

CRS Report for Congress

Direct-to-Consumer Advertising of Prescription Drugs

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Summary

The advertising of prescription drugs directly to consumers (DTC) by pharmaceutical companies has been characterized as any promotional effort that targets the general public in the lay media. Spending by the drug industry on DTC advertising has grown from \$791 million in 1996 to \$2.5 billion in 2000, with most of the money being spent to promote 50 drugs. Although the impact of this advertising is unclear, there is a growing consensus among health professionals and others that DTC advertising is linked in some way to the rising cost of health care.

Drug makers 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. Many physicians acknowledge that DTC advertising serves as an effective tool for conveying health information to consumers. Other health care providers, 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 towards 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 and benefits. Because most commercial advertising is limited in length, drug makers found compliance with these regulations difficult, particularly in television and/or radio advertising. FDA had given no guidance to the drug industry on how the "brief summary" requirements for broadcast advertising could be met. In 1997, FDA issued a draft guidance, finalized in 1999, clarifying that DTC broadcast advertising is different from print advertising, and stipulating that broadcast ads had to include the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. The agency's guidance provided that the DTC ads should give sources where 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 concerned that DTC advertising may be contributing to inappropriate prescribing by physicians and to higher health care costs. Two bills have been introduced that would limit tax deductions for this advertising (H.R. 2352 and S. 2486). Another would encourage stronger civil monetary penalties for infractions of FDA rules (H.R. 4833). This report examines these and other legislative options. They include authorizing FDA to expand its capability to take enforcement actions; creating an advisory committee to develop different standards for drug ads; and taking no action at all, if Congress believes FDA is successfully working with the drug industry to ensure that DTC ads are fulfilling the agency's statutory and regulatory requirements. This report will be updated periodically.

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Direct-to-Consumer Advertising of Prescription Drugs

Introduction

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

- “Product claim” ads which include a product’s name, and a therapeutic claim about the product.
- “Help-seeking” ads which 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 which call attention to the product’s name but make no claim about the health condition the drug is used to treat.

Of these three categories of advertisements, product claim ads are the only type of DTC advertisement that the Food and Drug Administration (FDA) directly regulates. This type of ad makes therapeutic claims which must not be false or misleading and are required to include all the risk information described in the drug’s approved label. The agency does, however, differentiate in its regulations between print and broadcast DTC product claim ads. Product claim ads in print must include all risk information about side effects, contraindications, and precautions listed in the product’s approved labeling. Broadcast advertisements tell patients where they can access this risk information from other sources.

Help seeking ads are directed towards consumers and make no health claims. Reminder ads also make no health claims but are primarily directed towards doctors and health care professionals who are more likely than consumers to know about the advertised product and its use.

¹Frank, R.G. et al. *Prescription Drug Policy Issues In California*. (Report prepared for the California HealthCare Foundation, April 1999) as found in Michael S. Wilkes, Robert A. Bell, and Richard L. Kravitz. Direct to Consumer Prescription Drug Advertising: Trends, Impact, and Implications, *Health Affairs*, March/April 2000. (Hereafter cited as Wilkes, Bell and Kravitz)

This report focuses on the impact of product claim ads and the regulatory requirements for these ads. This report also discusses the differences in the way that print and broadcast product claim advertisements are regulated.

Growth in Spending on DTC Advertising

DTC spending has reached significant levels in recent years. One study has estimated that spending on DTC advertising grew from \$791 million in 1996 to \$2.5 billion in 2000.² Another group estimates that in 2001 overall spending of DTC advertising was \$2.77 billion.³

Although experts have yet to agree on a methodology for collecting data to establish a cause and effect relationship between spending and product use, research has shown that drugs which are marketed heavily to consumers hold a substantial percentage of sales within their therapeutic category. For example, Claritin, Allegra, and Zytex – three heavily marketed oral antihistamines – account for 88.2% of the allergy prescription drug market.⁴

Other facts may also suggest the significant impact of DTC advertising.

- In 2000, most of the \$2.5 billion spent on DTC advertising went to promote 50 drugs.⁵
- Retail sales of those 50 drugs increased 21.4% in 2001.⁶ In comparison, the increase in the sales of all other drugs combined (9,482) was 13.8%.
- These top 50 drugs accounted for 44.4% (\$68.7 billion) of the \$154.5 billion spent on all prescription drugs in 2001.

²In 2000, the pharmaceutical industry spent \$15.7 billion on all its promotional activities including visits to physicians by sales people (called detailing), advertising at events for physicians, distribution of free product samples, and advertising in medical journals. Of this money, 15.9% or \$2.5 billion went to DTC. National Institute for Health Care Management Research and Educational Foundation (NIHCM). *(Prescription Drugs and Mass Media Advertising, 2000, November 2001. p. 2.)*

³This information is from Nielsen Media Research (nielsenmedia.com) and includes spending on corporate and non-branded consumer advertising. Scussa, Frank. Growth of Spending on Direct-to-Consumer Promotion has been Curtailed as Consumer, Government, and Regulatory Pressures Mount, *Med Ad News*, June 2002.

⁴NIHCM. *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002. Table 5. p.16.

⁵NIHCM. *Prescription Drugs and Mass Media Advertising, 2000*, November 2001. p. 7 and 11.

