

CHRONOLOGY OF DIRECT-TO-CONSUMER ADVERTISING REGULATION IN THE UNITED STATES

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ABSTRACT:

Promotion of pharmaceutical drugs to consumers, called direct-to-consumer (DTC) advertising, has increased significantly since 1997, when the US Food and Drug Administration (FDA) reevaluated its regulations of pharmaceutical manufacturers. DTC advertising has been debated in the literature, with most articles citing the 1997 shift in FDA policy. However, the current position of the US government on DTC advertising has more than a century of developments. This article outlines the legislative and regulatory milestones that have given rise to the current legal framework of DTC advertising in the United States.

Direct-to-consumer (DTC) advertising, in which pharmaceutical companies market therapeutic agents directly to consumers, is unique to the United States and New Zealand. The United States represents the largest DTC advertising market and accounts for approximately 50% of global pharmaceutical sales.¹

DTC advertising has been vehemently debated in the literature.¹ The primary argument in favor of DTC advertising is to provide disease and treatment information to health care consumers.² Opponents argue that harmful consequences can result from DTC advertising. A chief concern is that health care consumers may not adequately comprehend the use, benefits, and risks associated with such highly technical products as prescription drugs.^{1,2} Because the primary arguments for and against DTC advertising both scrutinize the role of health information, DTC advertising is an important consideration for medical writers. In fact, much of the technical information for DTC advertising comes from the documentation produced during the drug development process.³

In the United States, the Food and Drug Administration (FDA) is the government agency with the authority to regulate DTC advertisements.⁴ The FDA has noted an increase in DTC advertising and the crucial role of regulation. According to the FDA:⁴

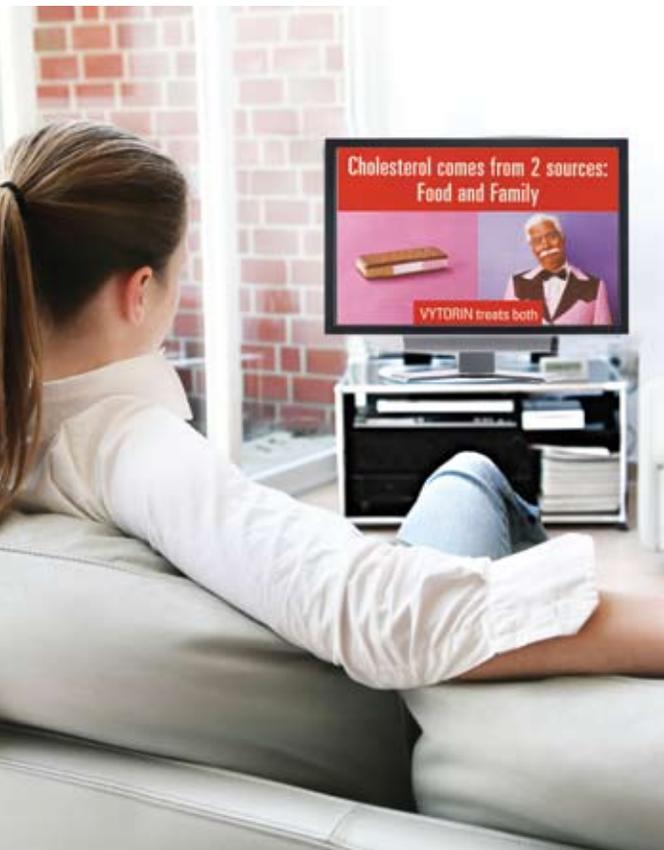
Accurate and complete information is vital to the safe use of drugs. While drug companies have traditionally promoted their products directly to physicians, more and more they are advertising directly to consumers. Advertising of OTC [over-the-counter] drugs is regulated by the Federal Trade Commission, but CDER [Center for Drug Evaluation and Research; a division of the FDA] oversees the advertising of prescription drugs.

Many papers published on DTC advertising provide limited historical context—focusing on the single decision in 1997 when the FDA clarified DTC advertising regulations and made advertisements feasible in the prominent broadcast media of the time (specifically television and radio). A few of the more extensive reviews provide more historical context—with a timeline extending to the 1980s, when the first modern examples of DTC advertising appeared on television.¹ This article chronicles the regulatory trends of DTC advertising in the United States and describes a century of legislation and regulation.

