FOOD AND DRUG LAW JOURNAL

Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products

The Development of Direct-to-Consumer Prescription Drug Advertising Regulation

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FDLI

VOLUME 57 NUMBER 3 2002

The Development of Direct-to-Consumer Prescription Drug Advertising Regulation

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I. INTRODUCTION

Direct-to-consumer (DTC) prescription drug advertising is now well known to practically all American households. One needs only to watch virtually any commercial television program or to browse through any consumer-directed magazine to view advertisements for a variety of prescription drugs. With regard to broadcast media, this is a relatively new phenomenon because, for many years, pharmaceutical manufacturers were reluctant to advertise their products directly to the consumer because of the "brief summary" requirement of the food and drug law and regulations. These historically have required that an advertisement contain a "brief summary," which requires a substantial amount of material about the drug product's side effects, contraindications, and effectiveness. Advertisements for prescription drugs were directed toward the ultimate decision-makers, the prescribers. Recent changes, however, in the Food and Drug Administration's (FDA's) guidance—introduced in 1997 and finalized in 1999—have opened the door to a plethora of advertisements, obviously designed to alter the decisionmaking balance between patients and physicians.

The growth of DTC advertising over the past eleven years has been exponential. Although there are numerous sources with slightly varying DTC expenditure figures, most reports provide numbers that are similar to those shown in Table 1, below.

Table 1

Year	DTC Spending
1989	$12 million
1990	$48 million
1991	$56 million
1992	$156 million
1993	$166 million[1]
1994	$242 million
1995	$313 million
1996	$595 million
1997	$844 million
1998	$1.17 billion
1999	$1.58 billion
2000	$2.24 billion
2001	$2.38 billion[2]

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The authors gratefully acknowledge the support of the Henry J. Kaiser Family Foundation. In addition, the authors acknowledge the assistance of University of Maryland School of Law students, Jennifer Kim, Kelly Trumpbour, Jean Kim, and Karena Cooper; and University of Maryland Pharmaceutical Health Services Research graduate students, Ashley Slagle and Prasun Subedi.

[1] The DTC spending figures for years 1989 to 1998 came from the table titled "Direct-to-Consumer Spending Over Time" in 18 MED. AD. NEWS 20 (June 1999).

[2] The figures for years 1999 and 2001 came from the table titled "Annual Direct-to-Consumer Advertising Expenditure for Prescription Brands" in 21 MED. AD. NEWS 42 (June 2002).

In 1989, the drug industry collectively spent only twelve million dollars on DTC advertising,[3] compared to $2.38 billion in 2001,[4] an increase of almost 200-fold in only twelve years. Over 70% of the promotional dollars spent by pharmaceutical companies in 2001 was spent on TV advertisements.[5] The names of many, if not all, of these advertised drugs, would come as no surprise to the public. A total of 105 prescription drugs were advertised directly to consumers in 2001.[6]

This article looks at the government agencies responsible for overseeing drug advertising, and presents the history of drug advertising laws, regulations, and policies as these items relate specifically to DTC advertising.

II. DTC PRESCRIPTION DRUG ADVERTISING: HISTORICAL OVERVIEW AND LEGISLATIVE EVOLUTION

Historically, prescription drug advertising in the United States was directed primarily to prescribers, who were once the sole decision-makers when choosing prescription medications. As patients became more involved in their treatment, drug companies expanded their promotional efforts to include consumers. The first U.S. prescription drug print advertisement directed to the consumer was issued in 1981 by Boots Pharmaceuticals, a British drug company whose American subsidiary was located in Shreveport, Louisiana, for the ibuprofen product, Rufen.[7] In the same year, Merck Sharp & Dohme released the second print DTC advertisement, for Pneumovax, its pneumonia vaccine. Other drug companies then voluntarily proposed DTC advertisements to FDA. In September 1982, faced with a novel concept for which FDA was unprepared, the Commissioner of FDA issued a formal request to the pharmaceutical industry for a voluntary moratorium on DTC advertisements, to allow FDA time to research the issue.

During the moratorium, FDA and the industry conducted several studies on the effects of DTC advertisements. One study, commissioned by FDA, showed that consumers retained more information about the benefits of the products than the risks.[8] Another notable study found that consumers wanted more information about prescription drugs and would view DTC advertising favorably.[9]

In September 1985, FDA finally settled on its position on the dissemination of DTC advertising.[10] In a *Federal Register* notice, FDA stated its jurisdictional authority and said that DTC advertisements must meet the same legal requirements as those directed at physicians. FDA maintained that pre-existing regulations governing prescription drug advertising would sufficiently safeguard consumers. With the moratorium lifted, pharmaceutical companies began to expand their promotional activities. DTC advertising seems to have evolved at a much more rapid pace, however, than the ability of the regulatory process to keep up with it.

The first comprehensive federal legislation regulating food and drugs was the Pure Food and Drugs Act of 1906, also known as the Wiley Act.[11] The 1906 Act was directed

[3] Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 491, 507 (1999). *See also supra* note 2.

[4] *See supra* note 3.

[5] Table, "Promotional Expenditure by Media," 21 MED. AD. NEWS 48 (June 2002).

[6] Table, "Direct-to-Consumer Spending by Brand," 21 MED. AD. NEWS 44-45 (June 2002).

[7] Pines, *supra* note 3, at 491.

[8] Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 FOOD & DRUG L.J. 497 (1984).

[9] Louis A. Morris, David Brinberg & Ron Klimberg et al., *The Attitudes of Consumers Toward Direct Advertising of Prescription Drugs*, 101 PUB. HEALTH REP. 82 (1986).

[10] 56 Fed. Reg. 36,677 (Sept. 9, 1985).