⁶All data can be found in: NIHCM. *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*. April 2002, Table 4. p.13. The data used to calculate the average prices were from the Bureau of Labor Statistics, Scott Levin, Inc., and IMS Health, Inc. Average prices paid at the point of sale are calculated using the total sales of a drug or category of a drug divided by the total number of prescriptions dispensed. The prices are not adjusted for dosage level or size (30 days versus 60 days) or the number of prescriptions filled through mail order.

- The number of prescriptions for the top 50 best selling drugs in 2001 rose 11.6% from 2000 to 2001. The number of prescriptions for all other drugs rose just 4.1%
- 20 of the top 50 most heavily advertised drugs in 2001 were also on the list of the 50 best selling drugs.

The data on prescription drug advertising have raised concerns about the potential contribution of this spending to higher drug prices and increased health care costs.

Impact of DTC Advertising

Consumers, physicians, health care organizations, and industry groups hold a variety of opinions on the effect of DTC advertising. Currently, most of these opinions are based more on anecdotal rather than empirical evidence. There is, however, a growing consensus among health professionals and others that the recent proliferation of DTC advertising may in some way be linked to the rising cost of health care.⁷

Most DTC advertising targets individuals with chronic health conditions, such as allergies, ulcers, depression, high blood pressure, and high cholesterol. Some advertisements target caregivers and family members or those who may be at risk for a given disease. 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 create both a demand for the drug and an increased interaction between patients and their doctors.

Company decisions on which medications to advertise are proprietary. It is clear that most of the top selling brand name products are extensively advertised, and that many more people are now asking their doctors for these drugs.⁸

Impact on Consumers. The proliferation of DTC advertising has led many patients to become aware of newly available medical treatments for certain health conditions. Some pharmaceutical companies call their messages “educational.” In some cases, some say, DTC ads do encourage patients to seek medical advice for conditions that sometimes go untreated.⁹ As such, these ads can lead to earlier patient/physician discussions especially about life-style changes that could be beneficial to their health (i.e., losing weight).¹⁰ At other times, DTC ads can improve

⁷Teinowitz, Ira. Congress Eyes DTC Ad Threat, *Advertising Age*, August 27, 2001. p. 3.

⁸Ibid.

⁹The nominee for FDA Commissioner, Mark McClellan, at a Senate hearing said he believed that television advertising for prescription drugs helped promote treatment of conditions that are seriously undertreated. Stolberg, Sheryl Gay, “Senate Hears Bush Nominee for F.D.A.,” *The New York Times*, October 8, 2002, Section A, p. 22.

¹⁰Borow, Wendy. The AMA explains its about-face on direct-to-consumer advertising. *Medical and Marketing & Media*, September 1993. p. 68-74. (Hereafter cited as Borow,

patient compliance with their physician's advice, particularly if physicians remind patients to take the medication as prescribed.

A FDA telephone survey of physicians (which is scheduled to be finished in 2002) will likely allow the agency to understand better the impact DTC advertising has on consumers and doctors.¹¹ The preliminary results of this telephone survey showed that patients seem to listen more closely to their doctor's explanation about a prescription drug's side effects, if they have seen the ad or have independently approached the doctor with a request for the medication.¹² Another study showed that when a drug's risk information is separated and enhanced as the summary statement in a different format from product claim ads, consumers are better able to distinguish individual product risks.¹³

However, some ads also may encourage consumers to believe a common health problem can automatically be fixed by a prescription drug. The concern is that people, who themselves have managed a small health problem with, for instance, over-the-counter medications, are now pressing physicians to provide prescription drugs that may not necessarily be needed.¹⁴ The process may expose some people to harmful side effects of drugs or to other problems.

Impact on Physicians. Many physicians recognize that DTC advertising serves as an effective tool for providing health information to consumers. Some believe that DTC advertising is one reason why 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, other doctors mistrust DTC advertising because, in their opinion, the ads often promote a view of medicine that is misleading. There is a view that the information presented in DTC ads obscures information about a drug's risks.¹⁵ Less expensive drugs can often work

¹⁰(...continued)
AMA)

¹¹Adams, Chris. FDA plans to Review Policy Allowing Direct-to-Consumer Drug Ads for TV. *Wall Street Journal*, March 28, 2001; FDA Survey of DTC Impact on Physicians Pushes Back Assessment Timeline. *FDA Week*, July 13, 2002. p. 17-18.

¹²Aikin, Kathryn J. Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results, Food and Drug Administration. Department of Health and Human Resources. Slide Presentation on April 18, 2002. (Hereafter cited as Aikin, Direct to Consumer)

¹³Risk and Product Info Placement, Demographics Affect DTC Ads Impact, *FDA Week*, July 13, 2001. p. 18.

¹⁴Woloshin, Steven, Lisa M. Schwartz, Jennifer Tremmel, and H. Gilbert Welch. Direct-to-Consumer Advertisements for Prescription Drugs: What are Americans Being Sold? *The Lancet*, v. 358, October 6, 2001. p. 1141-1146.

¹⁵Council on Ethical and Judicial Affairs of the American Medical Association. Direct-to-Consumer Advertisements of Prescription Drugs. *Food and Drug Law Journal*, v. 55, 2000. p. 121. (Hereafter cited as Council on Ethical and Judicial Affairs)

as well as the advertised drugs that may be the latest and costliest medicines¹⁶ 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.¹⁷ This attitude, some say, could contribute to an unwillingness on the part of the patient to make needed lifestyle changes. Most people understand that there is no one pill to ease all illnesses, and not surprisingly, DTC ads rarely, if ever, discuss non-drug forms of treatment.

