported in *Medicine & Health*, vol. 59, no. 8, Feb. 28, 2005.

a. PDUFA funds were not available until FY2003.

Critics contend that the reliance on PDUFA funding for employees has created a "cozy relationship" between the agency and drugmakers that has led to less scrutiny

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<sup>84</sup> See CRS Report RL31263, *Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law*, by C. Stephen Redhead, Donna Vogt, and Mary Tiemann.

<sup>85</sup> See CRS Report RL31453, *The Prescription Drug User Fee Act: Structure and Reauthorization Issues*, by Donna Vogt and Blanchard Randall IV.

of ads and other activities. Agency officials and industry spokesmen say that the user fee funding has not led to a lessening of agency objectivity.<sup>86</sup>

## Legislative Issues

All pharmaceuticals carry some risks to humans. Human drugs, by their definition, are intended to affect the structure or function of the body of man and are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.<sup>87</sup> At issue in recent congressional hearings is concern that the known risks from certain drugs have not been made public nor have risks been systematically evaluated. Some say that DTC ads have, in their presentation, minimized the risks as portrayed in the ads. In addition, there are unanswered questions regarding the relative contribution of DTC advertising of prescription drugs to health and health care generally. Congress in its oversight role is looking at what FDA can do under current legislative authority and what more authority FDA may need to meet new challenges.

## Risk and Health Information

One concern before Congress is whether physicians are receiving appropriate risk information to allow them to convey these risks to patients. Some believe that not only does the risk information need to be more systematically collected and released so health decisions can be made carefully, but also that more care needs to be taken with DTC advertising exposure. Adverse reactions to drugs, and negative interactions of one drug with another, often surface after the drug is used widely in patient populations. One critic, commenting on the DTC marketing of the COX-2 class of anti-inflammatory drugs, stated:

These drugs were mass-marketed from the moment they were commercially available in the new world of direct-to-consumer advertising, with unrealistic expectations about pain relief, marked gastrointestinal protection, and safety. Rather than a sufficient waiting period after approval to firmly establish safety in the large, representative “real world” population, the unbridled promotion exacerbated the public health problem. This is so poignantly clear for an indication such as arthritis, which is one of the most common conditions requiring medication.<sup>88</sup>

Yet, DTC advertising has brought benefits to patients. As noted above, survey information suggests that the increase in the number of DTC ads influences the way patients find out about certain health conditions. They are also a source of information about treatment options, benefits, and risks. It has been argued that DTC advertisements have educated patients and led them to take more responsibility for

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<sup>86</sup> “User fees debated as potential source of drug safety problems,” *FDAnews Drug Daily Bulletin*, vol. 1, no. 246 (Dec. 29, 2004). See [fdanews@enewsletters.fdanews.com].

<sup>87</sup> 21 U.S.C. § 321(g)(1)

<sup>88</sup> Eric J. Topol [editorial], “Arthritis Medicines and Cardiovascular Events — ‘House of Coxibs’,” *JAMA*, vol. 293, no. 3 (2005), 366 ff.

their health care, visiting their physicians more regularly so that certain health conditions are caught early, preventing more costly treatments later.

Critics, however, question the educational component of DTC advertisements and have suggested that creating greater access to post-marketing surveillance or clinical trial data, rather than just the information gained through submitted DTC ads, could provide patients with a different source of information about the adverse effects sometimes associated with new products.<sup>89</sup> If this information were collected by non-industry, independent sources, or even by FDA, and made available to the public through the Internet, and possibly also made accessible through local pharmacies, it could be used to counter any misinformation or omissions contained in DTC advertising.

### **Activity Under Current Authority**

One question is whether FDA is doing enough with its current authority to protect consumers from potentially misleading advertisements. Suggested activities involve FDA review of ad content; FDA-sponsored consumer education; and FDA enforcement of DTC advertising guidelines. While none of these may require legislative action to increase FDA's authority, their successful implementation could require additional resources.