[11] Pub. L. No. 59-384, 34 Stat. 768 (1906).

toward product labels[12] and contained no provisions regarding advertising because at the time of its enactment, the labels under which drugs were sold were the primary medium for drug promotions.[13] The Wiley Act defined a product as misbranded only if its label contained false statements about its ingredients' curative or therapeutic effects. Unfortunately, the Wiley Act did not require manufacturers to prove the safety or efficacy of their products prior to marketing. False claims for a drug that were not on the label were not prohibited by the 1906 Act, thus creating a loophole that could allow unsafe drug products to remain on the market. Moreover, although the Federal Trade Commission Act of 1914 gave the Federal Trade Commission (FTC) jurisdiction over advertising practices generally, the FTC did not have the authority to regulate deceptive advertisements unless it could prove that such advertisements injured another company.[14]

The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)[15] repealed and replaced the Wiley Act. In addition to major regulatory gaps in the 1906 Act, profound changes in the pharmaceutical industry and in technology during the intervening years necessitated new legislation, rather than merely amending the Wiley Act. In particular, advertising practices had evolved significantly; for example, radio had not been invented when the 1906 Act was enacted. Moreover, the advertising of foods, drugs, and cosmetics in magazines and newspapers had grown significantly since 1906.[16] Accordingly, consumer protection from fraudulent marketing techniques was one of the goals of developing a new food and drug law. Congress was concerned not only with dangerous products on the market, but false marketing claims as well.[17]

Early proposals to amend the Wiley Act explicitly addressed the issue of direct-to-consumer advertising. For example, Senate Bill 1944, drafted in 1933 by members of FDA and several staff members of the solicitor's office of the Department of Agriculture, was the first bill to propose an amendment to the 1906 Act. This bill contained a section on false advertising, which defined "false" for the purposes of the Act as any advertisement of a drug claiming to have any effect in the treatment of any of thirty-six diseases.[18] The Secretary of Agriculture[19] was given the power to delete or add to the list of

[12] Section 8 of the Wiley Act stated that a drug would be deemed misbranded if "its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article . . . which is false or fraudulent."

[13] HARRY AUBREY TOUMLIN, JR., A TREATISE ON THE LAW OF FOOD, DRUGS AND COSMETIC 16 (W.H. Anderson Co. 1942).

[14] FTC v. Raladam Co., 283 U.S. 643 (1931).

[15] Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301 et seq.

[16] TOUMLIN, *supra* note 13, at 16.

[17] For example, Senator Copeland, the sponsor of the new bill, stated that "[t]he taking of these 'remedies' for diseases which could not thus be cured or alleviated has resulted frequently in the disease becoming incurable by reason of delay of proper medical treatment." 79 CONG. REC. 47-48 (1906).

[18] S.1944 contained a provision on false advertisement. Section 9(c) of the bill stated that its purpose was:

> To discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be especially dangerous, or patently contrary to the interests of public health, any advertisement of a drug representing it directly or by ambiguity or inference to have any effect in the treatment of any of the following diseases shall be deemed to be false: Albuminuria, appendicitis, arteriosclerosis, blood poison, bone diseases, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, hear diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis, prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infections, smallpox, tuberculosis, tumors, typhoid, uremia, venereal diseases, whooping cough; except no advertisement shall be deemed to be false under this paragraph if it is disseminated to members of the medical and pharmacological professions only or appears in scientific periodicals . . . .

[19] The Bureau of Chemistry, under the Department of Agriculture, was the predecessor organization to FDA. In 1927, the Bureau of Chemistry was bifurcated; the regulatory functions were located in the Food, Drug, and Insecticide Administration, and nonregulatory research was located in the Bureau of Chemistry and Soils. The regulatory agency's name was shortened to the Food and Drug Administration under an agricultural appropriations act in 1930. In 1940, FDA was transferred from the Department of Agriculture to the Federal Security Agency, which became the Department of Health, Education and Welfare in 1953. The Food and Drug Administration Act of 1988 officially established FDA as an agency of the Department of Health and Human Services. *See* FDA, Milestones in U.S. Food and Drug Law History, *available at* www.fda.gov/opacom/backgrounders/miles.html (last visited Oct. 22, 2002).

diseases. An exemption from the bill was made for any advertisements of the listed diseases if disseminated to members of the medical and pharmacological professions and if appearing in scientific magazines. This led to strong criticisms from the drug industry, which believed that the bill would compromise an individual's right to self-medication.[20] S. 1944 also held publishers legally liable for accepting false advertisements.[21] A number of interest groups objected to the bill. These included the Proprietary Association, the United Medicine Manufacturers of America, the National Drug Trade Conference, American Newspaper Publishers Association, National Association of Retail Druggists, and the National Publishers Association.[22] Not surprisingly, the Periodical Publisher Association, representing 144 monthly and weekly journals, and the Editorial Association, representing small newspapers, were among those who objected to the bill. Thus, strong opposition to S. 1944 indicated to Congress that industry and trade-friendly amendments were necessary for passage.

Five years later, S. 5, which incorporated many changes since the introduction of S. 1944, was finally passed and became the FDCA.[23] Congress granted FDA jurisdiction over the labeling of all drugs, but decided to omit advertising provisions from the 1938 Act; instead, Congress amended the Federal Trade Commission Act in 1938 to give jurisdiction over all drug advertising to the FTC.[24]

Several factors led Congress to confer regulatory authority over prescription drug advertising to the FTC rather than FDA. Some in the drug industry favored the FTC having jurisdiction because, unlike the FDCA, the FTC Act was not a criminal statute and did not provide for imprisonment. Further, the FTC's cease-and-desist orders were preferable to FDA's seizure powers. Arguably the main reason why regulatory authority was given to the FTC was due to the lobbying efforts of its then-Commissioner. Ewin Davis, a former member of the House of Representatives.[25]

Today, the concern over DTC advertising relates to prescription drugs rather than over-the-counter (OTC) drugs. Yet, prior to 1951, there was no general official category of prescription drugs. While pharmacists would not dispense many drugs without a prescription, a prescription was not required by law, with the exception of narcotics. In 1951, the Durham-Humphrey Amendments to the FDCA required drugs that are not safe for use except under medical supervision to be dispensed only by prescription of a licensed practitioner.[26] The amendments had a two-fold objective: to protect the public from abuses in the sale of potent prescription drugs, and to relieve pharmacists and consumers from burdensome and unnecessary restrictions on the dispensing of drugs that can be taken safely without the supervision of a physician.[27]

In 1962, the Kefauver-Harris Drug Amendments to the FDCA transferred regulatory authority over prescription drug advertising from the FTC to the FDA, by enacting section 502(n) of the FDCA.[28] The FTC retained regulatory authority over OTC drug

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[20] CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL 37 (Princeton Univ. Press 1970).

[21] *Id.* at 51.

[22] *Id*. at 38-39.

[23] Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301 et seq.

[24] Wheeler-Lea Act, 52 Stat. 111, ch. 49 (1938).

[25] As Rep. Sam Rayburn of Texas, Chairman of the House Commerce Committee, stated, "There might be a little lobbying around here by some people, but there is nobody who has lobbied around this Capitol on any bill in the 23 years I have been in Congress more than members of the Federal Trade Commission have lobbied on this bill, and I love the Federal Trade Commission."

[26] Pub. L. No. 82-215, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353(b)).

[27] SEN. REP. NO. 82-946, at 195 (1951), reprinted in 1951 U.S.C.C.A.N. 2454.