Some physicians feel they are bombarded with unjustified requests for a prescription drug, and report that they are often met with hostility when they deny a patient's request for the latest prescription drug. Critics also suggest that, at a time when managed care is squeezing doctors' time with each patient, DTC advertising can make it more difficult for doctors to have in-depth conversations on alternative treatments.¹⁸ However, other doctors report the opposite.¹⁹ They believe that patients, who come in because of an ad, have already considered various treatment options and are often easier to treat.²⁰

An FDA official claimed that according to a 1999 agency telephone survey most physicians are comfortable with denying medications particularly when the requested drug is not right for the patient.²¹ In preliminary results of the 2002 FDA telephone physician survey mentioned above, another FDA official said that 93% of physicians welcomed questions about specific drugs from patients, and about half the time, the doctor prescribed the requested drug when a specific drug was requested.²²

Impact on Health Care Costs and Quality of Treatment. The increase in prescription drug spending appears to be the result of several factors: a significantly greater number of prescriptions being written for an aging population who often need more medical attention; a shift in prescriptions to newer higher cost

¹⁶NIHCM. *Factors Affecting the Growth of Prescription Drug Expenditures*. Prepared by Barents Group LLC, July 9, 1999. p. 14.

¹⁷Ibid., p. 7.

¹⁸Marks, Alexandra. A Harder Look at Prescription Drug Ads; Critics Say the Commercials Prompt Consumers to Spend too Much. *The Christian Science Monitor*, April 11, 2001.

¹⁹Borow, AMA.

²⁰Lyles, Alan. Direct Marketing of Pharmaceuticals to Consumers, *Annual Review of Public Health*, v. 23, 2002. p. 73-91. [<http://publhealth.annualreviews.org/current.shtml>]

²¹U.S. Department of Health and Human Resources. Ostrove, Nancy M. Deputy Director. Division of Drug Marketing, Advertising and Communications. Center for Drug Evaluation and Research. U.S. Food and Drug Administration. Testimony before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism. Senate Committee on Commerce, Science, and Transportation, July 24, 2001. p. 15-16. (Hereafter cited as Ostrove, Testimony)

²²Aikin, Direct to Consumer.

drugs; and overall price increases for those drugs.²³ The price of a drug is almost always set when the drug is first introduced into the market, but can fluctuate with time. If more people take the 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. Other factors that increase drug spending include more health plans with low copayments for drug coverage, and the growth in the proportion of people using medications.²⁴

Most experts agree that there is still too little information to determine with precision how DTC advertising affects consumer demand for drugs, physicians' prescribing practices or pharmaceutical companies' revenues, or what impact it has on the health status of patients.²⁵ 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 better therapies, consumers may substitute newer, higher-priced drugs for less expensive ones, thereby increasing health care costs.²⁶

Yet, studies sponsored by both industry and non-industry researchers suggest that the ads can lead to cost-effective treatments in some circumstances.²⁷ For example, statin drugs are found to lower blood cholesterol levels and are relatively cost-effective as secondary prevention in persons with existing heart disease but much less cost-effective than primary prevention.²⁸ Others argue that there is no proven causal link between DTC advertising of prescription drugs and cost-effective treatments.

A spokesman for the pharmaceutical industry in testimony before Congress stated that medicines are the "most cost effective form of health care" because they

²³Spending on prescription drugs grew faster than any other personal health category since 1997. Levit, Katharine, Cathy Cowan, Helen Lazenby, Arthur Sensenig, Patricia McDonnell, Jean Stiller, Anne Martin, and the Health Accounts Team. Health Spending in 1998: Signals of Change, *Health Affairs*, v. 19, no. 1, January/February 2000. p. 129.

²⁴Increasing co-payments for prescription drugs and requiring mandatory generic substitution reduced overall drug spending among working age enrollees with employer-provided drug coverage. Joyce, Geoffrey F., Jose J. Escarce, Matthew D. Solomon, and Dana P. Goldman, "Employer Drug Benefit Plans and Spending on Prescription Drugs," *JAMA*, v.288, n.14, October 9, 2002, p. 1733-1739.

²⁵Council on Ethical and Judicial Affairs, p. 120.

²⁶Heffler, Stephen, 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*, v. 20, no. 2, March/April 2001. p. 198.

²⁷Lichtenberg, Frank. Benefits and Costs of Newer Drugs: A Update, *Working Paper 8996*. National Bureau of Economic Research, June 2002. [<http://www.nber.org/papers/w8996>]

²⁸Examples 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 those patients with atrial fibrillation, immunosuppressive drugs for those with kidney transplants, and treatment with mood-altering drugs for people with depression. Neumann, Peter J., Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman. Are Pharmaceuticals Cost-Effective? A Review of the Evidence. *Health Affairs*, v. 19, no. 2, March-April, 2000. p. 97 and p. 99. (Hereafter cited as Neumann, Pharmaceuticals)

can keep patients out of hospitals and nursing homes and avoid surgery.²⁹ He quoted a National Institutes of Health study which found that clot-busting drugs used to treat stroke patients saves, on average, \$4,300 a year per patient by reducing the need for hospitalization, rehabilitation, and nursing-home care.³⁰ 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.”³¹

Impact on the Pharmaceutical Industry. Drug companies rely on DTC advertising to stimulate demand and to increase sales for pharmaceuticals.³² The drug industry claims that DTC ads have increased consumer awareness of some crucial health related information: 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.³³ Pharmaceutical Research and Manufacturers Association (PhRMA), the trade association representing the major drug manufacturers, believes that, in general, advertising, particularly DTC advertising, fosters competition among products which could lead to lower prices for consumers.³⁴ Observers remark 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. Decisions on prices and whether to pass the costs of this DTC advertising on to consumers are proprietary.

