Direct-to-Consumer Advertising of Prescription Drugs

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Summary

A phenomenon that has become more and more important over the last decade, direct-to-consumer (DTC) advertising has grown from about $800 million in 1996 to over $4.7 billion in 2007. Its supporters point to more informed consumers who then visit their doctors and become more involved in their own treatment, leading to better and earlier diagnosis of undertreated illnesses. The critics believe that industry's presentation of the balance of drug benefit and risk information may encourage the inappropriate use of advertised products and lead to higher than necessary spending. In addition to concerns with accuracy and balance, health professionals point out that DTC ads rarely mention alternative treatments, such as other or generic medications or non-drug interventions.

In 1962, Congress gave the Food and Drug Administration (FDA) certain authorities to regulate prescription drug advertising. Except in extreme circumstances, the law does not allow FDA to require pre-release review of ads. Regulations—written at a time when most ads were printed in medical journals for a physician audience—require that all drug ads disclose all of a drug's known risks.

However, as drug makers considered moving into broadcast advertising and wanted to get their messages to consumers, they noted, without explicit guidance from FDA, the difficulty in including all risks in the format of a 30-second commercial. FDA issued guidance in 1999 stipulating that broadcast ads had to include the advertised product's most important risks in the audio portion of the advertisement and should give sources where more complete risk information about a drug would be available.

FDA reviews ads once they are launched, and its enforcement options are notice-of-violation and warning letters, criminal prosecution (through the Department of Justice), civil monetary penalties, product seizures, and withdrawal of approval for sale. Despite these activities, Members of Congress and the public ask what FDA could do differently in light of the safety problems involving some heavily advertised medications.

Congress could consider a variety of options to allay concerns about DTC drug advertising. It could encourage FDA to expand activities allowed under current legislative authority, including provisions in P.L. 110-85 (the FDA Amendments Act of 2007): FDA could increase post-publication review of ads, expand its role in consumer education, and increase its enforcement activities. Other possible options would require Congress to grant new authority so that FDA could require pre-release review and approval; require changes to ads; use stronger enforcement tools; require data collection; require public posting of risk information; prohibit DTC ads when a drug is first approved; and set limits on the timing and placement of ads. Congress could go beyond FDA to encourage other industry-independent entities to provide public education or set standards; it could also use tax and other financial incentives to make DTC advertising less profitable to industry.

This report will be updated periodically.

Contents

Tables

Contacts

Introduction

In 2007, pharmaceutical companies spent $4.774 billion on DTC advertising. It was the first year such spending had declined, but it was still six times as much as the industry had spent in 1996.[1] DTC advertising of prescription drugs attracted enough congressional attention to warrant at least six bills in the 110th Congress as well as concerns from members in the 111th. Beyond the sheer size of this marketing operation, what are the issues that concern Members? What actions do critics propose—and supporters of DTC ads oppose? Is there common ground between both groups?

There is a spectrum of opinion about DTC ads.

Proponents of DTC advertising say the ads:

- educate consumers about medical conditions;
- alert them to treatments that exist;
- fairly present risks as well as benefits;
- detail non-drug approaches to improve health;
- remind and motivate consumers to comply better with drug therapy regimes; and
- help to de-stigmatize conditions.

Critics of DTC advertising say the ads:

- minimize the risks of some medications while promoting their benefits;
- lure patients into expensive drugs when cheaper ones work as well, thus increasing healthcare costs;
- persuade patients to ignore other medications with fewer side effects and more established safety track records;
- provide information that would be more credible coming from non-industry sources; and
- are susceptible to marketing needs that interfere with objective presentations.

Not all of these views necessarily conflict. It is possible to educate about medical conditions *and* omit information about alternate therapies, for example. As Congress considers arguments for and against DTC advertising of prescription drugs, context becomes important. All pharmaceuticals carry some risks. Human drugs, by their definition, are substances intended to affect the structure or function of the body.[2] Consumers can take too much—or too little. They can take drugs that interact with each other in ways not yet understood.

[1] "Total U.S. Promotional Spend by Type, 2007," IMS Health, 2007 U.S. Sales and Prescription Information, May 14, 2008, at http://www.imshealth.com. Although IMS Health has not yet released its 2008 data, news reports indicated that DTC drug advertising spending declined again in 2008 (Rich Thomaselli, "DTC Spending Falls for Second Consecutive Year: Recession, Regulation and Fewer Blockbusters Mean Less Ads," *Advertising Age*, November 12, 2008).

[2] 21 USC 353(b)(1).

Researchers do not know all risks at the time FDA first approves a drug for marketing. In fact, one effect of the 2005 controversy over Vioxx was that it heightened public awareness of how incomplete the data really are before tens of thousands of consumers use a drug in real-life conditions, which include use beyond the carefully controlled limits of clinical trials. Scientists then attributed approximately 100,000 excess heart attacks and sudden cardiac deaths to an unanticipated cardiovascular side effect of that heavily advertised blockbuster drug and others in its class (COX-2 inhibitors developed to treat pain without the associated stomach side effects common to other nonsteroidal anti-inflammatory drugs) before they were withdrawn from the market.[3]

While critics and supporters of DTC ads sharply disagree on many things, people all along the spectrum often seem united in their belief that DTC ads should meet four criteria. They must be:

- ***Accessible.*** We want consumers to have *access* to *information* that could—along with the treating physician—help them make the healthcare decisions they face. To do so, the information must be *understandable*, *accurate* (true), *balanced*, and *up-to-date*.
- ***Understandable.*** Although researchers—whether in academia, government, or industry—disagree about what it is that viewers need to learn from advertisements (drug, brand, disease recognition; risks; benefits; indication), they agree ads should present the information so that average Americans can understand it.
- ***Accurate* and *up-to-date***. There is little disagreement about whether DTC ads should be accurate and up-to-date. There is, however, disagreement about exactly what those terms mean. When should ads change to include postmarket findings? When risks or benefits vary by age or disease stage and other treatments, how much of these details should the ads present?
- ***Balanced.*** Most players in the debate acknowledge the need for some discussion of the balance between risks and benefits of a drug. They often disagree over the breadth of comparisons (for example, whether to consider other drugs or other treatments or cost) or methods to use.

Appearing on TV and radio, and in popular magazines and pop-up windows on the Internet, DTC ads are an anomaly when it comes to federal regulation. The Federal Trade Commission (FTC) regulates most advertising in the United States. In 1962, however, Congress assigned the regulation of prescription drug advertising to the Food and Drug Administration (FDA). In doing so, though, it did not give the agency enforcement authority similar to that granted to the FTC. According to some critics of DTC ads, this has prevented effective oversight, and created a phenomenon more misleading than educational. To other critics, however, FDA's organizational structure, reliance on industry fees, and inadequate appropriations are more important factors in what they see as the agency's less than rigorous enforcement of law and regulation.

[3] Testimony of David J. Graham, MD, MPH, to the Senate Committee on Finance hearing "FDA, Merck and Vioxx: Putting Patient Safety First?" November 18, 2004, at http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf; and Alex Berenson, "Plaintiffs Find Payday Elusive in Vioxx Cases," *New York Times*, August 21, 2007.

Nevertheless, support for some form of DTC ads from industry and consumers is strong: industry wants to increase sales,[4] and consumers want to actively participate in decisions about their own health. That, combined with advances in information technology and possible relevance to constitutional protections of free speech, makes an outright ban on DTC ads unlikely.

The concerns about DTC ads already expressed by Members of the 111th Congress are similar to those that have surfaced in the past. Interest in the 109th Congress was sparked by some Members who had seen its growth and noted controversies over heavily advertised drugs such as Vioxx. Senate and House committees in the 110th Congress considered drug safety bills that included restrictions on DTC advertising. The Food and Drug Administration Amendments Act of 2007 (FDAAA, P.L. 110-85) included some of those provisions, such as new industry fees for the advisory review of DTC television ads; expanded authority of the Secretary of Health and Human Services (HHS) to require certain disclosures and statements; and civil monetary penalties for false or misleading ads. So far, Members of the 111th Congress have indicated interest in DTC advertising in the context of drug safety, tax treatment of advertising expenses, risk communication, and general FDA-activity authority and oversight, sometimes in the context of broader discussions of health care costs and reform.

This report examines these and other issues. It (1) describes the current status of DTC drug advertising; (2) analyzes issues surrounding it; and (3) discusses potential options for Congress. Specifically,

Part I–Current Picture

- describes the types, history, and extent of direct-to-consumer drug advertising in the United States;
- reviews the authority Congress has given FDA to regulate DTC advertising and how FDA has used that authority; and
- describes voluntary guidelines of some interested groups.

Part II–Issues

- explores what manufacturers, clinicians, and consumers want the ads to achieve;
- examines how DTC ads affect consumers, clinicians, and drug manufacturers; and
- discusses the major issues now debated by proponents and opponents of DTC drug advertising.

Part III–Potential Options

- discusses potential oversight and legislative options for Congress; and

[4] Drug companies rely on DTC advertising to stimulate demand and to increase sales for the products (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, 107th Cong., 1st sess., July 24, 2001, hereinafter cited as Glover testimony).

- concludes by relating DTC drug advertising to some of the larger issues affecting U.S. health care: cost, access, safety, among others.

Current Picture of DTC Advertising

Defining DTC Advertising

The World Health Organization defines "drug promotion" as "all informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."[5] Richard G. Frank, Harvard Medical School professor of health economics, describes DTC advertising more specifically as "[A]ny promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media."[6]

Although the Federal Food, Drug, and Cosmetic Act (FFDCA) regulates prescription drug "advertising," Congress did not define the term in the law.[7] In its regulations, however, FDA has listed examples: "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."[8] Academic experts in prescription drug law have noted that "FDA generally interprets [prescription drug advertising] to encompass information, other than labeling, that promotes a drug product and is sponsored by a manufacturer."[9]

DTC print advertising appears in magazines, newspapers, non-medical journals, pharmacy brochures, and direct-mail letters; companies also run DTC ads on television, radio, videos, billboards, and Internet Web sites. The ads usually fall into one of three categories.

- ***Help-seeking ads*** discuss a particular disease or health condition, advise the consumer to "see your doctor," but do not mention the product's name. They are directed towards consumers, make no health claims, and mention no specific drug.
- ***Reminder ads*** call attention to the product's name but make no reference to the health condition it treats. They make no health claims and FDA does not require that they contain full risk information. Although reminder ads may acquaint consumers with brand names of products, they are directed primarily towards

[5] Pauline Norris, Andrew Herzheimer, Joel Lexchin, and Peter Mansfield, *Drug promotion: what we know, what we have yet to learn*, World Health Organization and Health Action Int'l., 2005, p. 3, at http://www.who.int/medicines/areas/rational_use/drugPromodhai.pdf.