[28] Section 502(n)(3) states in pertinent part that "no advertisement of a prescription drug . . . shall, with respect to the matters specified in this paragraph . . ., be subject to the provisions of section 12 through 17 of the Federal Trade Commission Act . . . ."

advertising. Whether Congress intended to confer jurisdiction to FDA specifically over DTC advertising of prescription drugs is ambiguous because the legislative history is silent on that point. Further, Congress was concerned mainly with promotions directed to the medical community.[29] Drug manufacturers did not practice DTC advertising of prescription drugs at the time that Congress was considering transfer of the regulation of prescription drug advertising to FDA.[30] Therefore, its absence from the annals of legislative history should not be surprising.

III. CURRENT REGULATION OF DTC AND PRESCRIPTION DRUG DTC ADVERTISING

A. *FTC Regulation of DTC Drug Advertising*

The Wheeler-Lea Act of 1938 granted the FTC jurisdiction over all drug advertisements, which the FTC retained until 1962 when authority over prescription drug advertising was transferred to the FDA. The FTC's authority to regulate OTC drug advertising is derived from section 5 of the Federal Trade Commission Act, which declares "unfair or deceptive acts or practices" to be unlawful, and directs the agency to prevent the use of such acts or practices.[31] In addition, section 12 of the FTC Act prohibits the dissemination of false and misleading drug advertisements,[32] defined in section 15 as those that are misleading in material respect.[33] The FTC's policy regarding deceptive advertising is outlined in its Deception Policy Statement[34] and its Statement on Advertising Substantiation.[35] An advertisement is considered deceptive if it contains a representation or omission that is likely to mislead consumers who are reacting reasonably under the circumstances, and the representation or omission is material. A representation or omission is material if it is likely to affect consumers' decisions with respect to purchase or use of a product. The FTC, in analyzing an advertisement, focuses on the net impression it conveys, rather than on the individual elements of the advertisement. The FTC also may find an advertisement deceptive due to the omission of material information; advertisements can mislead consumers by what they do not say.

B. *FDA Regulation of Prescription Drug Advertising*

In 1954, when FDA had jurisdiction over all drug labeling and the FTC had jurisdiction over all drug advertising, FDA and the FTC entered into the "Working Agreement

[29] SEN. REP. NO. 87-448, at 115 et seq. (June 27, 1961).

> There is a marked difference in the advertising and promotion of proprietary and ethical drugs. Proprietary drugs—those sold over the drugstore counter—are like most other products in that sales pressures are exerted upon the final consumer who is subjected to an intensive barrage of advertisements for brand name products in newspapers, magazines, radio, and television. In the case of ethical drugs—those sold under prescription—the brunt of promotion effort is directed to the prescribing physician. Since his prescription dictates the particular drug to be used, usually the brand name, the physician is the focal center of advertising and promotional pressures.

[30] *See* Lance S. Gilmore, *A Consideration of Direct-to-Consumer Advertising of Prescription Drugs and Potential Legal Problems With the Brief Summary Requirement: Is the FDA's Regulatory Authority Illusory?*, 46 FOOD DRUG COSM. L.J. 851-52 (1991).

[31] 15 U.S.C. § 45 (2002).

[32] *Id.* § 52.

[33] *Id.* § 55(a).

[34] 103 F.T.C. 110, 174 (1983).

[35] 49 Fed. Reg. 30,999 (Aug. 2, 1984).

Between the Federal Trade Commission and the Food and Drug Administration" to eliminate any duplication of effort.[36] This Agreement has been amended twice. To reflect the 1962 amendments to the FDCA and to provide explicit guidelines for prescription drug advertising, the working agreement was amended in 1968.[37] In 1971, the Agreement was amended to provide FDA with explicit and primary authority over prescription drug advertising.[38]

The FDCA does not actually define—although it does explicitly mention—advertisements,[39] but FDA generally interprets the term to encompass information, other than labeling,[40] that promotes a drug product and is sponsored by a manufacturer. In addition, FDA's regulations address advertising, and they provide a list of examples that constitute advertisements, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."[41]

The advertising provision of the FDCA is only one paragraph long, and requires simply that the advertisement include the drug's generic name and formula, and a brief summary describing the effectiveness of the drug and its risks.[42] To comply with the statutory mandate, FDA developed regulations that impose two major requirements on prescription drug advertisements. First, the "brief summary" requires that the advertisement must provide the drug's side effects, contraindications, warnings, and precautions, as well as the indications for use.[43] Second, the "fair balance doctrine" provides that the entire advertisement must present a balanced account of all clinically relevant information; the risks must be presented prominently and legibly so that the benefits are not unfairly emphasized.[44] For DTC ads, the agency has interpreted the fair balance doctrine to mean that balancing information should appear in the primary text of the promotional material, in language understood by consumers, so that consumers can evaluate drug benefit claims and form accurate opinions about prescription drugs.[45] The agency, through regulation, also has extended the FDCA's prohibition against false or misleading labeling to include advertising.[46] Furthermore, only information consistent with the approved labeling generally can be used in advertising.

FDA recognizes three broad categories of prescription drug advertisements, which are regulated in different ways: 1) reminder advertisements, 2) help-seeking or disease-oriented advertisements, and 3) product-claim or indication advertisements.[47] Reminder advertisements call attention to the name of the drug product, but do not include specifications of the drug product.[48] An example of this would be a ballpoint pen imprinted with a drug brand name. Help-seeking or "see your doctor" ads typically describe the symptoms of a disease or condition, and encourage consumers to consult their physician to discuss treatment options, but do not mention the drug's name.[49] Reminder

[36] 3 Trade Reg. Rep. (CCH) ¶ 9850.01.

[37] *Id.*

[38] Memorandum of Understanding, 36 Fed. Reg. 18,538 (Sept. 9, 1971).

[39] FDCA § 502(n) (21 U.S.C. § 352(n)).

[40] The FDCA defines labeling as "any written, printed, or graphic matter upon or accompanying the drug."*See* FDCA § 201(k) (21 U.S.C. § 321(k)).

[41] 21 C.F.R. § 202.1(l)(1) (1979).

[42] 21 U.S.C. § 352(n) (2002).

[43] 21 C.F.R. § 202.1(e) (1979).

[44] 21 C.F.R. § 202.1(e)(5)-(7) (1979).

[45] 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

[46] 21 C.F.R. § 202.1(e)(5)-(7) (1979).

[47] 60 Fed. Reg. at 42,581-83.

[48] *Id.*

[49] 60 Fed. Reg. at 42,582.

advertisements and help-seeking advertisements are exempt from the brief summary and fair balance requirements because they do not reveal information about the effectiveness of a drug.[50] Product-claim advertisements reveal the drug's name and indication, and thus must satisfy the brief summary requirements and maintain fair balance.