CATEGORIES OF DTC ADVERTISING

The FDA currently categorizes DTC advertising into 3 categories:⁵

- **Product claim**—includes the product name and therapeutic use of a product
- **Help-seeking**—discusses a disease and encourage a doctor's visit (these advertisements do not mention the product's name)
- **Reminder**—includes the product's name but does not refer to the disease



Of these 3 types of advertisements, the product claim advertisement is the only one over which the FDA has jurisdiction.⁵ The therapeutic claim must be accurate and not mislead the consumer. Print advertisements must have a “fair balance” between the space devoted to benefit and risk information and the space allotted to a summary of side effects, contraindications, and precautions directly from the product’s label. Broadcast advertisements, which typically range from 30 to 60 seconds, must clearly state important risk information and direct consumers to a source of more information (such as a Web site, toll-free telephone number, health care provider, or print source with large circulation).⁵

CHRONOLOGY OF US LEGISLATION AND REGULATION OF THE MARKETING AND ADVERTISING OF THERAPEUTIC AGENTS

Pharmaceutical drug development is a highly regulated process that ensures therapeutic agents are safe and effective for use. In the United States, the FDA’s regulatory authority dates back to 1906 when Congress passed the original Food and Drugs Act (Table 1).⁶ This act prohibited interstate commerce of misbranded and adulterated food and drugs. The original Food and Drugs Act provided limited regulation of the marketing claims made by drug manufacturers and salespeople, but it is important in establishing the role of the FDA.

In the first major case regarding marketing claims (*United States v Johnson* [1911]), the Supreme Court ruled that the 1906 Food and Drugs Act required manufacturers and salespeople to accurately divulge the ingredients or identity of a drug. Although an important step toward accurate marketing and advertising, this act had one critical limitation—it did not prohibit false therapeutic claims of agents. Therefore, as long as a therapeutic agent was properly identified, manufacturers and salespeople could

Table 1. Summary of Milestones

Date	Milestone	Description
1906	Congress passes the Food and Drugs Act	Prohibits interstate commerce of misbranded food and drugs; establishes regulatory authority of FDA
1911	Supreme Court decision in <i>United States v Johnson</i>	Requires manufacturers and salespeople to divulge the identity of a drug’s ingredients
1912	Congress passes Sherley Amendment	Prohibits labeling of medicines with false therapeutic claims with the intent to defraud consumers
1938	Congress passes The Federal Food, Drug, and Cosmetic Act of 1938	Requires manufacturers to show that new drugs are safe before they are marketed
1938	FDA limits access to certain drugs	Declares that select drugs must be administered by qualified experts
1951	Congress passes the Durham-Humphrey Amendment	Expands the list of drugs requiring medical supervision; restricts sales, requires prescriptions written by licensed practitioners
1962	Congress passes the Kefauver-Harris Amendments	Requires manufacturers to provide evidence to the FDA that drugs are safe and effective before they are marketed
1967	Congress enacts the Fair Packaging and Labeling Act	Requires manufacturers to provide drug information to consumers
1970	FDA requires patient package inserts	Requires manufacturers to provide information related to benefits and risks to consumers
1993	FDA regulates DTC advertising	Requires manufacturers to include all side effects and contraindications in DTC advertising; FDA requests that manufacturers voluntarily submit marketing materials for review
1997, 1999	FDA publishes <i>Guidance on DTCA</i> (draft and final version)	Permits promotional advertisements on broadcast media (eg, television, radio) that does not devote equal time to promotion and risks
2006	FDA updates product label requirements	Requires manufacturers to provide clear and concise prescribing information

legally claim that the agent could be used to treat or cure any disease.

In 1912, Congress quickly responded to the Supreme Court’s ruling by passing the Sherley Amendment, which prohibited the labeling of medicines with false therapeutic claims specifically intended to defraud purchasers. Although Congress intended to ensure accurate declarations of curative effects, the FDA reported that proving the intent deliberately to defraud consumers was a standard too difficult to prove in a court of law.