The following sections describe the statutory basis for current regulations of DTC advertisements, recent FDA actions and funding, legislative proposals and options introduced for consideration in the 107th Congress, and some other potential FDA actions under current authority.

FDA’s Existing Authority to Regulate Prescription Drug Advertising

The Federal Food, Drug and Cosmetic Act (FFDCA) sets forth the statutory requirements that pharmaceuticals must meet before they can be approved for

²⁹Glover, Gregory J. Testimony for the Pharmaceutical Research and Manufacturers of America before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism of the Senate Committee on Commerce, Science, and Transportation. July 24, 2001. (Hereafter cited as Glover, Testimony)

³⁰Fagan, S. C., L.B. Morgenstern, A. Petitta, R.E.Ward, B.C. Tilley, J.R. Marler, S.R. Levine, J.P. Brodeerick, 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*, v. 50, April 1998. p. 883-890.

³¹Neumann, Pharmaceuticals, p. 104.

³²Glover, Testimony, p.5

³³Calfee, John E. Testimony (at a hearing on Direct-to-Consumer Advertising of Prescription Drugs) before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism of the Senate Committee on Commerce, Science, and Transportation. July 24, 2001.

³⁴Glover, Testimony, p. 9.

marketing in the United States. 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. In 1962, Congress added Section 502(n) to the Act, to give the FDA the authority to regulate prescription drug advertising, including DTC advertisements. At the time, advertising was primarily printed material directed towards physicians.³⁵ In the same section, Congress prohibited FDA from issuing any regulations that would generally require prior approval of the content of any advertisement.

Final Regulations. In 1969, FDA issued final regulations governing drug advertising at 21 CFR §202.1.³⁶ Under these regulations, advertisements had to 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. Also, under these regulations, FDA could not demand that the advertisement be sent to the agency for approval before it was released; rather, it required that companies submit promotional materials at the same time that the product becomes available to the public.³⁷ Such materials must be supported by scientific evidence and be consistent with FDA-approved standards for patient 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

Differences Between Labeling and Advertising

FDA considers 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 (serious and non-serious but frequently occurring) side effects and 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 advertising, including DTC advertising.

the approved drug’s labeling. (See Text Box.)

FDA’s Current Activity. The agency often gets involved prior to the release of certain types of advertisements, particularly broadcast advertisements. Most drug manufacturers voluntarily submit draft materials to FDA for review and comment

³⁵21 United States Code (U.S.C.) 502 (n); Federal Trade Commission regulates the advertising of all consumer products other than prescription drugs.

³⁶Henney, Jane E. Challenges in Regulating Direct-to-Consumer Advertising. *MSJAMA – Report*, v. 284, November 1, 2000. p. 2242. (Hereafter cited as Henney, Challenges in Regulating)

³⁷21 *Code of Federal Regulations* (CFR) §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.”

prior to the ads being aired on TV and radio.³⁸ 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 because these ads can make or imply inappropriate claims just by their presentations. FDA receives about 32,000 ads (known as submissions to the agency) each year. These submissions include all types of promotional materials, both broadcast and print advertisements, and promotional labeling for new products, directed at all audiences including health care professionals.

A Problem for Drug Advertisers. Until 1997, the law required that if a 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 included in the product's approved labeling.³⁹ 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.⁴⁰ Although the regulations allowed for an alternative to presenting every risk in a broadcast advertisement, prior to 1997, FDA never issued any interpretation of how broadcast advertisements could present "brief summary" information to meet the alternative requirement.⁴¹ The industry assumed that FDA expected broadcast DTC advertising to meet the same requirements as ads in print.⁴²

Draft Guidance for Broadcast Ads. In August 1997, FDA issued a draft guidance on how pharmaceutical companies could apply existing regulatory requirements for advertising prescription drugs on radio and television. The draft guidance clarified that DTC broadcast advertisements were different from print advertisements and specified how to meet the regulatory requirements for broadcast ads. 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 also be in the video portion as well. The draft guidance was finalized, without major change, in August 1999.⁴³ The agency explained that the regulations had always allowed for broadcast advertisements to include **either** all the drug's risks or

³⁸See 21 CFR 314.81(b)(3)(i). According to an FDA official, most 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.

³⁹See [<http://www.fda.gov/cder/guidance/index.htm>]

⁴⁰Pharmaceutical Research and Manufacturers Association. *Direct to Consumer Advertising. Backgrounders and Facts*, at [<http://www.phrma.org/publications/backgrounders/2000>].

⁴¹21 CFR 202.1(e)1.

⁴²Pines, *History and Perspective*, p. 489-518.