**Pre- and Post-Publication Review.** One area of questioning involves the timing and the extent of FDA's review of DTC advertisements for accuracy and balance. As noted above, the law explicitly prohibits FDA from requiring pre-publication review and approval of ads. However, some manufacturers voluntarily choose to submit proposed ads to FDA prior to their release to the public to avoid the expense of pulling an already launched ad campaign.<sup>90</sup> All manufacturers, however, must submit to the agency (with Form 2253) the final ad in whatever form it was disseminated to the public. The agency believes that there is no problem currently with this voluntary pre-review and after-the-fact system for regulating DTC advertising. It claims that most of its reviews are timely, and the current statute does not give FDA the authority to do more than it is doing.<sup>91</sup> Agency officials do say that close monitoring of visual elements of advertisements is, at times, necessary because some visuals can mislead consumers about the benefits of a drug despite the apparently balanced audio presentations about risks. Absent any legislative change, the FDA currently has the statutory authority to impose requirements on the content of advertisements to ensure that ads provide accurate and unbiased information.

**FDA-Mounted Consumer Education.** Rather than leaving dissemination of information about new medications to DTC advertisers, the agency could sponsor public education campaigns to explain the risks and benefits of various types of

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<sup>89</sup> "Panel Backs Interactions Database, CERTs, Adverse-Event Repository," *FDA Week*, vol. 8, no. 24 (June 14, 2002), pp. 8-9.

<sup>90</sup> As noted above (p. 20) in 2003, FDA reviewed 161 broadcast and 221 print DTC ads prior to release to the public.

<sup>91</sup> Telephone conversation with FDA DDMAC official, Mar. 11, 2005.

classes of drugs, the role of promotional materials, and the need for patients to talk to their physicians. FDA could also ensure that any new information with respect to a particular drug or class of drugs would be widely disseminated particularly if the new information involved adverse events or new contraindications. FDA could also study whether consumers understand the risk and benefit information presented by ads or whether the information (such as Patient Medication Guides) about the risks and benefits received by the patient with each new prescription used. Nonetheless, the agency cannot guarantee how patients will use the added information. The FDA advisory committees that met in February 2005 to assess the safety of Vioxx and other COX-2 inhibitors discussed how FDA might act if its enforcement system of “untitled” and “warning” letters did not inhibit biased industry advertisements. They considered whether FDA itself might create drug information to counter the “biased” or “unbalanced” pictures the manufacturers present in DTC ads and to provide patients with medication guides outlining the risks of particular drugs.<sup>92</sup>

Recently, FDA announced it would create a website, called DrugWatch. In conjunction with a new Drug Safety Oversight Board (DSB) to oversee the management of drug safety issues, FDA intends to improve the information on possible side effects or other safety risks reaching patients and health providers.<sup>93</sup>

**Increase in FDA-Industry Collaboration.** Congress could also look at the experience of New Zealand which permits advertising for prescription, non-prescription and complementary medicines, medical services, medical devices, and health claims on food. All ads making therapeutic claims for these products must be pre-approved by the Association of New Zealand Advertisers, Therapeutic Advertising Pre-vetting Service.<sup>94</sup> Its success, some say, depends in part on the fact that it is an industry-based self-regulatory advertising framework or code of conduct. Also, the ads can be banned if found to be in violation, and the media, which depends

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<sup>92</sup> Gardiner Harris, “F.D.A. Panel Says Pain Relievers Should Remain on Market,” *New York Times*, Feb. 18, 2005.

<sup>93</sup> See [<http://www.fda.gov/oc/factsheets/drugsafety.html>].

<sup>94</sup> The only other developed country permitting brand advertising of prescription medications is New Zealand. New Zealand has a representative body called the Advertising Standards Authority (ASA) comprised of representatives from advertisers, advertising agencies, and all the media including TV, newspapers, radio, magazines, cinema, and direct marketing. It has developed a series of codes that seek to maintain standards of advertising so that ads are not misleading or deceptive. The code for therapeutic advertising covers all ads where a therapeutic claim is made irrespective of whether the product is a prescription, nonprescription, or herbal medicine. The code tries to promote voluntary self-regulation by advertisers. The ASA also funds the Advertising Standards Complaints Board (ASCB). This ASCB investigates and adjudicates all complaints it receives. Anyone can lodge a complaint stating the time, date, and channel or media where the ad was aired. Advertisers must then show that the advertisement adhered to the code. The advantage of this system is that complaints are processed quickly, often within six weeks. If an ad is found to breach a code, the media refuse to accept it or air it. In the 13 years of its existence, the ASCB has had 100% compliance with its adjudication decisions.