C. *FDA Regulation of DTC Advertising*

Within FDA, drug advertising is regulated by the Division of Drug Marketing, Advertising, and Communications (DDMAC), under the Center for Drug Evaluation and Research (CDER). No official regulations pertain specifically to DTC promotion. FDA's more recent approach in regulating prescription drug promotion does, however, recognize and account for the differences between healthcare professionals and consumers as recipients of the material. Differences include medical and pharmaceutical expertise, perception of pharmaceutical claims, and information processing. FDA monitors DTC promotion to ensure that adequate contextual and risk information, presented in understandable language, is included both to fulfill the requirement for fair balance and to help the consumer accurately evaluate promotional claims and presentations.

FDA does not require preclearance of promotional pieces unless the drug was approved on an accelerated basis.[51] Manufacturers are required, however, to submit advertising to FDA at the time of its initial dissemination. This is to be transmitted on an FDA Form 2253.[52] Nevertheless, FDA has requested that drug manufacturers voluntarily submit proposed DTC promotions before dissemination, thus allowing the agency the opportunity for review and comment.

To ensure compliance with prescription drug advertising laws and regulations in general, DDMAC employs a routine surveillance and monitoring program. Concerned citizens, healthcare practitioners, and competitor pharmaceutical companies also alert the agency to questionable advertisements. If DDMAC finds a promotional piece that is in violation of the law or does not comply with FDA guidelines, DDMAC issues a letter to the company disseminating the violative material. There are two types of letters that DDMAC issues to companies to notify them of violations: the first type is a Notice of Violation (NOV) Letter (or "untitled letter") that is sent for minor violations; the second type, a warning letter, is sent for more serious violations and essentially is FDA's promise to proceed against the manufacturer if it does not initiate corrective action. Letters sent to companies are posted on CDER's website.[53]

When DDMAC issues an NOV letter to a company in reference to DTC advertisements, the usual corrective action required by DDMAC is for the company to discontinue the referenced violative advertisements and any similar advertisement that would be considered violative. The company typically is asked to respond to DDMAC in writing within ten to fourteen days, indicating its intent to comply and providing a list of all violative advertisements that are being discontinued, with the dates of discontinuation.[54]

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[50] 21 C.F.R. § 202.1(e)(2)(i) (1979).

[51] 21 C.F.R. § 314.550 (2002).

[52] *Id.* § 314.81(b)(3)(i).

[53] DDMAC warning and untitled letters are online at FDA Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, *available at* http://www.fda.gov/cder/warn/index.htm.

[54] In a very few cases, the companies are asked to respond more quickly. For example, one NOV letter required that the company respond to DDMAC within four days. This particular letter referenced a lack of fair balance, minimization of risks, insufficient adequate provision, and inadequate communication of indication. The company had been alerted to the problem of inadequate communication of indication prior to receiving this NOV, and had not taken appropriate action.

On July 24, 2001, FDA stated that since 1997, DDMAC had issued thirty NOV letters on product claim broadcast advertisements, three warning letters on broadcast advertisements, twelve "untitled" letters on purported reminder broadcast advertisements, and three untitled letters on purported help-seeking broadcast advertisements.[55] According to FDA, most of the violations included overstating the product's efficacy, expanding the indication or the patient population for whom the drug is indicated, or minimizing risks through inadequate presentation or omission of material.[56] With regard to print DTC advertisements or promotional materials, in that same time period FDA issued forty-four "untitled" letters and two warning letters. Generally, product claim violations were similar to those identified for broadcast advertisements. The reminder advertisements contained enough information to require them to include a brief summary, and the help-seeking advertisements implied a particular product in their message.[57]

During the second half of the year 2001, FDA issued three additional warning letters.[58] One of the warning letters addressed promotional activities and materials used to market a prescription drug[59] and the other two letters addressed the package labeling for combination drug-dietary supplement products.[60] In the first ten months of 2002, FDA has issued eighteen untitled letters, but no warning letters to manufacturers of prescription drugs.[61]

D. *Regulation and Enforcement of Broadcast Promotion*

Although the brief summary requirement is easily satisfied in print advertising, it is too impractical for a thirty-second television commercial. Hence, FDA regulations allow sponsors of broadcast advertisements (television and radio) to make "adequate provision" of approved product labeling instead of the brief summary.[62] In October 1995, FDA held public hearings on DTC promotion.[63] FDA issued the "Draft Guidance for Industry, Consumer-Directed Broadcast Advertisements" in August 1997, facilitating manufacturer dissemination of DTC promotions through broadcast media. The agency released the Final Guidance in August 1999, after receiving comments on the Draft Guidance. Although this Guidance does not have the legal force of a law or regulation, it does serve to provide direction and stability within the industry on this issue. Essentially FDA informed the public that it would not consider a broadcast advertisement to be in violation if it complies with the Guidance.

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[55] *Hearings Before the Subcomm. on Consumer Affairs, Foreign Commerce and Tourism, of the Senate Comm. on Commerce, Science and Transportation* (statement of Nancy M. Ostrove, Ph.D., Deputy Director, Division of Drug Marketing, Advertising and Communications, FDA July 24, 2001), *available at* http://www.fda.gov/ola/2001/drugpromo0724.html (last visited Oct. 22, 2002).

[56] *Id.*

[57] *Id.*

[58] FDA Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, *available at* http://www.fda.gov/cder/warn/warn2001.htm (last visited Oct. 22, 2002).

[59] FDA Warning Letter to Merck & Co. (released Sept. 17, 2001), *available at* http://www.fda.gov/cder/warn/2001/9456.pdf.

[60] Warning Letter to Omni Nutraceuticals, Inc. (released Oct. 16, 2001), *available at* http://www.fda.gov/cder/warn/2001/02-HFD-312-02.pdf; Warning Letter to B.F. Ascher & Company, Inc. (released Oct. 16, 2001), *available at* http://www.fda.gov/cder/warn/2001/02-HFD-312-01.pdf.

[61] 'FDA did issue seven warning letters regarding promotion of dietary supplements and three warning letters regarding promotion of improper compounding. *See* http://www.fda.gov/cder/warn/warn2002.htm (last visited Oct. 17, 2002).

[62] *See* 21 C.F.R. § 202(e)(1) (1979); *see also* Food and Drug Administration, Guidance for Industry, Consumer-Directed Broadcast Advertisements (Aug. 1999), *available at* http://www.fda.gov/cder/guidance/1804fnl.htm (last visited Oct. 22, 2002).