[6] 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. The authors attribute the definition to R.G. Frank et al., *Prescription Drug Policy Issues In California,* a report prepared for the California HealthCare Foundation, April 1999.

[7] The Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) is the primary source of FDA's authority to regulate drugs.

[8] 21 CFR 202.1(l)(1).

[9] Francis B. Palumbo and C. Daniel Mullins, "The Development of Direct-to-Consumer Prescription Drug Advertising Regulation," *Food and Drug Law Journal*, vol. 57, no. 3, 2002.

doctors and health care professionals who are more likely than consumers to know about the product and its use.

- ***Product-claim ads***—the type of most concern to FDA—include a product's name and a therapeutic claim for it. The regulations require that therapeutic claims not be false or misleading and that the ad present full risk information.

FDA's regulatory oversight is minimal for the first two, reflecting its statutory authority.[10] The third commands most of its attention and resources. DTC advertising is only one of the pharmaceutical industry's tools to influence prescription drug sales. Companies also promote drugs to physicians. They use direct advertising, such as ads in medical journals; reminders, such as logo-embossed pads and pens; and less well-defined tools, such as industry-funded seminars, residency training support, drug samples, and visits by "detailers," drug company representatives who visit doctors' offices with drug samples and educational materials. Although not a focus of this report, industry promotion to physicians appears to influence prescribing patterns.[11]

Spending on DTC Advertising

The pharmaceutical industry increased its DTC spending by 536% from 1996 to 2007.[12] To put this growth in perspective, the Consumer Price Index (all items) (which approximates the change in real dollars of the cost of placing advertising spots increased 24% during the same time period.[13] The increase in DTC advertising spending was more than 22 times higher than the CPI.

The top row in **Table 1** shows pharmaceutical industry spending on DTC advertising for the last 10 years; the other rows show pharmaceutical industry spending for other categories of prescription drug promotion and advertising. Using data from IMS Health, a for-profit source for "pharmaceutical market intelligence,"[14] **Table 1** also includes spending directed to professional

[10] FDA, at http://www.fda.gov/cder/handbook/adverdef.htm.

[11] Most doctors deny that these items improperly influence them (see, for example, Frederick S. Sierles, "Clinical Case: The gift-giving influence," *Virtual Mentor: Ethics Journal of the American Medical Association*, vol. 9, no. 6, June 2006, pp. 372-376, at http://www.ama-assn.org/ama/pub/category/16252.html; and Ashley Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *Journal of the American Medical Association*, vol. 283, no. 3, January 19, 2000, pp. 373-380).
Those who disagree point to social science research that finds that even small gifts create an often unconscious "impulse to reciprocate" (TA Brennan, DJ Rothman, L Blank, D Blumenthal, SC Chimonas, JJ Cohen, J Goldman, JP Kassirer, H Kimball, J Naughton, Neil Smelser, "Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers," *Journal of the American Medical Association*, vol. 295, no. 4, January 25, 2006, pp. 429-433).

IMS, conducting a test for an advertising agency, sent e-mail product reminders to one group of doctors and none to a control group. Those sent the e-mails wrote 11.2% more new prescriptions for those brands than did the others (IMS Health, "The E-Detail: How Well Does it Work? Objectively Measuring Program Impact," at http://www.imshealth.com.

[12] Data from "Total U.S. Promotional Spend by Type, 2003," "Total U.S. Professional Spend by Type," and "Total U.S. Value of Free Product Samples," IMS Health, Integrated Promotional Services™ and CMR, June 2004; and "Total U.S. Promotional Spend by Type, 2005," "Total U.S. Professional Promotional Spend by Type, 2005," and "Total U.S. Value of Free Product Samples, 2004," at http://www.imshealth.com.

[13] Bureau of Labor Statistics, Consumer Price Index (CPI-U all items), 1996-2005, Department of Labor, at http://data.bls.gov/PDQ/servlet/SurveyOutputServlet.

[14] IMS Health, "Total U.S. Promotional Spend by Type, 2003," "Total U.S. Professional Spend by Type," and "Total U.S. Value of Free Product Samples," IMS Health, Integrated Promotional Services™ and CMR, June 2004, at http://www.imshealth.com.

promotion (to physician offices, hospital-based physicians and pharmacists, and medical journals), and the reported retail value of product samples given to office-based physicians. In 2007, according to IMS data, drug companies spent 41.7% of their reported promotional spending on DTC advertising ($4.774 billion out of $11.453 billion).[15]

Manufacturers actually may spend more than that on promoting prescription drugs to consumers. Some analysts may use data that **Table 1** does not include, such as industry expenses for new ways to reach consumers. An online news reporter wrote, in May 2006, that "Coupons, money-back guarantees, rebates and other supermarket-friendly promotions offering '10 percent off,' 'free-trial offers' or 'buy six prescriptions, get one free' are now standard marketing tools for many top-selling prescription drugs."[16]

As in the past, television and magazines continue to be the major media targets for DTC advertising. In 2007, they accounted for over 90% of spending.[17] **Table 2** shows drug industry spending on DTC ads by placement.[18] For the past decade, media analysts have predicted large increases in Internet ad spending.[19] In 2007, however, Internet ads represented about 3% of DTC drug ad spending, indicating the anticipated growth has not yet occurred.[20]

[15] In earlier years, IMS included the retail value of drug samples provided to health care professionals in its tables of promotional spending, although the actual cost of the samples to industry is only a small fraction of the retail price. When the total is calculated to include the retail value of samples, the DTC advertising percentage of all reported promotional spending is greatly reduced. For example, see 2004, the last year for which IMS provided the retail value of samples. Excluding samples, DTC advertising was 33.9% of the total. Including samples, DTC advertising was 14.4% of the total.
Although IMS Health has not reported drug sample values for years after 2004, other sources have described decreased numbers of samples in 2007 overall, but increases in the 10 most sampled brands (Susan Vargas, "Under pressure: promotional spending is down as companies rationalize and optimize budgets," *Pharmaceutical Executive*, vol. 28, no. 5, May 2008, p. 87).

[16] Tony Pugh, "Old-style marketing for new drugs: Coupons elicit FDA attention," MercuryNews.com, May 6, 2006.

[17] TNS Media Intelligence, in *Medical Marketing & Media*, vol. 43, no. 6, June 2008, p. 53.

[18] Data used in Tables 1 and 2 come from different sources and the total DTC expenditure figures do not match; within each table, relationships among rows should be internally valid. The industry tracks subcategories of spending as well. Television, for example, includes network television, cable television, syndicated television, spot television, Spanish language network TV, Spanish language cable TV (*Med Ad News*, vol. 25, no. 5, May 2006).

[19] A 1999 discussion of the law related to drug advertising on the Internet noted that "market researchers predict that the Internet will become the single greatest source of health care information within the next five years" (Leah Brannon, "Regulating Drug Promotion on the Internet," *Food and Drug Law Journal*, vol. 54, no. 4, 1999, p. 599). See, also, "Healthcare Advertising Faces Upheaval With Small Share of Total Online Spend, Yet Fastest Rate of Growth, According to New Outsell Report," PharmaLive.com, April 24, 2006, athttp://www.outsellinc.com/press/press_releases/healthcare_advertising_faces_upheaval.

[20] Susan Vargas, "Under pressure: promotional spending is down as companies rationalize and optimize budgets," *Pharmaceutical Executive*, vol. 28, no. 5, May 2008, p. 87.

Table 1. Total U.S. Promotional Spending on Prescription Drugs, 1996-2007

(dollars in millions)

Type of promotion	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Direct to consumers	791	1,069	1,317	1,848	2,467	2,679	2,638	3,235	4,024	4,237	4,811	4,774
Direct to office-based physicians and hospital-based physicians and pharmacists[a]	3,010	3,364	4,057	4,320	4,803	5,491	6,200	6,938	7,336	6,777	6,741	6,262
Journal ads	459	510	498	470	484	425	437	448	499	429	464	417
Subtotal	4,260	4,943	5,872	6,638	7,754	8,595	9,275	10,621	11,859	11,443	12,016	11,453
Retail value of samples	4,904	6,047	6,602	7,230	7,954	10,464	11,909	13,531	15,866	[b]	[b]	[b]
Total	9,164	10,990	12,474	13,868	15,708	19,059	21,184	24,152	27,725	[b]	[b]	[b]

Source: Data from "Total U.S. Promotional Spend by Type, 2003," "Total U.S. Professional Spend by Type," and "Total U.S. Value of Free Product Samples," IMS Health, Integrated Promotional Services™ and CMR, June 2004; "Total U.S. Promotional Spend by Type, 2005," "Total U.S. Professional Promotional Spend by Type, 2005," and "Total U.S. Value of Free Product Samples, 2004"; and "Total U.S. Promotional Spend by Type, 2007," at http://www.imshealth.com.

a. For 2003-2005, IMS Health presented a combined figure for office-based physicians and hospital-based physicians and directors of pharmacies.

b. IMS Health has not provided the retail value of samples for years after 2004; this also affects the total.

Table 2. DTC Spending on Product Ads, by Medium

(dollars in millions)

Medium	2006		2007	
Television	2,667	56.3%	2,870	58.5%
Magazine	1,689	35.6%	1,768	36.1%
Newspaper	152	3.2%	75	1.5%
Radio	55	1.2%	30	0.6%
Internet	163	3.4%	155	3.2%
Outdoor	11	0.2%	4	<0.1%
Total	**4,739**	**100%**	**4,904**	**100%**

Source: TNS Media Intelligence, in *Medical Marketing & Media*, vol. 43, no. 6, June 2008, p. 53.

As drug companies expand their use of social marketing techniques, the traditional definition of DTC advertising may evolve.[21] The published data do not include other areas in which some observers suggest industry may be promoting its products. For example, product placement: "the insertion of a product or service into a script or scene of a TV show or movie, usually for a price negotiated with the network, producer, or scriptwriter."[22] This marketing tool is used to promote cars and computers, but its use for pharmaceutical products has not been confirmed. One researcher, having shown an increase in prescription drug mentions on TV shows, notes a "regulatory void" that FDA and the Federal Communications Commission (FCC) have yet to address.[23]

Chronological History of FDA's Authority to Regulate DTC Advertising

The Federal Food, Drug, and Cosmetic Act (FFDCA) sets forth the statutory requirements that pharmaceuticals must meet before they can be approved for marketing in the United States.[24] The initial 1938 law (P.L. 75-717), in addressing FDA's regulatory authority over *labeling*, prohibited statements to the effect of "This drug is FDA-approved" in any labeling or advertising material.[25] Otherwise, until the 1962 Kefauver-Harris amendments to the FFDCA (P.L. 87-781), statutory

[21] For example, using disease-group Web sites and other social marketing techniques "allow drug companies to reach very small niche groups, such as patients with a specific type of cancer.... " (Linda A. Johnson, "Consumer drug ads down this year, report says," *USA Today*, November 14, 2008). The Internet is one part of what some marketers call a "surround sound approach" that could include direct marketing, materials in doctors' offices, phone calls from nurse counselors, surveys, and newsletters ("United States annual pharmaceuticals direct-marketing advertising expenditures by advertising medium in dollars for 2002 to 2007, and forecast for 2008 and 2012," *Medical Marketing & Media*, vol. 43, no. 2, February 2008, p. 58). A marketer might use varied tactics in a coordinated effort to attract patients to a drug, perhaps have them switch from another brand, and then to retain the patients as customers.