on ads for revenue, ensures that they only accept ads that show they have been pre-approved by the Service and comply with legislative requirements.<sup>95</sup>

If Congress encouraged it to do so, FDA could establish an advisory panel under the Federal Advisory Committee Act which could either itself recommend standards for prescription drug ads, or encourage the drug industry to develop a new set of standards for self-regulation.<sup>96</sup> Some in the drug industry believe that the formation of another advisory panel is unnecessary, and that the industry itself is able to voluntarily adopt its own standards to ensure that ads are reliable, understandable, and trustworthy.<sup>97</sup>

**Increase FDA’s Enforcement Activity.** At present, when FDA identifies an ad that does not follow FDA regulations, it can send a notice of non-compliance to the drug company (called an untitled letter by the agency); it almost always gets a satisfactory corrective response, according to the agency. Some question whether the agency sends enough notices. A second stronger FDA option response is a “warning letter.” This type of letter contains a deadline by which the ad sponsor must reply. If there is an unsatisfactory response or none, FDA can seek an injunction through the Department of Justice. FDA believes that the threat of a formal warning letter is a powerful tool in its regulatory arsenal. The drug industry too, believes this warning letter tool is sufficiently strong to gain compliance from the manufacturing community. Should any regulatory changes be proposed, First Amendment and commercial speech protections would most likely need to be considered.<sup>98</sup>

## **Additional Activity Requiring New Authority**

Another question is whether FDA has enough current authority to protect consumers from potentially misleading advertisements. Should Congress decide there is a need for greater enforcement of standards for ads, it could strengthen

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<sup>95</sup> Janet Hoek and Philip Gendall, “Direct-to-Consumer Advertising Down Under: An Alternative Perspective and Regulatory Framework,” *Journal of Public Policy & Marketing*, vol. 21, no. 2 (fall 2003), p. 202. Similar to U.S. law, New Zealand requires that the advertisement contain active ingredients and quantity, authorized uses, appropriate precautions, contra-indications, adverse reactions, the line that says “prescription medicine, and the name and address of the advertiser.”

<sup>96</sup> PhRMA adopted on April 18, 2002, a new voluntary marketing code to govern the pharmaceutical industry’s relationships with physicians and other healthcare professionals. It says that all interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education, available at [<http://www.phrma.org/mediaroom/press/releases/19.04.2002.390.cfm>].

<sup>97</sup> Testimony of Executive Director of EthicAd, Michael S. Shaw, in U.S. Congress, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, *Direct-to-Consumer Advertising of Prescription Drugs*, hearing, 107<sup>th</sup> Cong., 1<sup>st</sup> sess., July 24, 2001.

<sup>98</sup> For more information on First Amendment issues, see CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

FDA's ability to regulate these ads. It could also authorize more review, set different standards for ads, or even ban certain ads.

**Increase Compliance and Enforcement Tools.** Congress could give FDA the authority to impose punitive sanctions against companies that violate the law. For example, Congress could authorize civil monetary penalties so FDA could impose penalties in amounts high enough to encourage greater company compliance.

**Require Pre-Release Review.** Should Congress decide it was necessary, it could authorize FDA to review and approve all or a subset of DTC ads prior to their release to the public. One suggestion discussed in the federal advisory meeting mentioned above would be to categorize ads depending on the drug it was advertising so that if the opportunity for harm from misleading information is seen as large then a more rigorous review could be instituted.

**Set Limits on Timing and Placement of Ads.** Some suggest that the agency could also limit the number, type, or content of ads for a particular drug, or the places where the ad was aired, or when the ads could be seen. Others suggest aggressive oversight could increase the likelihood of effective self regulation by the industry.<sup>99</sup> Ray Woosley, president of the Critical Path Institute at the University of Arizona stated that a new drug's benefit-risk ratio should be better understood before millions of people are put at risk. He suggested that the agency require data collection on all new drugs that advertise to consumers.<sup>100</sup> In addition, drug companies may want to look at advertising in smaller markets rather than attempting to create national blockbuster sales. Carl Nathan off the Weill Medical College of Cornell University in Ithaca, N.Y. suggested that companies might take a few good drugs and market them conservatively.<sup>101</sup>