⁴³[<http://www.fda.gov/cder/guidance/1804fnl.html>]; 64 *Federal Register*, no. 152, August 9, 1999. p. 43197-43198. 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.

ensure that consumers would have “adequate access” to an advertised product’s approved labeling. The guidance suggested that one way to ensure that consumers with different information-seeking needs and capabilities have adequate access to the product labeling was by disclosing four different sources of this information. These sources,⁴⁴ which were to be broadly disseminated to the general public, must include: Internet sites,⁴⁵ toll-free telephone numbers, referral to health care providers, and other print sources with large circulations.⁴⁶

Draft Guidance on Print Ads. In April 2001, FDA published a draft guidance for the drug industry entitled: *Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements*.⁴⁷ The draft guidance clarifies that FDA will not object to drug companies fulfilling their detailed risk disclosure requirements in print advertising by using the risk-related sections of FDA-approved labeling. (The wording of this type of labeling is usually addressed to physicians.) In addition, DTC print advertisements can give a description of the frequently occurring side effects, warnings, precautions, and contraindications, in easily understood language, as long as these descriptions are accompanied by a reprint in full of the risk sections of the FDA-approved label. The agency calls these descriptions “patient labeling.” According to the draft guidance, patient labeling that is used to disclose the drug’s risks would not have to discuss infrequent or non-serious side effects, or specific warnings such as a drug’s carcinogenicity, mutagenesis, or effects on infertility, etc., if the risk of these occurrences is very small and not serious.⁴⁸

FDA’s Enforcement Activities. With regard to enforcement, while the law and regulations do not give FDA prior approval authority on prescription drug advertising, the law does give FDA authority to review the accuracy of claims of a prescription drug’s effects. In October 2001, an FDA official stated that the agency has become troubled at times by the unsubstantiated claims being made in some advertisements about how more effective the advertised drugs are than competitive

⁴⁴Food and Drug Administration. 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. This paper can be found at [<http://www.fda.gov/cder/guidance/1804q&a.html>].

⁴⁵Web-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. Frangos, Alex. Special Report: E-Commerce; Prescription for Change. *Wall Street Journal*, April 23, 2001.

⁴⁶[<http://www.fda.gov/cder/guidance/1804fnl.html>]; 64 *Federal Register*, no. 152, August 9, 1999. p. 43197-43198. Also see: Council on Ethical and Judicial Affairs of the American Medical Association. Direct-to-Consumer Advertisements of Prescription Drugs. *Food and Drug Law Journal*, v. 55, 2000. p. 120.

⁴⁷[<http://www.fda.gov/cder/guidance/index.html>]; 66 *Federal Register*, no. 78, April 23, 2001. p. 20468-20469.

⁴⁸See: [<http://www.fda.gov/cder/guidance/index.html>]; see draft guidance section; also 21 CFR 202(e)(1).

products.⁴⁹ In addition, she expressed concern that some ads obscure the warning information that is required to be given.⁵⁰

If the FDA feels that an advertisement for a drug does not contain the required information or is false or misleading, it can respond through a variety of enforcement actions.⁵¹ In most cases, the agency asks the company to withdraw voluntarily the violative ad. It sends 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.

A Recent “Untitled Letter”

FDA recently sent a letter to Roche, Inc. objecting to a radio broadcast commercial for its product for flu therapy, *Tamiflu*. In the ad, a celebrity stated that he “felt better ... soon” after taking the medication. The agency claimed that the ad had omitted critical information and was misleading because the drug had to be taken in the early stages of illness (within 2 days of getting the symptoms) to be effective. In addition, the company’s ad had not made “adequate provision” for dissemination of the required risk information because the ad had not provided where the general public could easily access product information. The company immediately stopped airing the advertisement.

Source: Roche. *Tamiflu* Celebrity Endorsement Ad Challenged by FDA. *The Pink Sheet*, June 17, 2002. p. 34.

Since 1997, the agency has sent 46 untitled letters for violative broadcast ads and 44 untitled letters concerning print materials that did not comply with the regulations.⁵² In cases where there are repeated violative activities, or public health concerns, FDA can issue an official “warning letter.” The warning letter asks that, in addition to stopping the violative activity, the company take corrective steps by alerting physicians and running ads to correct the misleading impressions. Usually, the companies respond immediately to the untitled letter. (See Text Box.) Since 1997, the agency has sent only three warning letters for violative broadcast ads, and one for a noncompliant print ad.⁵³ Lastly, if warning letters fail to rectify the situation, FDA can bring injunctions against companies, criminally prosecute firms, or seize products deemed to be misbranded by intentional and/or serious misstatements. In fact, only five cases have been brought to court for resolution. For

⁴⁹Ostrove, Testimony, p. 13.

⁵⁰FDA Continues to Send Letters Urging Improvements to DTC Ads. *FDA Week*, October 19, 2001. p. 15.

⁵¹Between 1999 and April 2002, FDA reviewed the content of 706 broadcast advertisements for 76 different pharmaceuticals. Only 6.5% or 46 broadcast ads warranted some type of regulatory notice.

⁵²Ostrove, Testimony. p. 13-14.

⁵³*Ibid.*

example, in 1995, a prominent company pleaded guilty to having promoted their acne treatment drug for use for treating sun-wrinkled or “photoaged” skin. The company paid a \$5 million fine and \$2.5 million for the costs of the investigation.