[22] "Pharmaceutical product placements: the next DTC?" *Pharmaceutical Executive*, vol. 28, no. 10, October 2008, p. SS8.

[23] Ibid.

[24] For a description of the U.S. drug approval process, see CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by (name redacted).

[25] Section 201, FFDCA, P.L. 75-717, 1938.

authority for regulating any *advertising*—including that for prescription and non-prescription drugs—lay with the Federal Trade Commission (FTC).[26]

In 1962, Congress added Section 502(n) to the FFDCA to give the FDA the authority to regulate not only labeling, but also prescription drug advertising, including DTC advertisements, and other descriptive printed matter.[27] At the time, advertising was primarily printed material directed towards physicians. However, Congress prohibited ("except in extraordinary circumstances") FDA from issuing any regulations that would require *prior approval* of the content of any advertisement.

Initial Regulations (1969)

After passage of the 1962 FFDCA amendments, FDA needed to promulgate regulations and to provide guidelines to an industry producing what were now called "prescription" drugs.[28] In 1969, therefore, it issued final regulations governing drug advertising.[29] Under them, advertisements had to have four basic attributes:

(1) they could not be false or misleading;

(2) they had to present a fair balance of information about the drug's risks and benefits;

(3) they had to contain facts relevant to the product's advertised uses; and

(4) in general, the advertisement's "brief summary" of the drug had to include every risk listed in the product's approved labeling.

The regulations required that companies submit promotional materials to FDA at the same time they make them available to the public.[30] The promotion within these materials had to be supported by scientific evidence and be consistent with FDA-approved product labeling.[31] The

[26] The two agencies acted to avoid overlap based on a 1954 "Working Agreement Between the Federal Trade Commission and the Food and Drug Administration." FDA and FTC amended the Agreement in 1968 "to provide explicit guidelines for prescription drug advertising" and again in 1971 (Francis B. Palumbo and C. Daniel Mullins, "The Development of Direct-to-Consumer Prescription Drug Advertising Regulation," *Food and Drug Law Journal*, vol. 57, no. 3, 2002).

[27] 21 USC 352(n).

[28] The 1951 Durham-Humphrey Amendment to the FFDCA defined in law for the first time a distinction between medications that required physician supervision and those that did not (Alan H. Kaplan, "Fifty Years of Drug Amendments Revisited: In Easy-to-Swallow Capsule Form," *Food and Drug Law Journal*, vol. 50, no. 5, 1995, pp. 179-196).

[29] 21 CFR 202.1.

[30] 21 CFR 314.81(b)(3)(I).

[31] FFDCA Sec. 201(m) defines labeling to include "... all labels and other written, printed, or graphic matter ... accompanying" the drug. FDA regulations (21 CFR 202.1(l)(2)) include examples of labeling, which is also known as the full prescribing information: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio or visual matter descriptive of a drug and references published (for example, the Physician's Desk Reference) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the FD&C Act." See FDA, "Advertising/Labeling Definitions," at http://www.fda.gov/cder/handbook/adverdef.htm.

ads could be the approved labeling or other promotional materials, but could not recommend or suggest any use of a drug that was not listed in the approved drug's labeling.

When FDA wrote the 1969 regulations, industry advertised its drugs to physicians through print ads in medical journals. Complying with the regulations was relatively straightforward. In 1981, when companies wanted to direct ads to consumers, FDA, after a two-year moratorium on DTC ads, announced that the current regulations were sufficient to protect the consumer. 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.[32]

It remained unclear, however, how TV and radio ads could comply with the regulations. Conveying all of a product's risk information in print advertising may be cumbersome but it is not difficult. However, the drug industry asserted,[33] including all details in a 30-second broadcast ad is cumbersome, expensive, and unlikely to be possible. FDA had not issued any interpretation of how broadcast advertisements could fulfill that requirement, so, until 1997, the industry assumed that FDA expected broadcast DTC advertising to meet the same requirements as ads in print.[34]

Guidance for Broadcast Ads (1999)

In August 1997, FDA issued draft guidance on how pharmaceutical companies could fulfill the existing regulatory requirements for advertising drugs on radio and television. It published the final guidance, without major change, two years later.[35] The agency explained that the 1969 regulations had always allowed broadcast advertisements to either include all the drug's risks or ensure that consumers would have easy access to the full prescribing information within FDA-approved labeling. The guidance made clear that DTC broadcast advertisements had to include what FDA called the "major statement"—the product's most important risks. This had to be in the audio portion of the advertisement, and could be in the video portion as well.[36] In addition, the advertisement had to describe how the consumer could obtain the full package labeling.

With the 1999 guidance—which is still in effect now—FDA attempted to ensure that consumers with different information-seeking needs and abilities have adequate access to the product labeling. As part of that attempt, the guidance presented "one acceptable approach" to the required broad dissemination of this information: that ads include an Internet site and a toll-free telephone number where listeners could get that information; a reminder that one's doctor may have more information and a list of other print sources with large circulations.[37]

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[32] See http://www.fda.gov/cder/guidance/index.htm.

[33] PhRMA, "Direct to Consumer Advertising," *Backgrounders and Facts*, at http://www.phrma.org/publications/backgrounders/2000.

[34] 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.

[35] FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements*, Division of Drug Marketing, Advertising, and Communications (DDMAC), August 1999, at http://www.fda.gov/cder/guidance/1804fnl.htm. 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, August 9, 1999).

[36] Pines, 1999.

[37] FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements*, August 1999. Also see Council on Ethical and Judicial Affairs of the American Medical Association, "Direct-to-Consumer Advertisements of Prescription (continued...)

Draft Guidance for Print Ads (2004)

By 2004, after an enormous increase in DTC ads, FDA moved to change its policy on those appearing in print. It was concerned that the long and technical risk descriptions in ads were hard for consumers to understand. FDA requires that any prescription drug advertisement contain "information in brief summary relating to the side effects, contraindications, and effectiveness" of the drug.[38] 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. Consequently, ads in print often include the entire section of the approved professional labeling with its side-effects and warnings.

Therefore, in January 2004, FDA issued three draft guidances: *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (referred to as Brief Summary Guidance below), "*Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* (referred to as Disease Awareness Guidance below), and a third on medical device advertising (which will not be discussed here).

FDA had long required that drug firms disseminate truthful, non-misleading, and scientifically accurate information. FDA now tried, with each of these three guidances, to improve required formats so consumers and health care practitioners could understand and use the information. Now, in 2009, while FDA still describes these documents as draft guidances, they represent current FDA practice.

Brief Summary Guidance

This 2004 draft guidance indicated that, to be in compliance with the statutory brief summary requirement, the following must be printed: 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. The draft guidance then offered manufacturers three options (other than printing the entire professional labeling) for presenting that information to satisfy the brief summary requirement for DTC print ads.[39]

The first option would be to reprint the FDA-approved *patient* labeling in full.[40] 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 would allow printing

(...continued)

Drugs," *Food and Drug Law Journal*, vol. 55, 2000, p. 120. 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 (Alex Frangos, "Special Report: E-Commerce; Prescription for Change," *Wall Street Journal*, April 23, 2001).

[38] FFDCA 502(n) [21 USC 352(n)].

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

[40] 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.

the "highlights" section of the professional labeling, a format FDA had proposed earlier.[41] But because this highlights section would be written for medical professionals, FDA recommended that it be rewritten so consumers could understand it. The agency also asked drug firms to consider the costs and benefits of each of these options and decide for themselves which option is best.

Supporters of the draft guidance say that shorter ads would mean that industry will spend less and consumers will understand more. Critics argue that this approach may be appropriate for only a small subset of products. They also argue that FDA should develop guidelines requiring risk disclosures that patients can use in discussions with health professionals.[42]

Because the Federal Trade Commission (FTC) regulates most advertising in the United States, FDA asked it to review the three January 2004 draft guidance documents. FTC 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 "determine ... the most effective means of providing drug risk information in DTC print ads."[43] They suggested assessing the various ways to present risk information, the influence on industry's advertising incentives, and other costs and benefits of the proposed and other formats.

Disease-Awareness Guidance

The agency clarifies in this guidance when it does and does not have jurisdiction over help-seeking ads, which encourage consumers to seek treatment for a medical condition.[44] The draft "Disease Awareness Guidance"[45] provides recommendations on how to make these ads perceptually distinctive from product advertising.[46]

FDA Amendments Act of 2007

Congress addressed DTC advertising more than once in its wide-ranging FDAAA. The issue fit within provisions for funding, drug safety, labeling, and enforcement.[47]

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[41] 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.

[42] 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*, Issue 6, November/December 2004, pp. 8-12.

[43] FTC, "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/2004/05/040512dtcdrugscomment.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/dtcdrugs.htm.

[44] The FTC 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, specifies drugs and devices).

[45] FDA, "[Draft] Guidance for Industry: 'Help-Seeking' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms," January 2004, at http://www.fda.gov/cder/guidance/6019dft.doc.

[46] "Disease Awareness Ad Guidance Stresses Need for 'Distinct' Messages," *The Pink Sheet*, F-D-C Reports, Inc., Chevy Chase, MD, February 9, 2004, p. 6.

[47] CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by (name redacted) and (name redacted).

New Fees for the Advisory Review of Advertisements

The law authorized the assessment and collection of fees relating to advisory review of certain drug advertisements. Manufacturer requests for pre-dissemination review of direct-to-consumer (DTC) television drug advertisements would be voluntary, and FDA responses would be advisory. Only manufacturers that request such reviews would be assessed the new fees, which would include an advisory review fee and an operating reserve fee. The law authorized $6.25 million in revenue for each of FY2008 through FY2012, adjusted for inflation and workload. It also set a date by which the Secretary would have to had collected at least $11.25 million in advisory review fees and operating reserve fees combined or else the DTC television advertisement advisory review user fee program could not begin.