**Ban DTC Advertising.** Many members of the federal drug advisory panel that considered the COX-2 inhibitors recommended banning DTC ads for these drugs; some recommending a ban on all DTC advertising. A former FDA official, William Schultz, suggested at the Senate Health, Education, Labor and Pension hearing on March 1, 2005, that "[o]ne possibility is to ban consumer advertising for a period of time (one or two years) after a drug has been approved, as additional data are collected on the drug's safety. Another alternative is to require more explicit and more prominent disclosures [in the ads] about the safety of prescription drugs. In the case of new drugs, manufacturers could be required to include a standard disclosure about the inherent risks of new drugs."<sup>102</sup>

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<sup>99</sup> Frank et al., *Prescription Drug Policy Issues*, p. 124.

<sup>100</sup> "Academic Hopes to Partner with FDA on Tiered Drug-Approval Plan," *Inside Health Policy*, Mar. 3, 2005.

<sup>101</sup> Rob Stein, "Studies on Painkillers in Jeopardy: Researchers Assess Risk-Benefit Ratio," *Washington Post*, Dec. 26, 2004, p. A1.

<sup>102</sup> Testimony of William B. Schultz, in U.S. Congress, Senate Committee on Health, Education, Labor and Pensions, *FDA's Drug Approval Process: Up to the Challenge?* hearings, 109<sup>th</sup> Cong., 1<sup>st</sup> sess., Mar. 1, 2005.

## Previously Proposed Legislation

So far, no bills have been introduced into the 109<sup>th</sup> Congress that would have a direct impact on DTC advertising. Several congressional Members proposed legislation in the 108<sup>th</sup> Congress that would have affected DTC advertising. One bill would have amended the Internal Revenue Code to prohibit a deduction for any amount paid or incurred by the manufacturer for a direct-to-consumer advertisement of a prescription drug.<sup>103</sup> Another would have denied tax deductions for DTC advertising if drug makers failed to provide information about risks or presented the drugs in an unbalanced way, or if the agency determined that a drug's risks were not listed in the advertisement in the same proportion as its benefits.<sup>104</sup> A third would have mandated comparative research on the effectiveness and safety of drugs covered by the Federal Employees Health Benefits Program.<sup>105</sup> It also would have required regulations for ads, mandating that the advertisements balance risk and benefit information, set civil penalties for violations, and required an annual report which specified details of all DTC ads, including which ads violated the law and describing what the Secretary of Health and Human Services had done to respond to the violation. It also would have required expedited review of DTC ads. None of these bills was reported out of their committees of referral.

## Conclusion

DTC promotes the advantages of prescription drugs and is used to sell drugs by manufacturers. The issue for Congress is whether FDA's current policies on DTC ads give consumers information that is balanced with risks and benefits represented equally, and whether ads misrepresent important information patients need prior to purchasing or consuming the drug. The agency and others say that evidence suggests that DTC ads influence the way patients find out about certain health conditions. Supporters point to the ads as a source of information about treatment options, benefits, and risks. They also attributed to ads educating patients and leading them to take more responsibility for their health care, visiting their physicians more regularly so that certain health conditions are caught early, and preventing more costly treatments later.

Others argue for stricter requirements for ads coupled with penalties for infractions to assure consumers of a balance in the information about drugs. They suggest that ads should be approved prior to release to the public to ensure the risk and benefit of the drugs are balanced. Still others have suggested banning or severely limiting ads until a drug's safety profile becomes more extensive.

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<sup>103</sup> The Say No to Drug Ads Act (H.R. 149), Rep. Jerrold Nadler.

<sup>104</sup> The Fair Balance Prescription Drug Advertisement Act of 2003 (H.R. 3155), Rep. Pete Stark.

<sup>105</sup> The Direct to Consumer Prescription Drug Advertising Act of 2004 (S. 2445), Sen. John Edwards. The text of S. 2445 was presented and defeated twice as amendments to the Prescription Drug and Medicare Improvement Act of 2003.

With the level of congressional and public interest in drug safety and consumer and physician access to information, FDA and Congress may consider whether and if so how to regulate DTC advertising to bolster its potential positive impact on consumer and physician knowledge and choice while protecting against the potential of the ads to accentuate the benefits and downplay the risks of prescription drugs