[63] Department of Health and Human Services, FDA Public Hearing on Direct-to-Consumer Promotion, Silver Spring, MD (Oct. 18-19, 1995).

FDA determined that broadcast advertisements must disclose the product's major risks in either the audio or visual parts of the presentation. This disclosure of risks is known as the "major statement."[64] The Guidance provides recommendations for fulfilling the "adequate provision requirement":

- Disclosure in the advertisement of an operating toll-free telephone number, through which the consumer should be given the option of having the labeling mailed to them in a timely manner or having the labeling read to them over the phone;
- Reference in the advertisement to an alternative mechanism, such as reference to a print advertisement, to provide package labeling to consumers with restricted access to the Internet or those who are uncomfortable actively requesting additional information;
- Disclosure in the advertisement of an Internet web page address that provides access to the package labeling; and
- Disclosure in the advertisement that pharmacists, or healthcare providers, may provide additional information.[65]

Recently, a new version of DTC broadcast advertisements has emerged. These advertisements are actually two complementary advertisements: a help-seeking advertisement and a reminder advertisement, separated by another sponsor's commercial for an unrelated product. Each spot runs less than thirty seconds and, standing alone, would not require a major statement or adequate provision.[66] While the advertisements may have an educational benefit, such practices strain the more lenient FDA guidelines for broadcast promotion. FDA is increasingly vigilant in this area, and the agency is challenging these types of practices. There is no indication, however, that DTC advertising will abate. In 1999, FDA undertook a survey of attitudes and behaviors associated with DTC advertising. While the survey was quite detailed and comprehensive, it is interesting to note that about half of the patients who responded indicated that an advertisement for a prescription drug had caused them to look for more information. And twenty-seven percent of those who had seen a doctor in the last three months indicated that an advertisement caused them to ask a doctor about a medical condition or an illness of their own, about which they previously had not talked to a doctor.[67] Rather than attempt to deter DTC advertising, FDA appears to be concentrating on making certain the advertising is informative and well balanced, and that it adheres to the current Guidance.

IV. DTC ADVERTISING IN OTHER COUNTRIES

The United States is somewhat unique in that the government allows DTC advertising of prescription drugs, whereas the rest of the world, with the exception of New Zealand, does not.

A. *European Economic Community*

The European Economic Community (EEC) has required member states to prohibit DTC advertising of prescription drugs. The EEC, comprised of fifteen member coun-

[64] *Id. See also* Food and Drug Administration, Guidance for Industry, *supra* note 62.

[65] *See* Food and Drug Administration, Guidance for Industry, *supra* note 62.

[66] C. Adams, *Xenical Skirts FDA Regulations by Avoiding Unpleasant Effects*, WALL ST. J., Apr. 3, 2001.

[67] Office of Medical Policy, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration, Attitudes and Behaviors Associated With Direct-to-Consumer (DTC) Promotion of Prescription Drugs—Main Survey Results (May 26, 1999), *available at* http://www.fda.gov/cder/ddmac/dtcindex.htm (last visited Oct. 22, 2002).

tries,[68] was formed in the 1950s as a trade organization to encourage free trade among European states. The EEC developed into a governing body through its status as a trade regulator. Uniform standards became increasingly desirable to promote free trade. The EEC developed into the European Union, to promote its status as a governing body rather than just a trade organization.

On March 31, 1992, the EEC enacted Council Directive 92/28/EEC, which outlines the various prohibitions against advertising of prescribed medications.[69] The legislation bans all forms of prescription drug promotion aimed at the general public and also prohibits the distribution of free samples of prescription drugs to anyone other than people who are authorized to write prescriptions.[70] There are exceptions, however, for the advertising of approved vaccination campaigns.[71] Prescription drug advertising may be directed at doctors or pharmacists authorized to write prescriptions, but even then it must be subject to monitoring.[72] The EEC states in its preamble that it wants professionals who fill prescriptions to have access to neutral and objective sources of information about the drug and not to be coaxed into filling prescriptions based on financial incentives provided by drug companies.[73]

In the United Kingdom, self-regulation is exercised through the Association of British Pharmaceutical Industry (ABPI).[74] The ABPI developed a code, which is intended to provide comprehensive coverage of British legal requirements as well as ethical requirements developed by the World Health Organization.[75] The Prescriptive Medicines Code of Practice Authority (PMCPA) branched off from the ABPI and updates a system for the maintenance of quality in communication. If a company or a health professional wants to challenge how a company distributes information, they would first go to the PMCPA. All companies would have to adhere to whatever decision was reached by that body or by the Code of Practice Appeal Board. This board is chaired by an independent, legally qualified chairman and includes three medically qualified independent members, an independent pharmacist, and an independent member from a body that provides information on medicines. Eight senior executives and four medical directors from pharmaceutical companies make up the rest of the membership of the Appeal Board. This board is the final arbiter on complaints.[76] The PMCPA also has the power to prosecute companies who violate communication standards, and to require companies to submit materials for pre-approval.[77]

While the EEC prohibitions remain in place, pressure from industry, the widespread use of Internet and digital television, and patient demand for product information have led many to believe that DTC is inevitable in Europe.[78] For example, in the United Kingdom, the ABPI code opposes DTC advertising.[79] In September 2000, however, the British Medi-

[68] The member states are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

[69] Council Directive 92/28 /EEC of 31 Mar. 1992 on the advertising of medicinal products for human use.

[70] *Id.*

[71] Council Directive 92/28/EEC, Art. 3.

[72] *Id.*

[73] *Id.*

[74] *The Development of Controls on the Promotion of Prescription Medicines*, ESRA RAPPORTEUR, July/Aug. 1999, at 15-18.

[75] *Id.*

[76] *Id.*

[77] Compliance with the code is obligatory for members of the ABPI. About 70 other nonmember companies have agreed to comply with the code, thus covering nearly all of the relevant companies.

[78] Richard Sullivan, *Direct-to-Consumer Advertising: The Future in Europe*, 93 J. ROYAL SOCIETY OF MED. 400-01 (Aug. 2000).