In 1933, the FDA recommended a complete revision of the 1906 Food and Drugs Act. As part of the recommended revisions, the FDA requested the authority to prosecute false therapeutic claims. Despite this request by the FDA, it took a US catastrophe in order for major changes to be legislated. In 1938, the S.E. Massengill Company began selling a liquid form of sulfanilamide, which had been used in tablet and powder form to treat streptococcal infections. The liquid configuration, called elixir

sulfanilamide, provided sulfanilamide dissolved in diethylene glycol. This drug was quickly released to the market—without testing. The solvent, chemically related to antifreeze, was poisonous and resulted in the deaths of 107 persons, many of whom were children, the prime consumers of the fragrant and good-tasting liquid. Unfortunately, at that time the law did not prohibit the sale of dangerous, untested, or poisonous drugs.

In response to the elixir sulfanilamide incident, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938. This legislation had a significant impact on the marketing of therapeutic drugs. Manufacturers were required to show that new drugs were safe before they could be marketed. Included with these revisions was the elimination of the Sherley Amendment, which required the proof of false therapeutic claims specifically intended to defraud purchasers. In a significant step of consumer protection, Congress extended these regulations to cosmetics and therapeutic devices. Under the Wheeler-Lea Act, the Federal Trade Commission was authorized to oversee advertising associated with products, including pharmaceutical agents.

Also in 1938, the FDA required that sulfanilamide and other selected drugs be administered under the direction of qualified experts. This regulation established the foundations for therapeutic drugs purchased by prescription only. The regulation of therapeutic agents was expanded in 1951 by the Durham-Humphrey Amendment, which established a list of drugs that required medical supervision and restricted the sale of these therapeutic agents to prescription by licensed practitioners. As a result of these regulations, therapeutic drug manufacturers shifted their advertising and marketing of drugs from the general public to these “qualified experts” who could in turn recommend the agents for treatment of diseases.¹

In 1960, the William S. Merrell

Company submitted a new drug application for Kevadon (a brand name of the drug thalidomide), a sleeping pill that had been available for treatment in Europe since 1956. The FDA medical officer assigned to review the drug application, Dr Frances Kelsey, believed that the data were incomplete to support safe use, and this drug was not approved for sale in the US market. In 1961, the drug was suspended from the German market because of birth defects in which newborns exhibited abnormally short limbs with toes sprouting from the hips and “flipper-like” arms. News reports that the strict FDA regulation kept this drug from the US market fostered public support for stronger drug regulation. As a direct result of these events, Congress passed the Kefauver-Harris Amendments in 1962, which require that manufacturers prove to

The conclusions of the FDA were mixed—DTC advertising has both a positive and negative impact.

the FDA that their drugs are safe and effective before they can be marketed. Furthermore, the FDA gained the responsibility and authority to regulate the advertising of prescription drugs.

Although the distribution of prescription drugs has remained essentially the same since 1960, the FDA and Congress have continued to refine modes by which drug information is communicated to consumers. In 1967, Congress enacted the Fair Packaging and Labeling Act, which stated:⁷

Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.

In 1970, the FDA required the first prescription drug information, commonly referred to as the patient package insert. This document reports specific risks and benefits of the therapeutic agent.

Through the 1980s, the FDA did not prevent drug manufacturers (ie, modern-day pharmaceutical companies), from advertising to the general population. In general, pharmaceutical companies focused advertising to health care professionals, and the absence of DTC marketing was primarily a result of the lack of attention by the pharmaceutical companies to the health care consumer.¹ In the 1980s, the pharmaceutical industry started to redirect their marketing of therapeutic drugs to the general public. The advertising of therapeutic agents at that time was for “recognized nonserious conditions”

such as arthritis. For example, in the early 1980s, Rufen was advertised on television for arthritis pain. In 1982, the FDA requested a voluntary moratorium on DTC advertising while the agency evaluated the shifting trend in directing advertising more toward consumers and less toward health care practitioners. In 1985, the FDA lifted this moratorium, and DTC advertising gradually increased.⁸

In the early 1990s, pharmaceutical companies began advertising therapeutic agents for more serious conditions such as migraine and epilepsy.¹ In 1993, the FDA requested that pharmaceutical companies voluntarily submit marketing and advertising materials targeted to patients and the general public for review and comment. As part of this change in policy, the FDA mandated that these DTC advertising materials included a list of all side effects and contraindications for use of the therapeutic agent. These regulations specified that pharmaceu-

tical companies had to devote equal space to advertising and risk communication. Thus, if 1 page in a magazine contained advertising information for a drug, a second page was needed to convey the risk information. Although this regulation could be easily accommodated in print, pharmaceutical companies found television and radio advertising to be impractical.¹