FDA announced in January 2008 that it would not begin the DTC television advertisement advisory review fee program. FDAAA authorized FDA to collect and spend user fee funds for the advisory review of DTC television advertisement only if the fees have been appropriated. The Consolidated Appropriations Act, 2008 (P.L. 110-161) did not appropriate user fee funds for that program (*Federal Register*, vol. 73, no. 11, January 16, 2008, p. 2924).

Review Before Dissemination

FDAAA authorized the Secretary to require a pre-review (at least 45 days before dissemination) of any television advertisement for a drug. Based on this review, the Secretary may recommend changes that are necessary to protect the consumer, or that are consistent with prescribing information for the product under review; and, if appropriate, statements to include in advertisements to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities. The Secretary may, in formulating recommendations, take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities. Although the amended law described the process for the Secretary to make recommendations, it did not authorize the Secretary to make or direct changes in any material submitted pursuant to this subsection. [Note that this provision addresses the law's earlier prohibition of FDA's requiring *pre*-publication review and approval of an ad. The law continues to require the manufacturer to submit the ad to FDA upon its release.]

Disclosure Requirements

The Secretary may require inclusion of a disclosure in an advertisement if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved.

The Secretary may require, for not more than two years from approval, the advertisement to include a specific disclosure of the approval date if the Secretary determines that the advertisement would otherwise be false or misleading.

Presentation of Side Effects and Contraindications

In a television or radio direct-to-consumer (DTC) advertisement of a drug that states the name of the drug and its conditions of use, the major statement relating to side effects and contraindications must be presented in a clear, conspicuous, and neutral manner. The Secretary

must establish standards, by regulation, for determining whether a major statement meets those criteria.

Civil Penalties

FDAAA established civil penalties for the sponsor of a drug or biologic who disseminates a DTC advertisement that is false or misleading. It authorized a civil monetary penalty not to exceed $250,000 for the first violation in any three-year period, and not to exceed $500,000 for each subsequent violation in any three-year period. No other civil monetary penalties in this act shall apply to a violation regarding DTC advertising. Repeated dissemination of the same or similar advertisement prior to the receipt of a written notice shall be considered one violation. After such notification, all violations under this paragraph occurring in a single day shall be considered one violation. The law directed how to consider publications published less frequently than daily, and specifies procedures, after the provision of written notice and opportunity for a hearing, regarding reviews, subpoenas, modifications, and judicial review. Civil penalties may not be assessed if the sponsor had submitted an advertisement for pre-review and incorporated each comment received from the Secretary. If an applicant fails to pay an assessed civil penalty, the Attorney General may recover that amount plus interest.

Study on Risk Communication in DTC Advertising

The Secretary must, with the advice of the Advisory Committee on Risk Communication and within two years of enactment, report to the Congress on DTC advertising and its ability to communicate to subsets of the general population. The Advisory Committee on Risk Communication must study DTC advertising as it relates to increased access to health information and decreased health disparities for these populations, and make recommendations in a report that the Secretary must submit to Congress.

Study on Benefit-Risk Assessments

The Commissioner must submit to Congress, within a year of enactment, a report on how best to communicate to the public the risks and benefits of new drugs and the role of the FDAAA-required risk evaluation and mitigation strategy (REMS) in assessing such risks and benefits. As part of such study, the Commissioner shall consider the possibility of including in the labeling and any DTC advertisements of a newly approved drug or indication a unique symbol indicating the newly approved status of the drug or indication for a period after approval.

Toll-Free Number in Print Ads

Any published DTC advertisement must include the following statement printed in conspicuous text: “You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.”

The Secretary must, in consultation with the Advisory Committee on Risk Communication, study whether the statement required in published DTC advertisements is appropriate for television DTC advertisements; and report findings and determinations to Congress. If the Secretary determines that including the statement is appropriate, the Secretary must issue regulations to implement such a requirement.

FDA's Review and Enforcement Activities

In 2003, FDA received approximately 38,000 promotional items from drug companies. Of those, somewhat more than 6,000 were print or broadcast ads, and other pieces, aimed at consumers.[48] Manufacturers submit these ads to fulfill the legal requirement that they notify FDA that the ads were running. Manufacturers are not seeking approval of the content or permission to run the ads. It is up to FDA to decide whether the agency should review an ad to see whether it contained false or misleading information—or left out information the law required.

If FDA believes an ad is problematic, it can respond with increasingly severe steps. While the passage of FDAAA in 2007 authorized additional tools (described earlier in this report), FDA continues to respond through its traditional steps: an untitled letter, a warning letter, and an injunction.

Letters. FDA can send two types of letters to inform the company that the advertisement violates the FFDCA. The first step is a Notice of Violation, which the agency calls an "untitled letter." 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 risk. FDA has the authority to use a second and stronger option. The "warning letter" orders advertisers to respond by a specific deadline. If they don't FDA can take a third step.

Injunction. If warning letters don't succeed, FDA can work with the Department of Justice to seek injunctions against companies. These present companies with a number of possibilities: criminal prosecution, FDA seizure of drugs intentionally misbranded or misleadingly advertised, or the withdrawal of FDA approval for the drug. Very few such cases have actually come to court. In 1995, though, 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.

FDA believes that the threat of such action makes the warning letter a powerful tool in its regulatory arsenal.

How often does FDA take any of these actions? In 2008, the agency sent 21 letters—10 warning and 11 untitled—concerning promotional labeling, broadcast ads, or print ads that did not comply with regulations.[49]

What kinds of corrections does FDA usually demand? It asks companies to stop running the offending ad. It also may ask them to disseminate corrective information to segments of the audience such as physicians, pharmacists, and patients. At times, FDA directs the companies to run ads in the same media to correct the misleading impressions left earlier.

Courts that have examined FDA's authority to regulate DTC advertisements, have ruled that the agency should not impose unnecessary restrictions on "commercial speech."[50] One unfavorable

[48] Estimate from statement of Janet Woodcock, CDER director, FDA, before the Senate Special Committee on Aging, July 22, 2003, at http://www.fda.gov/ola/2003/AdvertisingofPrescriptionDrugs0722.html.

[49] See FDA warning letters at http://www.fda.gov/cder/warn/warn2008.htm.

[50] 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.

court decision[51] on such regulation led the agency to question whether it continues to have enough authority to do so. In reaction, FDA published in the Federal Register in May 2002 a notice requesting comment on "commercial speech" issues under the First Amendment.[52] The notice solicited public comments about FDA's legal basis for its regulations, guidances, policies, and practices to ensure the agency continues to comply with the law. Comments have come in over the years but FDA has not yet responded.

The Government Accountability Office (GAO) November 2006 report on DTC drug advertising, noting that FDA reviews only some of the ads, pointed to FDA's "lack of documented criteria for identifying and prioritizing DTC materials for review." Nor does FDA, wrote GAO, track what ads are received or which are reviewed.[53] GAO had made similar comments in a 2002 report.[54] Both reports discussed the amount of time FDA takes to issue regulatory letters, a period during which consumers are exposed to false or misleading information. That length of time increased between the two reports, which the GAO attributes to a 2002 FDA policy that requires the Office of the Chief Counsel to review all draft regulatory letters.

FDA has the statutory authority to impose requirements on the content of advertisements to ensure that ads provide accurate and balanced information. Although FDA officials say the agency does not keep track of the number of ads it receives and reviews, it does not review all DTC ads. In its proposal for a new user fee program to fund its review of DTC television advertising (enacted in FDAAA), FDA proposed a FY2008 performance goal that indicated the agency's current limited resources. Based on an estimated 225 ads (both original and resubmissions), FDA proposed to review 50% of the original submissions within 45 days.

The 111th Congress will likely assess how FDA—with its FDAAA-enhanced authority and possible new directions from a new administration—proceeds.

So far this section has reviewed steps in the formal procedure granted FDA by statute. There is an important informal practice, however, that influences ads aimed at consumers: *prior review*.

Although the law prohibits FDA from requiring prior approval of ads, it does allow FDA to review draft materials that manufacturers voluntarily submit for comment. Drug manufacturers do that to avoid the expense of pulling an already launched ad campaign. In 2007, the agency issued

[51] *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). In this case, the Supreme Court struck a 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.

[52] "FDA Seeks Comment on Ad Regs: Can Rx Be More Regulated Than OTCs?" *The Pink Sheet*, v. 64, no. 20, May 20, 2002, p. 14; and HHS, FDA, Request for Comment on First Amendment Issues, 67 *Federal Register* 34942, May 16, 2002. See also CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by (name redacted).

[53] U.S. Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, GAO-07-54, November 2006.

[54] U.S. General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177, October 2002.

520 advisory letters to companies regarding their proposed promotional pieces, including items intended for both consumers and clinicians.[55]

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.[56]

Funding

Within FDA's Center for Drug Evaluation and Research (CDER), the Division of Drug Marketing, Advertising, and Communications (DDMAC) handles the bulk of review and enforcement activities regarding drug promotion.[57] According to FDA's Office of Budget and Program Analysis, the DDMAC's total budget for FY2008 was over $9 million, of which 63% was for the review of DTC advertisements. This reflects about a $6 million increase in direct appropriations for DTC advertising review that Congress also included in the Omnibus Appropriations Act for FY2009 (P.L. 111-8).[58]

One source of funds for regulating DTC advertising could be fees collected under the Prescription Drug User Fee Act (PDUFA).[59] PDUFA's initial authorization in 1992 and its 1997 reauthorization (PDUFA II) restricted FDA's use of user fees to new drug reviews. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), which included the PDUFA III authorization, expanded that authority to drug safety activities. It also *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 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. Although the authorization reflected Congress' general concern over drug safety, Congress did not appropriate those sums.

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 and to increase the agency's efforts to provide consumers with the latest information about newly approved drugs.[60]

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[55] FDA, "CDER 2007 Update: Drug Promotion Review," July 31, 2008, at http://www.fda.gov/cder/reports/rtn/2007/12_promotion_review.htm.

[56] Thomas W. Abrams, FDA Division of Drug Marketing, Advertising, and Communications, "DDMAC Update-Regulation of Prescription Drug Promotion," February 26, 2004, slide presentation at http://www.fda.gov/cder/ddmac/Presentations/DIA/DIA%20022604%20Slides.ppt.

[57] DDMAC had about 50 full-time equivalent employees in FY2008 (FDA Office of Budget and Program Analysis, telephone conversation, March 18, 2009). In 2003, about 40 people worked in DDMAC (Woodcock, July 2003 Senate testimony).

[58] The FDA Office of Budget and Program Analysis provided details of FY2008 direct appropriations for DDMAC (by telephone, March 18, 2009, in response to CRS request to the FDA Office of Legislation). In contrast, DDMAC's total budget for FY2006 was $4.26 million, of which almost 21% was for the review of DTC advertisements.

[59] For a description and analysis of PDUFA, see CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by (name redacted).