Recently, the agency has had its authority questioned in the courts as to the way it regulates DTC advertisements and other forms of prescription drug promotion. The rulings emphasized that the agency should not impose unnecessary restrictions on “commercial speech.” 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.⁵⁴ (FDA had extended the deadline for comments until September 13, 2002.) In the notice, FDA mentions a recent loss of a court decision⁵⁵ on its regulation of commercial speech. The loss led the agency to question whether it continues to have overall 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.⁵⁶ The notice is soliciting public comments about FDA’s legal basis for its regulations, guidances, 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?⁵⁷

⁵⁴U.S. Department of Health and Human Services. Food and Drug Administration. Request for Comment on First Amendment Issues. *Federal Register*, v. 67, no. 95, May 16, 2002. p. 34942-34944. See CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

⁵⁵*Thompson v. Western States Medical Center*, 535U.S. ___, No. 01-344(April 29, 2002). In this case, the Supreme Court struck the FDA Modernization Act (FDAMA) pharmacy compounding provision. 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 of the Constitution. *FDA Week*, June 21, 2002.

⁵⁶FDA Seeks Comment on Ad Regs: Can Rx Be More Regulated Than OTCs? *The Pink Sheet*, v. 64, no. 20, May 20, 2002. p. 14.

⁵⁷*Ibid.*

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.

Recent Administration Activity and Funding

Monitoring compliance and enforcement of DTC regulations is the responsibility of FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC), a division within the Office of Medical Policy. On June 21, 2002, the director of DDMAC announced a reorganization of the division, likely to take several months, which would divide employees into teams, one of which will focus on review of DTC materials. The DTC team will answer information requests and enforce FDA regulations on DTC advertising.⁵⁸ The division's FY2002 appropriation is \$3.7 million out of a total FDA FY2002 appropriation of \$1.531 billion or .2%. Currently, this division's appropriation funds 39 full time equivalent (FTE) positions. The President's FY2003 request for this division is \$3.9 million. With this request, the agency has indicated that this division does not need additional staff because, if this small increase in funding is appropriated, very few new staff could be hired to assist in the division's efforts to monitor DTC advertising. Neither the House nor the Senate FY 2003 appropriations bill includes any additional funding for FDA to monitor DTC advertising.

However, there were additional funds *authorized* for the DDMAC by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). This law authorizes 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 FY2007 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.⁵⁹

Another source of funds for post-market surveillance could be from fees collected under the Prescription Drug User Fee Act (PDUFA) [P.L. 107-188, known as PDUFA III].⁶⁰ Post-market surveillance activities were agreed to in the performance goals of PDUFA III by the agency and industry. In the reauthorization process for this Act, 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 will be used in activities related to the review of DTC advertising and to

⁵⁸FDA Ad Division Will Increase Focus on Outcomes Claims After Reorganization. *The Pink Sheet*, June 24, 2002. p. 31-32.

⁵⁹See 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.

⁶⁰Goetzl, Davis, and Ira Teinowitz. Legislators May Move on DTC Drug Advertising. *Advertising Age*, April 2, 2001. p. 3 and 35.

increase agency efforts to provide consumers with the latest information about newly approved drugs.⁶¹

Access to better post-marketing surveillance 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.⁶² If this information were collected by non-industry independent sources, or even by FDA, and made available to the public through the Internet, and/or possibly be accessible through local pharmacies, it could be used to counter any misinformation or omissions contained in DTC advertising.⁶³

Legislative Issues

As stated above, there are unanswered questions regarding the relative contribution of DTC advertising of prescription drugs to health care costs generally. Anecdotal evidence suggests that the increase in the number of DTC ads has encouraged patients to seek out physicians to ask for newer, more expensive drugs rather than using older therapies that are often less expensive.⁶⁴ Studies have shown that the increase in prescription drug spending is due in part to an increase in the prices of drugs, and because new innovative drugs cost more, and more people are buying and using them.⁶⁵ The pharmaceutical industry argues that new drugs actually reduce overall health care spending for they reduce hospitalizations, side effects, and prevent disease. The industry often quotes a study that found the use of newer medicines increased drug costs by \$18, but reduced hospital and other non-drug costs by \$71.09.⁶⁶ They also argue that the advertisements have educated patients and led them to take more responsibility for 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 stated that DTC advertisements are about selling a product and creating demand, not about educating patients. Further research on the

⁶¹See CRS Report RL31453, *The Prescription Drug User Fee Act: Structure and Reauthorization Issues*, by Donna Vogt and Blanchard Randall IV.

⁶²Panel Backs Interactions Database, CERTs, Adverse-Event Repository. *FDA Week*, v. 8, no. 24, June 14, 2002. p. 8-9.

⁶³H. R. 4832, Prescription Drug Comparative Effectiveness Act of 2002, introduced May 23, 2002, would authorize funding for the Agency for Healthcare Research and Quality to study the comparative effectiveness and cost effectiveness of the most commonly prescribed and most expensive drugs taken by Medicare and Medicaid eligible patients. Representative Allen: Report Backs Need for DTC and Drug Efficacy Legislation. *FDA Week*, v. 8, no. 23, June 7, 2002.

⁶⁴Telephone conversation with Larry Levitt, Kaiser Family Foundation, January 15, 2002.

⁶⁵Mullins, C. Daniel, Junling Wang, Francis B. Palumbo, and Bruce Stuart. The Impact of Pipeline Drugs on Drug Spending Growth. *Health Affairs*, v. 20, no. 5, September/October 2001. p. 210-215.

⁶⁶Lichenberg, Frank R. Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS. *Health Affairs*, September/October 2001.

contribution to DTC advertising to increases in health care costs may be needed. (See Text Box.)