[79] *Id.*

cal Association announced plans to work with the British pharmaceutical industry to help develop regulations on DTC prescription drug advertising.[80] The pharmaceutical industry has been encouraging this move, arguing that DTC improves public health, helps increase patient awareness of health issues, and communicates available treatments.[81]

B. *Canada*

Canadians are facing similar issues. Like Europe, Canada prohibits DTC prescription drug advertising. The country has banned the practice since 1949.[82] Recent legislation, Section C.01.044 of the Food and Drug Regulations, allows for advertisements that are aimed only at professionals and contain only the name, price, and quantity of the drug.[83] A self-regulation group known as the Therapeutic Products Programme (TPP) was given jurisdiction to monitor all prescription drug advertising in Canada, but the Pharmaceutical Advertising Advisory Board (PAAB) maintains a code of acceptable electronic broadcast advertising standards, which apply only to advertisements to health professionals. [84] The PAAB is made up of several private professional organizations including the Canadian Drug Manufacturers Association, Canadian Medical Association, Canadian Pharmacists Association, and Association of Medical Advertising Agencies.[85]

As in Europe, the Canadian pharmaceutical industry has been testing the limits of its country's regulations.[86] A recent set of contraceptive advertisements has tried to bypass the provision that prevents companies from including the name of the product and its uses, by using phrases and symbols in the advertisement that suggest the company's product.[87] As a result, a coalition of twenty women's and consumer's groups, known as the Working Group of Women and Health Protection, has sent a letter of protest to the Canadian Health Minister, calling for a stop to those advertisements.[88]

Supporters of DTC advertising in Canada have argued that Canada's strong regulations do little when America's close border permits Canadians to view American advertisements via television and radio broadcast, and when access to the Internet can transcend geographically imposed limitations.[89] In addition, a 1992 case in the Supreme Court of Canada struck down the ban against tobacco advertising as an unjustified limit to free speech, possibly heralding the downfall of prescription drug advertising restrictions if such a case were to arise.[90]

There is concern that treating prescription drugs as a "commodity" in Europe or Canada would drive up the price of government-funded healthcare systems.[91] DTC

[80] *DTC Ads in U.K. Should Be Negotiated With Industry—Medical Association*, F-D-C REP. ("The Pink Sheet"), Sept. 4, 2000, at 13.

[81] Sullivan, *supra* note 78, at 400.

[82] Philip Lundrigan, *This Ad's forYou: Industry Pushes for Direct-to-Consumer Advertising of Prescription Medications*, LIVING + NEWS & TREATMENT INFO. FROM THE BC PERSONS WITH AIDS SOC'Y, July/Aug. 2000, No. 7, at 15, *available at* http://www.bcpwa.org/pdf/issue7.pdf.

[83] Canada Food and Drugs Act, Section C.01.044, Food and Drug Regulations.

[84] The Pharmaceutical Advertising Advisory Board, Code of Advertising Acceptance, disclosure/prescribing information, section 7.9 (Apr. 28, 2000).

[85] *About PAAB*, *available at* http://www.paab.ca/about_en.html (last visited Oct. 22, 2002).

[86] Planned Parenthood Federation of Canada, *Hot Issues—Coalition Concerned About Direct-to-Consumer Prescription Drug Advertising, available at* http://www.ppfc.ca/issues/june2000.htm#2 (last visited Oct. 22, 2002).

[87] *Id.*

[88] *Id.*

[89] Lundrigan, *supra* note 82, at 1.

[90] *Id.*

[91] Canadian Pharmacists Association, *CPHA Position Statement on Direct to Consumer Advertising (DTCA) App. 1, DTCA Backgrounder* (Differences Between Canada and the U.S.) (Feb. 2000), *available at* http://www.pharmacists.ca/content/about_cpha/Who_We_Are/Policy_Position/pdf/dtca.pdf.

advertising might increase the cost of the drug itself and promote more visits to the doctor.[92] Both the Canadian government and the EEC also indicate they want to ensure that objective information is released to patients rather than information that is based on a profit motive.[93]

C. *New Zealand*

New Zealand is the only other country, in addition to the United States, that allows for DTC advertising. Like Europe and Canada, New Zealand provides public healthcare for its citizens. Groups such as the Researched Medicines Industry (RMI) Association of New Zealand, a nonprofit professional trade association, have looked at both sides of the debate and have concluded that DTC ads can serve a public benefit.[94] The RMI also believes, however, that DTC ads may put pressure on the government's pharmaceutical budget, may put pressure on doctors to prescribe drugs if requested by a patient, are driven by commercial considerations, and are insufficient for consumers to make well-informed decisions. The RMI would address these concerns through preventive regulatory measures.[95] The Association noted that if physicians, pharmacists, government officials, and consumer groups work together, DTC ads would present far fewer problems than imagined and would help keep the country's citizens well informed about healthcare issues.[96]

V. U.S. LEGISLATIVE ACTIVITY REGARDING DTC ADVERTISING

A number of bills have been introduced in Congress in the past few years that propose to limit pharmaceutical advertising of prescription drugs.

Several bills have sought to amend the Internal Revenue Code to deny deductions for pharmaceutical advertising in general. In May 2002, similar bills, such as the one titled the "Fair Advertising and Increased Research" (FAIR) Act, were introduced in both the U.S. House of Representative and the Senate.[97] Each bill proposed to amend the Internal Revenue Code of 1986 to limit the deduction for advertising of FDA-approved prescription drugs by the manufacturer of such drugs to the level of such manufacturer's research and development expenditures.[98] Specifically, the proposed bills state that

> [N]o deduction shall be allowed . . . for any taxable year for any expenditure relating to the advertising, promoting, or marketing (in any medium) of any FDA prescription drug manufactured by the taxpayer to the extent that the aggregate amount of such expenditures exceeds the taxpayer's aggregate research and development expenditures for such taxable year.[99]

Both bills have gone to committee—the Senate bill to the Committee on Finance and the House bill to the Committee on Ways and Means.

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[92] *Id.*

[93] *Id.*

[94] Researched Medicines Industry, *DTC Advertising Can Enhance Public Health: The Case for Direct-to-Consumer Prescription Medicine Advertising* (June 2000), *available at* http://www.rmianz.co.nz/pdfs/fulldtc.pdf.

[95] *Id.*

[96] *Id.*

[97] H.R. 4821, 107th Cong. § 208I (2002); S. 2486, 107th Cong. § 208I (2002).

[98] H.R. 4821 and S. 2486, *supra* note 97.

[99] H.R. 4821 and S. 2486, *supra* note 97 (Limitation on Tax Deductions for Advertising by FDA Prescription Drug Manufacturers).