[60] See CRS Report RL31453, *The Prescription Drug User Fee Act: Structure and Reauthorization Issues*, by (name red acted) and (name redacted).

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 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.[61]

PDUFA IV, part of FDAAA of 2007, authorized $6.25 million per year in new user fees to help fund the review of the DTC television ads that manufacturers ask FDA to review before their public release. FDA noted that this would more than double the entire DDMAC budget and increase sevenfold the amount spent on review of DTC ads. The fees would fund an additional 27 full-time equivalent (FTE) reviewers; currently, there are about 8 FTEs who review broadcast ads.[62] Rather than allow the collection of this new user fee, the appropriators increased the direct appropriations for DTC advertising review, as noted above.

Voluntary Guidelines from Other Interested Parties

To continue the status quo leaves the United States as one of only two countries that allow DTC prescription drug advertising.[63] The federal government, though, is not the only organization trying to create ethical standards for DTC ads. The American Medical Association (AMA) adopted changes in its policy statement on DTC advertising at its annual convention in June 2006.[64] The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a set of 15 DTC advertising guidelines, effective January 2006, as part of a plan that included a new Office of Accountability, an Independent Review Panel, and reports to the public. In a December 2008 revision (effective March 2, 2009), PhRMA added items reflecting the AMA position on physician participation in ads and actors portraying physicians.[65]

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[61] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by (name redacted).

[62] Presentation to congressional staff by Theresa Mullin, FDA Assistant Commissioner for Planning, accompanied by Jane Axelrad and Steve Mason, January 2007.

[63] The only other country allowing DTC advertising is New Zealand. The United States and New Zealand do not have the same regulatory system. New Zealand relies on an industry-based advertising framework or code of conduct. All ads making therapeutic claims must be pre-approved by the Association of New Zealand Advertisers, Therapeutic Advertising Pre-vetting Service; also, the media, which depends on ads for revenue, is responsible for accepting only ads that have been pre-approved (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 2002, pp. 202-212). Similar to the United States, the New Zealand law requires that the advertisement contain information including active ingredients, authorized uses, appropriate precautions, contraindications and adverse reactions. New Zealand and Australia had worked to combine regulatory activities that concern prescription drugs and advertising. Their proposed model for advertising, accepted by an interim council in 2005, set forth three key principles and 11 requirements. In 2006, they issued the "Draft Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006" for public comment (The "Joint Regulatory Scheme for Advertising of Therapeutic Products" and other relevant documents are available at http://www.tgamedsafe.org/advert/advmodel.htm; and the 2006 rule is at http://www.anztpa.org.nz/consult/dr-advertrule.pdf). In 2007, plans for a trans-Tasmanian regulatory authority were dropped ("Postponement of the ANZTPA Establishment Project," New Zealand Medicines and Medical Devices Safety Authority, at http://www.anztpa.org.nz).

[64] The AMA website presents all of the 2006 convention recommendations marked-up to show the changes to be made to existing policy; this is available at http://www.ama-assn.org/ama1/pub/upload/mm/471/comeannotateda06.doc. The approved AMA Policy H-105.988, "Direct-to-Consumer Advertising of Prescription Drugs and Implantable Medical Devices (DTC)," is at http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-105.988.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/H-100.997.HTM&nxt_pol=policyfiles/HnE/H-105.988.HTM&.

[65] PhRMA, "PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines," revised (continued...)

Issues

Most of the controversy over DTC advertising revolves around five questions:

- Does DTC advertising create an adequately informed consumer?
- Does DTC advertising increase communication between doctor and patient?
- Does DTC advertising lead to better diagnosis, treatment, or disease management?
- Does drug use influenced by DTC advertising harm patients?
- Does DTC advertising affect consumer spending?

These questions are addressed below.

Does DTC advertising create an adequately informed consumer?

There is little dispute that DTC advertising informs consumers; however, the extent to which consumers are adequately informed is less clear. In general, ads describe real conditions, list documented symptoms, and contain or refer to pages of labeling information carefully reviewed for accuracy by the FDA.

DTC ads reach many people, as well. In a 2002 FDA national telephone survey, most patients (81%) were aware of DTC ads and knew that the ads contained both benefit and risk information.[66] A 2003-2004 telephone survey by *Prevention* magazine focused on ads for eleven prescription drugs. It found that 96% of its 1,502 interviewees had seen an ad for at least one of the drugs.[67]

But if one defines "informed consumers" as those who not only read or hear an ad, but also understand it—and understand the limitations of what the ad includes—then the picture is less clear.

The question that concerns critics of DTC ads is really whether consumers are *adequately* informed. Are the ads accurate enough? Are they complete enough? Do they balance the

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November 2005, at http://www.phrma.org/files/2005-11-29.1194.pdf; revised December 2008, at http://www.phrma.org/files/PhRMA%20Guiding%20Principles_Dec%2008_FINAL.pdf.

[66] 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, November 19, 2004. (Hereinafter FDA–Aikin, 2004.) The survey included English-speaking adults who had visited a health care provider within the last three months for a health condition of their own. For the 1999 survey, a 65% response rate yielded 960 patients. For the 2002 survey, a 53% response rate yielded 944 people. The physician survey, which interviewed 250 primary care and 250 specialty physicians, achieved a 46% response rate from physicians chosen randomly from the American Medical Association master file.

[67] Ed Slaughter, Corporate Director, Advertising and Trends Research, Rodale Inc., 7th Annual Survey (2003-2004), "Consumer Reaction to DTC Advertising of Prescription Medicines," *Prevention Magazine*, 2004. (Hereinafter Prevention—Slaughter, 2004.)

discussion of risks and benefits in a way that reflects the research? Can consumers understand them?

To look closely at those questions is to see several important issues. First, most people do not read the entire ad. After seeing a DTC print ad, only 10% of respondents to the FDA survey said they read the entire "brief summary"—the detailed material dealing with risks and benefits.[68]

Second, not all consumers understand the DTC ads they do read or hear. Half of all American adults read at or below an eighth grade reading level.[69] What does this mean when it comes to health literacy and behavior? The most often-quoted survey on this issue is still a 1995 Emory University study of patients seeking care at two urban, public hospitals. One telling finding: 42% could not understand the sentence, "Do not take on an empty stomach."[70]

That many consumers cannot understand the technical language in DTC ads does not necessarily implicate the pharmaceutical industry. Researchers on "health literacy" now see the effects of reading levels on how Americans seek care, follow treatment and medication instructions, and use Internet health material. Compounding these difficulties is an artifact of the historical development of DTC drug advertising. In the 1960s, when Congress added the advertising section to the FFDCA and FDA promulgated the related regulations, almost all drug ads were print ads aimed at doctors.[71] The requirement that those print ads contain the FDA-approved labeling language ensured that physician-readers would have all the information about a drug's risks and benefits. The requirement continues today. Thus, even now the labeling language that appears in many ads is more complicated than what a consumer at an average reading level could understand.[72]

In addition to what consumers do or understand, there is a third issue contributing to whether they are adequately informed. Information may be understandable but not be wholly accurate or balanced. One 2000 study found that less than a third of DTC ads acknowledge competing treatments, and only 9% contain estimates of how often drugs are effective.[73]

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[68] FDA–Aikin, 2004.

[69] Darrell M. West, "State and Federal E-Government in the United States, 2003," September 2003, at http://www.insidepolitics.org/egovt03us.html.

[70] M.V. Williams, P.R. Parker, D.W. Baker, N.S. Parikh, K. Pitkin, W.C. Coates and J.R. Nurss, "Inadequate functional health literacy among patients at two public hospitals," *Journal of the American Medical Association*, vol. 274, no. 21, December 6, 1995. A similar study in a Medicare managed care population found that 48% of the patients with inadequate or marginal health literacy (34% of English speakers and 54% of Spanish speakers) could not correctly interpret directions "How to take medication on an empty stomach" (Julie A. Gazmararian, David W. Baker, Mark V. Williams, Ruth M. Parker, Tracy L. Scott, Diane C. Green, S. Nichole Fehrenbach, Junling Ren, and Jeffrey P. Koplan, "Health Literacy Among Medicare Enrollees in a Managed Care Organization," *Journal of the American Medical Association*, vol. 281, no. 6, February 10, 1999, pp. 545-551).

[71] David L. Riggs, Stacy M. Holdsworth, and David R. McAvoy, "Direct-To-Consumer Advertising: Developing Evidence-Based Policy To Improve Retention And Comprehension," *Health Affairs*, Web Exclusive, April 28, 2004, pp. W4-249-252.

[72] Yet, many, but not most, consumers believe they are getting sufficient information. The *Prevention* report (Prevention—Slaughter, 2004, tables 22, 24, and 34) notes, for example, that among the 36% who read the "brief summary" in a print ad, 32% found it "very clear." It also found that 32% say that the DTC ad "provides enough information to decide if benefit of using advertised drugs outweighs risk."

[73] Wilkes et al., 2000.

In 2000, questions about the information conveyed in advertising led the American Medical Association (AMA) Council on Ethical and Judicial Affairs to review studies of ad content accuracy, arguments for and against DTC advertisements, and physician attitudes.[74] The Council found, for example, that 44% of promotional material to physicians "would lead to improper prescribing," and recommended that physicians "assess and enhance the patient's understanding of what the treatment entails ... resist commercially induced pressure to prescribe such drugs when not indicated ... deny requests for inappropriate prescriptions ... educate patients ... [and] remain vigilant to ensure that DTC advertising does not promote expectations."

Language and persuasion experts agree that one way of persuading audiences is to use the well-respected expert. But what if pharmaceutical ads present an actor who plays an expert in a show, or celebrities Americans admire—and therefore trust—with no expertise at all? Recently such ads have starred well-known performers speaking of their own conditions (Dorothy Hamill, Robert Dole), popular actors (Mandy Patinkin), or real physicians who are not experts in the condition they endorse (Robert Jarvik). Other celebrities (Terry Bradshaw) appear on talk shows, speaking about their own medical difficulties and treatment without acknowledging that a drug company pays them for that exposure.

Concerned that these activities could mislead the public, the American Medical Association issued guidelines in 2006 urging advertisers to, first, not cast actors as physicians in DTC drug ads, and, second, if they do, to include a prominent disclaimer. The AMA guidelines also urged its members to avoid appearing in DTC promotions.[75]

The 2006 AMA trustees' committee report on DTC ads asked "Is DTC educational?" It reported that survey data indicate most doctors would not agree and that their "views are supported by a growing body of scientific research that suggests DTC is not as educational as its proponents would like it to be believed."[76]

A recent study of what information people would like to see in drug advertisements indicated that consumers wanted additional—and quantitative—information about side effects. The author notes that these preferences go beyond what FDA now requires; he concludes by recommending that FDA make specific changes to its regulations.[77]

But DTC ads do not have to meet all the claims of their boosters to be educational. "The good news," says health economist Frank, referring to ads about depression, "is that many people now come in [for treatment] who have serious problems, who otherwise might not."[78] Billy Tauzin, president and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), an association representing U.S. research-based pharmaceutical and biotechnology companies, refers

[74] American Medical Association (AMA) Council on Ethical and Judicial Affairs, "Direct-to-Consumer Advertisements of Prescription Drugs," *Food and Drug Law Journal*, vol. 55, 2000, p. 121.