In 1997, the FDA published preliminary guidelines for DTC advertising. In *Guidance to Industry: Consumer-Directed Broadcast Advertising*, the FDA clarified vague regulation of DTC advertising by permitting promotional advertisements on broadcast media (such as television and radio) that did not devote an equal amount of time to promotion and risks, as long as sources for more information were provided. After the 1999 publication of the FDA's *Final Guidance on DTCA*, pharmaceutical companies began large marketing campaigns for therapeutic agents. In 2002, the authority of the FDA to regulate DTC advertising was challenged, as this authority was considered by one company to violate its First Amendment right of "freedom of speech." The reported outcome was that DTC advertising was not banned in the United States and the FDA could continue to regulate advertising as part of the organization's mandate to protect consumers.¹

Starting in 1999, the FDA began to investigate the impact of DTC advertising through large surveys of patients and physicians. In the final report, published in 2004, the FDA concluded that DTC advertising appears to increase awareness of conditions and treatments, motivate questions for health care providers, and help patients ask better questions.⁹ However, in the same survey, patients expressed a modest rating of the understandability of a product's risks. The conclusions of the FDA were mixed—DTC advertising has both a

positive and negative impact. However, because the negative impact did not appear to outweigh the positive benefits of DTC advertising, the FDA will probably continue to permit DTC advertising.

In an ongoing effort to improve health communication, the FDA updated the requirements for prescription drug information: Clear and concise prescribing information must be provided with the most important drug information being prominently displayed. This new regulation, which went into effect in 2006, benchmarks a century of the FDA's refinement of communication of drug information among manufacturers, physicians, and consumers.

CONCLUSION

This article has chronicled a century of US regulation of therapeutic drug agent manufacturers. An important conclusion from this review is that advertising to consumers, although not prominent in recent history until the FDA decision of 1997/1999, was primarily due to a lack of focus on this audience. The sale of drugs by prescription only, which began in 1938, resulted in the manufacturers shifting their focus from consumers to prescribers. DTC advertising has been prominent in the US media since the late 1990s. This trend illustrates that modern pharmaceutical companies are refocusing again on the final consumer. While this change may appear to be a recent and significant change, the historical analysis of DTC advertising regulation shows that advertising to the consumer has had a much longer history in the United States.

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References

1. Auton F. The advertising of pharmaceuticals direct to consumers: a critical review of the literature and debate. *Int J Advert.* 2004;23:5-52.
2. Cohen JB. Introductory comments: direct-to-consumer prescription drug advertising: evaluating regulatory policy in the United States and New Zealand. *J Public Policy Mark.* 2002;21:172-173.
3. Foote M, Neumann TK. A primer of drug development. *AMWA J.* 2003; 18:61-66.
4. US Food and Drug Administration. From test tube to patient: protecting America's health through human drugs. 2006. Available at www.fda.gov/fdac/special/testtubetopatent/default.htm. Accessed July 10, 2008.
5. US Food and Drug Administration. *The CDER Handbook*. Available at www.fda.gov/cder/handbook/. Accessed July 10, 2008.
6. Time line: chronology of drug regulation in the United States. 1999. Available at www.fda.gov/cder/about/history/time1.htm. Accessed July 10, 2008.
7. US Food and Drug Administration. Fair Packaging and Labeling Act. 1966. Available at www.fda.gov/opacom/laws/fplact.htm. Accessed July 10, 2008.
8. Calfee JE. Public policy issues in direct-to-consumer advertising of prescription drugs. 2002. Available at www.fda.gov/ohrms/DOCKETS/dailys/02/Sep02/092302/02N-0209_emc-000183-01.pdf. Accessed July 10, 2008.
9. US Food and Drug Administration. Patient and physician attitudes and behaviors associated with DTC promotion of prescription drugs—summary of FDA survey research results. 2004. Available at www.fda.gov/cder/ddmac/researchka.htm. Accessed July 10, 2008.