On September 9, 2002, Representative Patrick Kennedy (D-RI) introduced H.R. 5350, titled the "Prescription Affordability and Medicine Safety Act of 2002." This bill seeks to amend the Internal Revenue Code to limit deductions for advertising, promoting, or marketing (in any medium) of prescription drugs to fifty percent of the manufacturer's aggregate research and development expenditures per year.[100] Representative Jerrold Nadler (D-NY) introduced a bill in July 2002 (H.R. 5105, titled the "Say No to Drug Ads Act") that also seeks to deny *any* deduction for DTC advertisements of prescription drugs.[101]

Other bills have targeted DTC advertising. A bill titled "Accuracy in Pharmaceutical Advertisements Act" (H.R. 4833), introduced by Representative Thomas Allen (D-Maine) and co-sponsored by nineteen Democrats and Representative Bernard Sanders (I-VT), seeks to amend the FDCA to establish authority for the imposition of civil penalties for DTC advertisements that violate the FDCA. The bill was referred on June 23, 2002, to the Subcommittee on Health of the House Committee on Energy and Commerce.[102]

Representative Pete Stark (D-CA) introduced a number of bills in the U.S. House of Representatives to limit DTC advertising. In June 2000, he introduced H.R. 4686, which proposed to amend the Internal Revenue Code of 1986 to deny any deduction for DTC advertisements of prescription drugs that fail to provide certain information or to present information in a balanced manner. H.R. 4686 also proposed to amend the FDCA to require reports regarding such advertisements. In June 2001, Stark introduced very similar legislation, H.R. 2352, the "Fair Balance Prescription Drug Advertisement Act of 2001." Each of these bills was referred to both the House Committee on Energy and Commerce and the House Committee on Ways and Means.

Much federal legislative activity focuses on the issue of the cost of prescription drugs. Two recent bills include provisions that propose research into the effects of DTC advertising. Senator John Rockefeller (D-WV) introduced a bill on June 25, 2002 (S. 2677, titled "Consumer Access to Prescription Drugs Improvement Act of 2002") that is designed to improve consumer access to prescription drugs by, in pertinent part, creating a Pharmaceutical Advisory Committee as part of the Medicare Payment Advisory Commission, that would be charged with reviewing payment policies for drugs in the Medicare and Medicaid programs. The committee would be responsible for considering the effects of DTC marketing and the use (and barriers to use) of generic drugs when recommending payment policies.

Representative Charles B. Rangel (D-NY) and others introduced H.R. 5019 on June 26, 2002, which, in addition to its Medicare provisions, provides for a General Accounting Office study to determine

> whether and to what extent there have been increases in utilization rates of prescription drugs that are attributable to guidance regarding direct-to-consumer advertising of such drugs that has been issued by the Food and Drug Administration … and if so, whether and to what extent such increased utilization rates have resulted in increases in the costs of public or private health plans, health insurance or other health programs.[103]

The study will address specific issues such as:

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[100] H.R. 5350, 107th Cong. § 280I(a) (2002).
[101] 107 Bill Tracking H.R. 5105; 148 CONG. REC. H4552 (July 11, 2002).
[102] 107 Bill Tracking H.R. 4833; 148 CONG. REC. H3036 (May 23, 2002).
[103] H.R. 5015, 107th Cong. § 731 (2002).

- The extent to which DTC advertisements have resulted in effective consumer education about the prescription drugs involved, including an understanding of the risks of the drugs relative to the benefits.
- Whether physicians believe that the advertisements interfere with the exercise of their medical judgment by influencing consumers to prefer advertised drugs over alternative therapies.
- Whether DTC ads have affected consumer decisions to seek advertised drugs rather than lower-cost alternative therapies and whether there has been a corresponding increase in healthcare costs for taxpayers, employers, or consumers.

Some states also have entered the DTC debate. For example, a new law in West Virginia allows the state to investigate innovative strategies to manage drug costs, including requiring manufacturers to disclose expenditures for advertising, marketing, and promotion and to establish counter-detailing programs to educate prescribers about the relative costs and benefits of various drugs.[104] In January 2001, a bill was introduced in Connecticut that would require pharmaceutical companies that provide prescription drugs in that state to disclose all prescription drug advertising and promotional costs in order to determine the impact of such costs on prescription drug prices and on state residents. In March 2001, the Vermont House of Representatives passed a joint resolution that urges FDA to institute a moratorium on DTC advertising and to develop more stringent regulatory restrictions on DTC promotional activities.[105]

VI. PERSPECTIVES OF STAKEHOLDERS

Many interest groups take part, directly or indirectly, in the legislative and regulatory process and are regularly part of the public debate on any particular issue. This article presents some of the key stakeholders and their points of view on DTC advertising.

A. *Pharmaceutical Industry*

The pharmaceutical industry clearly supports DTC advertising of prescription drugs.[106] While successful DTC advertising can lead to financial benefit for these companies,[107] the industry also cites a number of nonfinancial reasons to support their position.

The Pharmaceutical Research and Manufacturers Association (PhRMA), the industry trade group representing most of the brand name U.S. pharmaceutical manufacturers, contends that DTC advertising can "foster competition among products, which can lead to improved quality and lower prices for consumers."[108] In addition, PhRMA also indicates that consumer-directed ads may also benefit the public health by starting a dialogue between patients and physicians, which can lead to the education and treatment of the patient.[109]

The industry argues that DTC advertising enhances consumer knowledge by making consumers aware of new products, as well as helping them identify symptoms and new

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[104] W. VA. CODE § 5-16C-9 (2002).

[105] Vt. House Jt. Res. 60, 66th Biennial Sess. (Mar. 2, 2001); 2001 Bill Tracking VT H.J.R. 60.

[106] *See, e.g.,* PhRMA, Backgrounders and Facts: Direct-to-Consumer Advertising, *available at* http://www.phrma.org/publications/quickfacts/03.10.2000.176.cfm (last visited Oct. 17, 2002). PhRMA is a leading organization representing the nation's research-based pharmaceutical and biotechnology companies.

[107] Research Brief, Prescription Drugs and Mass Media Advertising, National Institute for Health Care Management (NIHCM) Research and Educational Foundation, at 6-7 (Sept. 2000).

[108] PhRMA, Backgrounders and Facts, *supra* note 106.