[75] Editorial, "Building a better drug ad: Direct-to-consumer marketing," *American Medical News*, July 24/31, 2006, at http://www.ama-assn.org/amednews/2006/07/24/edsa0724.htm.

[76] AMA, Report 9 of the Board of Trustees (Duane M. Cady, Chair), "Direct-to-Consumer Advertising of Prescription Drugs," for consideration at the 2006 annual meeting regarding resolutions 507, 519, 524, 532, 533, and 534 from the 2005 annual meeting, at http://www.ama-assn.org/ama1/pub/upload/mm/471/bot9A06.doc.

[77] Joel J. Davis, "Consumers' Preferences For The Communication Of Risk Information in Drug Advertising," *Health Affairs*, vol. 26, no. 3, May/June 2007, pp. 863-870.

[78] Richard Frank interview quoted in: Ashley Pettus, "Psychiatry by Prescription," *Harvard Magazine*, July-August 2006, p. 90.

to DTC advertising as "a powerful tool for reaching and educating millions of people,"[79] and gives examples of people learning from ads about diseases and treatments.

In addition to citing evidence of the important and positive effects of DTC promotion, Tauzin spoke of ongoing challenges that other industry leaders acknowledge, referring to DTC advertising as "a lightening-rod in the health care debate." Introducing PhRMA's *Guidelines on Direct-to-Consumer Advertising*, Tauzin acknowledged responsibilities that go beyond legal compliance with FDA regulations.[80]

Do DTC ads adequately inform consumers? The cautious tone of the AMA statement, as well as the questions that both critics and supporters raise about understandability, completeness, and accuracy, suggest that consumers could still use more—or different—information than they get.

Does DTC advertising increase useful communication between doctor and patient?

According to surveys of patients and clinicians, DTC ads do increase discussions. Those surveys, however, indicate mixed views of whether that communication is useful. The FDA patient survey reported that DTC ads prompted 43% of respondents to look for more information about a drug or medical condition, with almost 89% of those individuals seeking the information from their physicians (i.e., about 38% of all surveyed).[81] Similarly, 32% of respondents to the *Prevention* survey reported discussing an advertised drug with their physicians.

In April 2006, *PLoS* (Public Library of Science) *Medicine* ran seven essays on "disease mongering," which the lead article defined as "... the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments."[82] The next month, a *Washington Post* article—with the headline "Marketing the Illness and the Cure? Drug Ads May Sell People on the Idea That They Are Sick"—used "restless legs syndrome" to point out the inexact line between attempts to diagnose and treat the small number of people with a serious "bona fide condition," and industry and media actions that take "something that is within normal bounds and label[ing] it a disease needing pharmaceutical treatment."[83]

In a 2002 survey, FDA asked office-based physicians how DTC advertising influenced their practices and their relationships with patients. The respondents reported mixed opinions, saying

[79] Billy Tauzin, "Putting Patients First to Keep Health Care in America the Best in the World," keynote address before the American Legislative Exchange Council Annual Dinner, Gaylord, Texas, October 24, 2005, at http://www.phrma.org/straight_talk_from_billy_tauzin/.

[80] Pat Kelly, "DTC Advertising's Benefits Far Outweigh Its Imperfections," *Health Affairs*, Perspectives, April 28, 2004, pp. W4-246-248; Hank McKinnell (former Chairman & CEO, Pfizer Inc.) with John Kador, *A Call to Action: Taking Back Healthcare for Future Generations*, New York: McGraw-Hill, 2005, p. 180; and Billy Tauzin, "A Research-based Pharmaceutical Sector Built to Meet The Challenges of the 21st Century," remarks before the National Venture Capital Association, San Diego, Calif., April 26, 2006, at http://www.phrma.org/straight_talk_from_billy_tauzin/.

[81] Respondents said they sought information (after seeing a DTC advertisement) from their pharmacists (51%), their physicians (89%), reference books (40%), and friends, relatives, and neighbors (38%) (FDA–Aikin, 2004).

[82] Ray Moynihan and David Henry, "The fight against disease mongering: Generating knowledge for action," *PLoS Med* 3(4):e191, April 2006.

[83] Rob Stein, "Marketing the Illness and the Cure? Drug Ads May Sell People on the Idea That They Are Sick," *Washington Post*, May 30, 2006, p. A3.

that DTC ads increased patients' awareness of possible treatments (72%), but lead patients to overestimate the drugs' efficacy (75%). Among the primary care physicians, 38% responded that the overall influence on their patients and practices of DTC ads was somewhat or very negative; 27% of the specialists responded similarly.[84]

Does DTC advertising lead to better diagnosis, treatment, or disease management?

The 2002 FDA survey found that DTC ads *can* improve patient compliance with physician advice, particularly if physicians remind patients to take the medication as prescribed.[85] At least as of 2000, the authors noted that there is "little research on the clinical consequences" of DTC advertising.[86] To examine this would involve measurement of compliance, outcomes, and other issues.

The industry argues, and some consumers report, that DTC ads encourage patients to seek medical advice for conditions that sometimes go untreated. IMS Health cites urinary incontinence and erectile dysfunction as examples of underdiagnosed and undertreated conditions for which some consumers would not seek medical attention or would be reluctant to discuss with a clinician. The information and tone in DTC ads could precipitate a visit to a doctor.[87]

There is some quantitative evidence supporting the view that DTC ads influence at least some diagnoses and treatment decisions. A group of Harvard and Harris poll researchers asked consumers and physicians how DTC ads affected their encounters. Among consumers who had seen a DTC advertisement, 35% had discussed advertised drugs with their doctors, one-fifth discussed a new concern, one-third discussed a possible change in treatment, and one-quarter were given new diagnoses. The authors discussed the benefits of these diagnoses, 41% of which were for what they called "high priority" conditions.[88]

Despite those figures, the Harvard/Harris survey drew a response from another Harvard health researcher, Jerry Avorn, who criticized the study's industry funding and its conclusion that the "practice [of DTC advertising] is benign."[89] Avorn wrote that the group's data showed, "those heavily influenced by (DTC ads) were no more likely to have new conditions diagnosed or confirmed and were much less likely to have laboratory studies ordered or lifestyle changes recommended."

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[84] FDA–Aikin, 2004.

[85] FDA–Aikin, 2004; and 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, 108th Cong., 1st sess., July 22, 2003.

[86] Wilkes et al., 2000.

[87] IMS, "DTC at the Crossroads: A 'Direct' Hit or Miss?" 2004.

[88] 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*, February 26, 2003, pp. W3-82 to W3-95. This national telephone survey of 3,000 adults had a 53% response rate. The authors used the following "high priority" conditions: cancer, diabetes, emphysema, high cholesterol, HIV/AIDS, hypertension, ischemic heart disease, stroke, arthritis, asthma, gall bladder disease, stomach ulcer, back problems, Alzheimer's disease and other dementias, and depression and anxiety disorders.

[89] Jerry Avorn, "Advertising And Prescription Drugs: Promotion, Education, And The Public's Health," *Health Affairs*, Web Exclusive, February 26, 2003, pp. W3-104-108.

The Harvard/Harris group sounded a cautionary note, however, when it reported on its interviews with physicians. It found that when patients requested a drug they had seen advertised, doctors would prescribe the drug 39% of the time. But this didn't mean the doctors believed this was the best medical—or economic—option. Over half of the time, the physicians felt that another drug would be equally as effective. Almost 6% of the time that they prescribed a requested advertised drug, physicians felt another drug or type of treatment would have been better for the patient.[90]

Does drug use influenced by DTC advertising harm patients?

Little statistical evidence exists on the scope of harm potentially resulting from DTC ads. Many researchers, though, point to *ways* such adverse effects occur. Sometimes a harmful reaction to a drug occurs in such a small proportion of the people taking it, that the association cannot be identified until after extensive use. Once on the market, a heavily advertised drug can reach millions of people before researchers uncover the potential risk.[91] This was the case not only with Vioxx but also with the heartburn medicine Propulcid following reports of heart rhythm abnormalities and deaths, and the statin Baycol following reports of muscular weakness.[92]

DTC ads potentially put a second group of people at risk: those with characteristics or conditions for which the drug has not been carefully researched. With very few exceptions, once a drug is approved, a physician can prescribe that drug for any purpose.[93] Many of these people will have personal and disease characteristics different from those in the initial clinical trials. A drug approved for use in adults may be prescribed to children. A drug approved for one disease may be prescribed to treat another. Safety and effectiveness for these uses, not having been examined by FDA, are not indicated on the FDA-approved product labeling—hence, the term *off-label* uses.

Off-label use is not necessarily bad; in fact, it can be very good medicine. However, no one, including physicians, yet fully understands the effects of new drugs on unresearched groups or conditions. Even a careful reader of a DTC ad will not learn about the potential risks of off-label use.

Health experts mention indirect damage from what DTC ads might lead people *not* to do. They describe four possibilities.

First, patients might insist on a drug that treats symptoms they have seen described in an ad for one disease, when they have a different disease causing the same symptoms. One researcher cites hypothyroidism and depression as two diseases sometimes confused, but with very different

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[90] 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, April 28, 2004, p. W4-226. Questionnaires were sent to 1,300 physicians, of whom 53% responded.

[91] A side effect that occurs in, say, 1 out of 10,000 patients may not have been encountered in premarket trials involving 2,000 patients. It would, however, harm 100 of the first million people to take the drug after approval.

[92] FDA, "Janssen Pharmaceutica Stops Marketing Cisapride in the US," *FDA Talk Paper*, March 23, 2000, at http://www.fda.gov/bbs/topics/ANSWERS/ANS01007.html; and FDA, "Bayer Voluntarily Withdraws Baycol," *FDA Talk Paper,* August 8, 2001, at http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01095.html.

[93] Remarks by Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs, FDA, before the American Medical Association, June 12, 2006, at http://www.fda.gov/oc/speeches/2006/ama0612.html; and statement by William B. Schultz, Deputy Commissioner for Policy, FDA, before the Committee on Labor and Human Resources, United States Senate, February 22, 1996, at http://www.fda.gov/ola/1996/s1447.html. In general, the practice of medicine (and pharmacy and other health professions) is regulated at the state level.

treatments.[94] Although the key error here would be the physician's failure to adequately work-up the patient, a contributing factor could be the persuasive power of DTC ads.