Because of interest generated by DTC ads, patients are requesting and receiving prescription drugs in record numbers. One concern before Congress is whether patients are receiving inappropriate prescriptions that could cause serious health risks and compromise patients' health.⁶⁷ A survey of consumers in 1999 showed that 58%

Proposed GAO Study

In the debate over H.R. 4954, the Medicare Modernization and Prescription Drug Act of 2002, some Members of Congress called upon the General Accounting Office (GAO) to study some of the questions raised about DTC advertising and submit to Congress, within 2 years of enactment, a report providing its findings. The requirement for a study was not included in the final bill that passed the House on June 28, 2002.

In the proposed study, GAO would have determined whether and to what extent utilization rates of prescription drugs have increased because of DTC advertising since FDA issued its final guidance on this advertising in 1999. If utilization rates have increased because of DTC advertising, the study would also have determined whether and to what extent such increases have resulted in increases in the costs of public or private health plans, health insurance, or other health programs.

The study would also have included determinations of the following: (1) the extent to which DTC advertisements have resulted in effective consumer education about prescription drugs, including an understanding of the risks and benefits of the drugs involved; (2) the extent of consumer satisfaction with these DTC advertisements; (3) the extent of physician satisfaction with the ads including whether physicians believe that the DTC ads interfere with the exercise of their medical judgment by influencing consumers to prefer the advertised drugs over alternative therapies; (4) the extent to which DTC ads have increased health care costs for taxpayers, employers, or consumers due to consumer decisions to seek advertised drugs rather than lower-cost alternative therapies; and (5) the extent to which DTC ads have decreased health care costs for taxpayers, employers, or consumers due to decreases in hospitalization rates, fewer physician visits (not related to hospitalizations), lower treatment costs, or reduced instances of employee absences to care for family members with diseases or disorders.

of respondents said that the advertisements "make the drugs seem better than they are."⁶⁸ Adverse reactions to drugs, and negative interactions of one drug with another, often surface after the drug is used widely in patient populations. Under current regulations, information about negative reactions or interactions is immediately distributed to physicians across the country. There is, however, a time lag in this communication that could put some patients at risk.

⁶⁷Telephone conversation with Steve Findley, NIHCM on January 15, 2002. Inappropriate prescribing can be driven by demands of misinformed patients and time wasted by physicians in explaining why a particular therapy or product is not appropriate. See Rosenthal, M.B., E.R. Berndt, J.M. Donohue, R.G. Frank, and A.M. Epstein. Promotion of Prescription Drugs to Consumers. *New England Journal of Medicine*, v. 346, February 14, 2002. p. 498-505.

⁶⁸Henney, Challenges in Regulating.

Another concern for Congress is whether FDA has sufficient authority and funding to enforce its regulations on DTC advertising. Should Congress decide there is a need for greater enforcement of standards for ads, it could give FDA the authority to impose punitive sanctions against companies that violate the law. Or it could impose civil monetary penalties in amounts high enough to encourage greater company compliance. Some would like to have the agency give closer scrutiny to DTC ads and have FDA exercise much more vigilance in screening them. Others, however, believe that FDA has sufficient authority to take any enforcement action that it needs to and does not need any additional authority to implement its regulations.⁶⁹

Not only could Congress enact legislation that would strengthen the compliance of companies with FDA's rules and/or mandate a study on the impact of DTC advertising, it could also do nothing. Taking no action is possible, particularly if Congress and the FDA believe that the current regulatory environment has allowed the agency to work successfully with the drug industry to ensure compliance.

Proposed Legislation in the 107th Congress. Several Members of Congress have proposed legislation that would affect DTC advertising. Supporters argue that advertising of prescription drugs should be more tightly regulated because drugs are not like other consumer articles in that there is an inherent health risk in their consumption. Supporters also believe that DTC advertising leads patients to demand drugs that are not medically necessary and may prevent consumers from requesting alternative generic drugs. Critics feel there is no need for more regulation.

In the first session of the 107th Congress, Representative Pete Stark introduced the Fair Balance Prescription Drug Advertisement Act of 2001 (H.R. 2352), whose stated intention is to inject accountability in prescription drug advertising. The bill would deny tax deductions for 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. Current law requires DTC advertising to comply with these provisions or FDA would take enforcement actions against the companies airing the ads. Critics point out that the threat of an FDA enforcement action appears to be keeping companies in compliance. Since 1997, as stated above, the agency has taken relatively few enforcement actions against 32,000 annual submissions, (i.e., 46 untitled letters for violative broadcast ads and 44 letters concerning noncompliant print materials.)⁷⁰

On May 8, 2002, Senator Debbie Stabenow introduced a related bill, S. 2486, the Fair Advertising and Increased Research Act (FAIR). This bill prohibits tax deductions for any drug manufacturer for expenditures relating to the advertising, promoting, or marketing of any FDA prescription drug to the extent that the aggregate amount of such expenditures exceeds the manufacturer's aggregate research

⁶⁹Ostrove, Testimony, p. 13-14. Also see Guidance for Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements, found at [<http://www.fda.gov/cder/guidance/1804q&a.htm>]

⁷⁰Ostrove, Testimony, p. 13-14.

and development expenditures. It also directs the Secretary of the Treasury to estimate the amount of additional tax revenues raised by enforcement of the Act, and allocates these funds to Medicare's Federal Hospital Insurance Trust Fund.⁷¹ Supporters hope that the possible loss of a valuable tax deduction for excessive advertising would encourage drug companies to change some of their marketing practices. The drug industry opposes the proposal and argues that there is no need for such a law since their advertising already complies with current FDA regulations. Until FDA changes its policies, or Congress changes the statute, they argue that the costs of DTC advertising should remain a legitimate business expense and tax deduction. Other critics claim that the bill does not sufficiently address the real problem which is that the volume of DTC advertising has led to an increase in the number of prescriptions written and filled and that this additional utilization has contributed to the rise in health care costs.