Second, people who have managed a small health problem with over-the-counter medications or lifestyle actions (such as diet or exercise) may now press physicians to provide prescription drugs. FDA's director of the Center for Drug Evaluation and Research, Janet Woodcock, has called this kind of indirect effect the "medicalizing of health," saying that some believe, due to DTC advertising, that "all aches should be treated with some pill."[95]

Third, a person may insist on an advertised drug rather than a more appropriate one. A favorite example of DTC critics: taking Claritin, which at the FDA-approved dose worked only 11% better than a placebo, instead of medicine that relieves allergy symptoms more effectively. "The great majority of DTC drugs," argues Marcia Angell, former Journal of the American Medical Association editor, "are for very expensive me-too drugs that require a lot of pushing because there is not good reason to think they are any better than drugs already on the market."

Finally, there is a fourth indirect effect that deserves a section of its own—the effect of DTC advertising on spending.

Does DTC advertising affect consumer spending?

It seems likely that DTC advertising does influence consumer behavior, although it is difficult to obtain precise information on how DTC ads affect consumer drug purchasing. However, in 2004, IMS Management Consulting studied 49 advertised drugs for the advertising's return on investment (ROI). For 90% of the drugs, the study showed a positive ROI; that is, more was gained than was spent on advertising. One brand showed a return of $6.50 per advertising dollar invested.[96] A Kaiser Family Foundation study of 1996-1999 data found that a dollar spent on DTC advertising yielded an additional $4.20 in sales.[97]

Although some had posited that by allowing competition via advertising, prices to consumers would be lower,[98] the consensus of economists seems to be that recent growth in DTC advertising has persuaded consumers to substitute new, more expensive drugs for older, lower-priced ones.[99] Although some suggest that advertising costs are passed on to consumers as higher prices, the data on how pharmaceutical companies set prices are proprietary.

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[94] Wilkes et al., 2000.

[95] Comments made by Janet Woodcock, then Director of the Center for Drug Evaluation and Research, at a public meeting called "Research on Consumer Directed Advertising," held by the FDA, Center for Drug Evaluation and Research, September 22-23, 2003. Wilkes et al., 2000, also refer to the "medicalization of trivial ailments," p. 121. Weissman et al., 2003, warn of the harm that follows "possibly deceptive advertising, or overuse that may result from targeting relatively healthy people or by 'medicalizing' nonmedical problems."

[96] IMS Management Consulting, "DTC at the Crossroads: A 'Direct' Hit or Miss?" *IMS Issues and Insights*, September 23, 2004, at http://www.imshealth.com.

[97] 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," The Kaiser Family Foundation, June 2003, pp. 18-19.

[98] Glover testimony, 2001.

[99] Stephen Heffler, Katharine 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, March/April 2001, pp. 193-202.

Both price and quantity affect total spending. Overall spending reflects more than the price of a specific drug. Increases in drug spending also include significantly greater number of prescriptions being written for an aging population, new standards of medical practice encouraging greater use of drugs, and treatment of previously untreated patients.[100] To assess whether a particular spending level or trend is appropriate would involve more than just examining the amount consumers spend on one advertised drug.

DTC advertising supporters sometimes argue that DTC ads increase spending on drugs but reduce health care spending in other areas. Studies sponsored by both industry and academic researchers suggest that this can sometimes be the case.[101] For example, one National Institutes of Health study 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.[102] Others who study the cost-effectiveness of pharmaceuticals, though, say it "depends critically on the context in which the drug is used and the intervention to which it is being compared."[103]

Discussion and Possible Legislative Options

The expectations consumers bring to DTC ads may lead them to inaccurate conclusions. A 1999 study found that 43% of the public believed that only "completely safe" drugs could be advertised and half believed that such ads had been submitted to FDA for approval.[104] Neither belief is correct. Many FDA-approved drugs carry risks for certain consumers and may be harmful if used inappropriately by anyone. DTC ads do not have the imprimatur of the agency.

Nevertheless, both industry and consumers strongly support some form of DTC ads. Industry wants to increase sales,[105] and consumers want to actively participate in decisions about their own health. That, combined with advances in information technology and possible relevance to constitutional protections of free speech, makes an outright ban on DTC ads unlikely.[106]

However, Members of the 111th Congress have indicated interest in DTC advertising in the context of drug safety, tax treatment of advertising expenses, risk communication, and general

[100] Testimony of Paul Antony, chief medical officer, PhRMA, to the U.S. Senate Special Committee on Aging hearing on direct-to-consumer advertising, September 29, 2005, at http://www.phrma.org/publications/testimony_and_official_submissions.

[101] 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.

[102] 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, April 1998, pp. 883-890.

[103] 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, March/April 2000, pp. 97, 99, and 104. The authors cite examples of successful interventions that produce health benefits for relatively little cost or save money for the health care system: warfarin therapy to prevent stroke in those patients with atrial fibrillation, immunosuppressive drugs for those with kidney transplants, and drug treatment for some people with depression.

[104] Wilkes et al., 2000.

[105] Drug companies rely on DTC advertising to stimulate demand and to increase sales for the products (Glover testimony, 2001, p. 5).

[106] For a related discussion, see CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by (name redacted).

FDA-activity authority and oversight, sometimes in the context of broader discussions of health care costs and reform. Legislators with concerns about DTC advertising still have a range of options to address those concerns. Some would require new statutory authority and some FDA could institute with its current authority.

Activities for Which FDA Already Has Authority

Congress could urge FDA to act more aggressively in its review of ad content, consumer education, and enforcement. FDAAA explicitly directed FDA to increase its dissemination of drug safety and effectiveness information to the public. The law specified, for example, clinical trial results, reviews of approved new drug applications, labeling decisions, adverse event analyses, risk evaluation and mitigation strategy (REMS) decisions. It also required FDA to study how to communicate risk and benefit information to the public.

Increase Post-Publication Review

Although the law explicitly prohibits FDA from requiring pre-publication review and approval of an ad, it does require the manufacturer to submit the ad to FDA upon its release. In congressional testimony and budget justification documents, FDA indicates that it reviews less than half of those within 45 days. That delay in identifying possible inaccurate or imbalanced presentation of risk and benefit information could put the public at risk. FDA could:

- Do a more complete and timely post-publication review of all DTC ads. Set goals; estimate needed resources to do so.
- Track the ensuing recommendations and industry response. With documented counts of numbers of violations; requests for change; and speed, completeness, cooperation (not just the letter of the law); FDA could assess what it could do better under current law and what changes in law it might need to do better.

Expand Industry-Independent Consumer Education

Critics who question the educational component of DTC advertisement have suggested alternatives to consumers' relying on the benefit and risk information gained through submitted DTC ads.[107] FDA or other industry-independent sources could then counter any misinformation or omissions contained in DTC advertising. FDAAA provisions[108] might boost the likelihood of some of the experts' suggestions:

[107] "Panel Backs Interactions Database, CERTs, Adverse-Event Repository," *FDA Week*, vol. 8, no. 24, June 14, 2002, pp. 8-9; and Eric J. Topol, "Editorial: Arthritis Medicines and Cardiovascular Events—'House of Coxibs,'" *Journal of the American Medical Association*, vol. 293, no. 3, January 19, 2005, pp. 366-368.

[108] FDAAA required that the Secretary develop and maintain an Internet website with an extensive range of easily searchable drug safety information to allow patients and health care providers better access to information. The website must include links to other government sites; professional and patient labeling; FDA alerts, warning letters, guidance documents, and regulations; summaries of aggregate surveillance data; and the clinical trials registry and results data bank.

- Rather than leave dissemination of information about new medications to DTC advertisers, FDA could mount public information campaigns itself or encourage or fund others to do so.[109]
- Coordinate consumer information dissemination and research with other federal agencies, such as the Centers for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ).
- Create greater access to post-marketing surveillance or clinical trial data.
- Make information available to the public through the Internet, and, possibly, through local pharmacies.[110]
- Clarify to the public the extent of its control over ad content. Surveys indicate that many consumers believe, wrongly, that FDA approves all ads and that some consumers believe, wrongly, that FDA allows ads for only "completely safe" drugs or that these drugs have been shown to be "better" than other drugs.
- Sponsor public education campaigns. In these, FDA could 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.
- Study consumer reaction to ads. FDA could increase its study of consumer understanding of 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 is used. Nonetheless, the agency cannot guarantee how patients will use the added information.[111]
- Create drug information to counter any "biased" or "unbalanced" pictures the manufacturers present in DTC ads. FDA could also use that information to provide patients with medication guides outlining the risks of particular drugs. The FDA advisory committees that met in February 2005 to assess the safety of Vioxx and other COX-2 inhibitors considered these options.[112]

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[109] In 2008, FDA launched a new Web page called "Be Smart About Prescription Drug Advertising: A Guide for Consumers" that includes a list of questions to consider when seeing a DTC advertisement (at http://www.fda.gov/cder/ethicad/background.htm). Purporting to provide accurate science-based information, the FDA-sponsored project drew criticism from the Center for Science in the Public Interest (CSPI) and some Members of Congress because they say the nonprofit group (EthicAd) the agency contracted to develop the site has strong pharmaceutical industry ties (see "Pay No Attention to the Industry-Funded Group Behind the Website," Center for Media and Democracy, at http://www.prwatch.org/node/7765).

[110] FDA has instituted new ways to disseminate drug information to the public. WebMD, in partnership with FDA, hosts public health alerts and safety information on FDA products (at http://www.WebMD.com/FDA). Also, FDA, along with CDC, is using "social media resources," such as podcasts, YouTube video, Twitter, and blogs, to inform consumers about product recalls (HHS, "Social Media Resources Tapped to Deliver Consumers Information on Salmonella Typhimurium Outbreak, *News Release*, February 2, 2009).

[111] Complying with FDAAA requirements, FDA has met with the Advisory Committee on Risk Communication in connection with: seeking public comments regarding how DTC advertising communicates to subsets of the general population regarding increasing access to health information and decreasing health disparities (FDA, *Federal Register*, vol. 73, no. 82, April 28, 2008, pp. 22959-22960); and a study on visual distractions in broadcast ads and their relationship to whether ads meet the FDAAA requirement that side effects and contraindications be presented in a clear, conspicuous, and neutral manner (FDA, *Federal Register*, vol. 73, no. 152, August 6, 2008, pp. 45773-45776).

[112] Gardiner Harris, "F.D.A. Panel Says Pain Relievers Should Remain on Market," *New York Times*, February 18, 2005.