On May 23, 2002, the Accuracy in Pharmaceutical Advertisement Act (H.R. 4833) was introduced by Representatives Thomas Allen and Marion Berry. It would authorize FDA to impose civil monetary penalties of up to \$500,000 on individuals (or corporations) for repeated violations of false or misleading advertising rules, \$5 million for any other person, but not to exceed \$10 million for all violations in a single proceeding. It would also grant FDA the authority to fine companies who fail within 6 months to comply with an FDA written notice of violation. (See "Untitled Letter" text box above.) It also authorizes appropriations for FDA to hire more staff to oversee DTC advertising and to report to Congress on the number, type, and location of DTC ads and any enforcement actions that the agency takes. Supporters say that the bill gives FDA additional needed authority to prevent and stop false and misleading DTC advertisements. Critics claim that Congress has already authorized new monies in the bioterrorism bill for the DDMAC that would allow the agency to hire more staff. Stronger penalties are not needed, they say, because there is little evidence of deception in the ads; when drug companies are cautioned or warned by FDA, they comply quickly.⁷²

None of these bills has been reported out of their committees of referral. In the area of oversight, issues for Congress include an examination of the FDA's exercise of its existing authority. Currently, FDA has the legislative authority to impose and enforce greater restrictions, but appears reluctant to do so.

Potential FDA Actions Within Current Authority

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. Under the national initiative to identify and reduce preventable threats to health, published as *Healthy People 2010*, FDA has committed itself to ensure that patients know the benefits and risks associated with

⁷¹Federal Hospital Insurance Trust Fund was established under Section 1817 of the Social Security Act.

⁷²Calfee, John E. Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs. Unpublished paper of the American Enterprise Institute, April 26, 2002.

using medical products.⁷³ One way the agency is meeting this goal is by increasing the distribution of information about the risks and benefits of a drug when patients receive a new prescription. Nonetheless, even with the added information, the agency cannot guarantee how patients will use the information.

As seen in the statistics mentioned above, not many ads are found to violate FDA's policies and most ads incorporate FDA's recommendations for changes prior to their release. FDA depends on its own surveillance or on voluntary reports from other competing pharmaceutical companies to learn about DTC ads that may be noncompliant or misleading.⁷⁴ Critics have complained that FDA does not always have the resources to review the proposed ads in a timely way. The agency believes that there is no problem currently with this 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.⁷⁵

At present, when illegal ads are recognized, the agency sends a notice of non-compliance to a drug company, and almost always gets a satisfactory corrective response. The threat of a formal warning letter is the most powerful tool the FDA has in its regulatory arsenal. The drug industry believes this tool is sufficiently strong to gain compliance from the manufacturing community. Should any proposed regulatory changes be made, they would most likely be balanced by First Amendment and commercial speech protections.⁷⁶

Close monitoring of visual elements of advertisements is, at times, necessary because some visuals can mislead consumers about the benefits of a drug. The agency could sponsor public education campaigns in general to explain the risks and benefits of various types of classes of drugs, the role of promotional materials, and the need for patients to talk to their physicians. Some suggest that the agency could limit the number of ads for a particular drug, or the places where the ad was aired, or when the ads could be seen. Restrictions on advertising would need to be crafted in the context of First Amendment and commercial speech guarantees.⁷⁷ Aggressive oversight could increase the likelihood of effective self regulation by the industry.⁷⁸

⁷³U.S. Department of Health and Human Services. *Health People 2010*, v. 2, November 2000. p. 17-8.

⁷⁴U.S. Department of Health and Human Services. Food and Drug Administration. Division of Drug Marketing, Advertising, and Communications. *Briefing Background*, January 2001.

⁷⁵Ostrove, Testimony.

⁷⁶For more information on the First Amendment see CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen. (Hereafter cited as CRS Report 95-815)

⁷⁷"The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." A quote from the Supreme Court case of 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 502 (1996) as found in CRS Report 95-815, p.10.

⁷⁸Wilkes, Bell, and Kravitz, p. 124.

Finally, if Congress encouraged it to do so, FDA could establish an advisory panel under the Federal Advisory Committee Act which would either itself recommend standards for prescription drug ads, or encourage the drug industry to develop a new set of standards for self-regulation.⁷⁹ Some in the drug industry believe that the formation of another advisory panel is unnecessary, and that the industry itself is able to adopt voluntarily its own standards to ensure that ads are reliable, understandable, and trustworthy.⁸⁰

⁷⁹PhRMA adopted on April 18, 2002, a new 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. [<http://www.phrma.org/press/newsreleases/2002-04-19.390.phtml>]

⁸⁰Shaw, Michael S. Executive Director of EthicAd. Testimony (at a hearing on Direct-to-Consumer Advertising of Prescription Drugs) before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism of the Senate Committee on Commerce, Science, and Transportation. July 24, 2001.