Establish a Commission to Recommend DTC Advertising Standards

If Congress encouraged it to do so, FDA might establish an advisory panel under the Federal Advisory Committee Act which could either itself recommend standards for prescription drug ads,[113] or encourage the drug industry to develop a new set of standards for self-regulation.[114] 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.[115]

Increase FDA's Enforcement Activity

Until the expanded authority from FDAAA, when FDA saw objectionable things in an ad, it could send what is called an "untitled letter" explaining its objections, refer the matter to the Department of Justice, seize the product as misbranded, or revoke product approval. Even in the small percentage of ads FDA reviews, it rarely takes any of these steps. Congress could encourage FDA to take such steps more often, use the new FDAAA-authorized tools, and even set target goals for increased enforcement activity.

Activities Requiring New Legislation

There are some options Congress might consider for which FDA does not have authority. The most extreme would be a total ban on DTC drug advertising. Aside from that, Congress could opt to not intervene at this time or it could act to increase FDA's authority and ability to take strong, but less absolute, action.

Give FDA Additional Resources

FDA current authority covers more consumer education and DTC advertising enforcement activities than most observers think the agency has the resources to fulfill. To increase the funds available to FDA, Congress could, as examples:

- Amend the user fee statute. As first enacted, the prescription drug user fee statute applied to new product review only. When reauthorizing it in 2002, the Congress expanded FDA's authority to use the collected fees to include limited parts of postmarket surveillance.
- Require industry to bear the cost, through user fees, of direct-to-consumer advertising oversight.[116]

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[113] FDA's Risk Communication Advisory Committee considers some related issues.

[114] PhRMA adopted, in April 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, at http://www.phrma.org/press/newsreleases//2002-04-19.390.phtml.

[115] Testimony of Michael S. Shaw, Executive Director of EthicAd, 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, 107th Cong., 1st sess., July 24, 2001.

[116] Congress authorized, in FDAAA, a new fee to cover costs of FDA advisory review of industry-proposed DTC television ads. The appropriators, however, have taken steps that prevent FDA from assessing or collecting such fees.

- Create an industry-financed fund to allow an independent entity to perform a range of activities. Examples given include development of ads, Internet and other public information activities, comparative assessment research, and research into what makes ads effective.[117]
- Provide appropriations that more closely match the task.

Ban DTC Advertising

The most extreme approach would be for Congress to ban DTC advertising, although opponents of this approach have raised constitutional issues.[118] 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. Two of six DTC advertising resolutions presented at the 2005 American Medical Association annual meeting proposed a total ban.[119]

A group of 39 organizations, including the American Medical Student Association, Commercial Alert, Florida Alliance for Retired Americans, Gray Panthers, National Women's Health Network, and Physicians for a National Health Program, began in 2006 to circulate a draft Public Health Protection Act that would ban DTC advertising and serves as an example of what some consumers would like to see. The draft bill presents a set of provisions that would go into effect if the courts were to find that a ban is unconstitutional. These include additional warnings to inform consumers that this drug was approved based on testing of only a few thousand people and that it may be dangerous to your health in ways that this limited research has not yet revealed; a statement that FDA does not certify that this drug is more effective, safer or cheaper than other drugs in its class; changes to the tax code to make DTC advertising expenses not deductible and to add a windfall profits tax to fund NIH-controlled comparative effectiveness studies and their dissemination.[120]

Require Pre-Release Review and Approval

Congress could mandate that FDA review and approve all or a subset of DTC ads prior to their release to the public. The federal advisory meeting mentioned above suggested one possible first step: categorize ads by their potential to create harm. For example, FDA might institute a more rigorous review for extremely popular drugs posing a large opportunity for harm were information to be misleading. FDAAA authorized the Secretary to require review of a television advertisement before its dissemination; the law specifically prohibits the Secretary from requiring changes, allowing only recommendations about changes to the planned ad.

[117] Models could include the public-private consortia that produce public service announcements about tobacco use, drug driving, and illegal drug use.

[118] See CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by (name redacted).

[119] At the June 2006 annual meeting, a trustees group recommended a temporary moratorium on ads for newly approved drugs rather than a total ban on DTC drug advertising (Rich Thomaselli, "AMA Gives Up Push to Ban DTC Drug Ads," *Advertising Age*, June 5, 2006; and Rich Thomaselli, "Nothing but blue skies?" *Advertising Age*, October 2, 2006).

[120] The organization Commercial Alert website posted, on May 24, 2006, the bill text, a list of sponsors, and other material at http://www.commercialalert.org/issues/health/.

Authorize FDA to Require Changes to Advertising and Labeling Material

Until FDAAA, FDA had approval control over every detail of labeling at the time of a drug's approval, but could not require changes to labeling based on information (about either risk or benefit) that it learns afterward. FDAAA expanded the Secretary's authority to require labeling changes.[121] Because advertising content is limited by law to FDA-approved labeling information, Congress might review FDA's implementation of the FDAAA provisions and then assess the need for more explicit authority regarding changes to advertisements.

Increase Compliance and Enforcement Tools

- Authorize FDA to impose punitive sanctions against companies that violate the law. As FDA begins to implement its FDAAA-provided authority to impose civil monetary penalties for false or misleading advertisements, Congress could assess whether the authorized penalty levels are sufficient to encourage company compliance.

Require Data Collection on All New Drugs Having DTC Ads

Right now, FDA requires drug companies to report quarterly (and annually after three years) about potential problems with a drug and within 15 days of learning of a serious and unexpected adverse event.[122] In response to questioning at Congressional hearings, FDA scientists noted that a signal of a true adverse event can be lost in the enormous amount of material the companies submit.[123]

- Congress could direct FDA to identify a better procedure for industry to flag important safety data and authorize the agency to require companies to comply.

Currently, FDA is not generally authorized to require studies designed to aggressively follow patients (and their diagnoses, pharmaceutical and other medical treatments, and outcomes). Congress, with FDAAA, increased FDA authority to require postmarket studies in certain circumstances. As FDA proceeds with implementation, Congress could assess whether to amend the law with additional or revised authority to:

- Change post-market study requirements to include mandatory reevaluation.

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[121] FDAAA authorized the Secretary, upon learning of new relevant safety information, to require a labeling change. The law also expanded the definition of misbranding to include the failure to comply with certain requirements regarding REMS, postmarket studies and clinical trials, and labeling and established civil monetary penalties for violations of those requirements.

[122] 21 CFR Sec. 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications; and 21 CFR Sec. 314.80 Postmarketing reporting of adverse drug experiences.

[123] FDA's adverse event reporting system, MedWatch, is intended to identify problems encountered as drugs are used in the wider population and to relate this information back to physicians and medical care personnel. It is, however, a passive surveillance system, gathering anecdotal and often incomplete information from only those physicians and consumers who volunteer the information. It, therefore, provides a count of events but does not provide the total number of users to be able to assess impact. As such, a cluster of MedWatch-reported events serves as a red flag for the agency and at times prompts it to conduct further investigation. For a discussion of the adequacy of adverse event surveillance to protect the public, see CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by (name redacted).

- Strengthen risk evaluation and mitigation strategy (REMS) options or implementation.
- Require commitments to specific postmarket surveillance and studies for initial approval.
- Require commitments to comparative effectiveness trials for initial approval.
- Require commitments to study likely users not considered in preapproval trials.
- Require postmarket studies of situations that had not been anticipated at the time of approval

Prohibit DTC Ads When a Drug Is First Approved

Ray Woosley, president of the Critical Path Institute, testified to the Senate Committee on Health, Education, Labor, and Pensions 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.[124] At the same hearing, former FDA official William Schultz suggested 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."[125] FDAAA gave the Secretary the authority to require, for not more than two years from approval, that an advertisement include a specific disclosure of the approval date if the Secretary determines that the advertisement would otherwise be false or misleading.

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.

- Restrict ads with adult themes to programming aimed at adult audiences. There are those who see a danger to the public, not just in the ad itself but when and where it is placed.

Make DTC Advertising Less Profitable to Industry

There are those who feel DTC ads are not in the public interest and favor banning DTC ads, but see such restrictions as politically or constitutionally unfeasible. They have proposed changes to the Internal Revenue Code and the Social Security Act (SSA) that would decrease the incentive of drug companies to advertise. Three such proposals:

- Prohibit a tax deduction for any amount paid or incurred by the manufacturer for DTC advertising.

[124] Ray Woosley, president of the Critical Path Institute at the University of Arizona, was quoted in: "Academic Hopes to Partner with FDA on Tiered Drug-Approval Plan," *Inside Health Policy*, March 3, 2005.

[125] 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, 109th Cong., 1st sess., March 1, 2005.

- Deny tax deductions for drug ad expenses for manufacturers who do not participate in negotiated rebate and discount agreements with the federal government for residents not otherwise eligible for reduced price prescription drugs.
- Attach requirements to Medicare or Medicaid participation. Because a manufacturer's price is lowered by the rebates and discounts it negotiates with state governments, pharmacies, and others, some have proposed changing the SSA to reflect in those rebates the amount a manufacturer spends on advertising.

Conclusion

In his book *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*, Philip Hilts describes the early days of patent medicines as "one of the first fully national markets that used nationwide marketing."[126] DTC advertising is not new, and the government's role—to protect the public's health—has not changed. But, as biologic, chemical, and manufacturing knowledge has increased, so too have societal medical and social standards. Current law gives government responsibility for assuring that drugs are safe and effective, yet many now ask increasingly complex questions: Just *how* safe and *how* effective do we want these drugs to be? How much information does the consumer or the doctor need?

Should they rely completely on the government's assessment of the balance of known risks and expected benefits? Is it possible to satisfy the expectation that we summarize what some scientists study for decades in a 60-second television commercial clearly enough for the general U.S. public[127]—to understand?

Finally, we can analyze DTC advertising while paying attention to its role as part of a larger picture. DTC advertising—and the issues it raises of accuracy and balance of safety and effectiveness information—is one piece of the healthcare picture. Widening the focus one step brings us to advertising and other promotion to healthcare providers and the issue of the continuing education of doctors. Other safety and effectiveness issues include drug approval; comparative effectiveness research (among drugs and between drugs and other kinds of treatment); and consideration of off-label prescribing and changing patterns of use. Even broader concerns involve drug research and development and incentives toward the development of drugs that address major public health conditions (measured by number of people affected and seriousness of the disease); risk communication; and access to medical care, including drugs.

[126] Philip J. Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*, New York: Alfred A. Knopf, 2003, p. 23. He depicts citizens complaining in 1840 that advertisements covered every surface.

[127] The U.S. public reads, on average, at a seventh grade reading level ("Comprehension and reading level," *The Informatics Review, e-journal of the Association of Medical Directors of Information Systems*, vol. 9, no. 11, June 1, 2006, at http://www.informatics-review.com/FAQ/reading.html).

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