[109] *Id.*

treatments for previously untreatable diseases.[110] Moreover, consumers are encouraged to discuss with their doctors medical conditions and illnesses they may never have discussed before.[111] Furthermore, the industry argues that patient compliance with drug regimens could be enhanced, because patients who have seen advertisements for medicines that they are taking may feel better about the drug.[112] Overall, DTC advertising is viewed by the industry as good for both manufacturers and patients alike because it can "improve public well-being."[113]

Pharmaceutical manufacturers recognize that there are many arguments against DTC advertising, primarily related to the potential for advertising's effect on pharmaceutical spending. The recent upward trend in the cost of pharmaceuticals has sparked much concern among lawmakers;[114] DTC advertising often is blamed for at least a portion of the cost increase.[115] The industry admits that total expenditures for pharmaceuticals are rising, but has stated that "this increased utilization reflects the extraordinary value that medicines provide, to patients and to the healthcare system."[116]

As for any negative effects of this type of marketing, PhRMA suggests there is little chance of DTC advertising leading to inappropriate use.[117] Physicians act as gatekeepers, and patients can obtain prescription medications only under a doctor's supervision.[118] In other words, the patient is equipped with information, not the power to prescribe.[119] Furthermore, PhRMA points out that patients have the right to ask for information, and manufacturers have the right to provide it in an "accurate, direct, and user-friendly manner."[120]

B. *Managed Care*

The managed care industry holds a somewhat apprehensive view of DTC advertising. As drugs are becoming the largest-growing sector of healthcare expenditures,[121] many insurers believe that DTC advertising increases demand, which in turn increases their costs.[122]

The concern is that DTC advertisements spur the use of new, higher-cost drugs when there are cheaper alternatives available (brand or generic drugs).[123] The Health Insurance Association of America (HIAA) noted in a 1999 white paper that "direct-to-

[110] Alan F. Holmer, *Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians,* 281 JAMA 380-82 (1999).

[111] *Id.*

[112] *Id*. This was based on a 1998 *Prevention Magazine* study based on a survey with technical assistance by FDA.

[113] PhRMA, Backgrounders and Facts, *supra* note 106.

[114] *See, e.g.,* 147 CONG. REC. E317 (daily ed. Mar. 8, 2001) (statement by John J. Duncan, Jr., regarding the high cost of medications in America); 147 CONG. REC. S2476-77 (daily ed. Mar. 20, 2001) (statement by Tim Johnson, M.D., discussing the increase in prescription drugs costs).

[115] *See* 146 CONG. REC. S11489-90 (daily ed. Nov. 1, 2000) (statement by Tim Johnson, M.D., on the DTC advertising phenomenon and its effects on drug costs to the consumer); MICHIE I. HUNT, PRESCRIPTION DRUG COSTS: FEDERAL REGULATION OF THE INDUSTRY (Blue Cross/Blue Shield Ass'n 2000).

[116] PhRMA, Backgrounders and Facts, *supra* note 106.

[117] *Id*.

[118] *Id*.

[119] Holmer, *supra* note 110.

[120] PhRMA, Backgrounders and Facts, *supra* note 106.

[121] Health Insurance Association of America (HIAA), Useful Facts, Chart B, *available at* http://www.hiaa.org/research/usefulfacts.cfm (last visited Oct. 22, 2002).

[122] *Id*.; HUNT, *supra* note 115, at 7, 14.

[123] PRESCRIPTION DRUGS: COST AND COVERAGE TRENDS (HIAA Sept. 1999); Michael D. Dalzell, *Direct-to-Consumer Advertising: Can Everyone's Interests Be Balanced?*, MANAGED CARE, Dec. 1999, *available at* http://www.managedcaremag.com/archiveMC/9912/9912.dtc.html (last visited Oct. 22, 2002).

consumer advertising is placing the burden on the provider to prescribe requested medications, despite cost or efficacy."[124]

Insurers say that the more expensive drugs targeted to consumer audiences, many of which are unnecessary, cost a lot of money to cover.[125] Pressure by subscribers may force managed care organizations to yield to consumer opinions by putting the most popular prescription drugs on their formularies.[126] The Blue Cross Blue Shield Association has indicated that consumer-directed advertising raises concerns in public policy because of the potentially great impact on health-system utilization and cost.[127]

C. *Physicians*

Many doctors state that they are increasingly pressured by patients to prescribe drugs seen in an advertisement.[128] Physicians also believe that misleading advertisements may lead to unreasonable patient expectations about the effectiveness of a product,[129] and that patients may request medications that are inappropriate for their needs.[130] Other physicians perceive a risk of losing reputable standing if they are not knowledgeable about new products.[131] Some physicians fear that DTC promotion will harm the doctor-patient relationship (e.g., the consequences of refusing to prescribe unnecessary medications the patient desires) and strain their responsibility as gatekeepers.[132]

A 1998 position paper by the American College of Physicians (ACP) conveys its support for increased consumer healthcare awareness, but questions whether the type of information typically provided in DTC advertisements is truly accurate and whether this is the best way of distributing healthcare information.[133] "Though information may be put forth in advertisements by drug manufacturers to educate, these ads are primarily calculated to encourage increased consumption of the advertised product."[134] ACP recognizes, however, that DTC advertising is now a fixture of the healthcare marketplace, and offers suggestions on how such advertisements might be regulated by FDA.[135] ACP would like doctors to receive DTC ads prior to distribution so that they might better prepare for patient questions/concerns.[136]

The American Medical Association (AMA) has opposed many aspects of DTC advertising for years.[137] The AMA states that it is concerned with the impact DTC advertising might have on the doctor-patient relationship, as well as its impact on the rising cost of healthcare.[138] The organization has disapproved particularly of product-

[124] PRESCRIPTION DRUGS: COST AND COVERAGE TRENDS, *supra* note 123.

[125] *Id*.

[126] Tamar V. Terzian, *Direct to Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149-67 (1999).

[127] HUNT, *supra* note 115, at 18.

[128] Terzian, *supra* note 126, at 159.

[129] *Id*. at 158.

[130] *Id*.

[131] HUNT, *supra* note 115, at 22.

[132] Terzian, *supra* note 126, at 165.

[133] American College of Physicians, Governmental Affairs and Public Policy: Direct to Consumer Advertising for Prescription Drugs, *available at* http:// http://www.acponline.org/hpp/pospaper/dtcads.htm (last visited Oct. 22, 2002).

[134] *Id*.

[135] *Id*.

[136] *Id*.

[137] American Medical Association, House of Delegates, *available at* http://www.ama-assn.org/meetings/public/annual98/reports/comm-e/res506.htm (last visited Oct. 22, 2002).

[138] *Id*.

specific advertisements that do not follow AMA guidelines.[139] AMA Policy H-105.988 established certain principles for DTC advertising, including:

- advertisements should be disease-specific to enhance consumer education;
- advertisements should convey a clear and accurate health education message;
- advertisements should be fairly balanced and clearly explain warnings and potential adverse reactions so as to encourage communication between patient and physician; and
- advertisements should be part of a manufacturer's education program targeting both physicians and consumers.[140]

Even within the AMA, however, debates still exist on the validity of DTC advertising.[141] If done appropriately, DTC advertising is thought to have some beneficial effects, as well.[142] The AMA has called for vigilance on the part of physicians to prevent false expectations by patients,[143] and also has called upon FDA, other federal agencies, and the pharmaceutical industry to investigate the effects of DTC advertising.[144] At its June 2001 annual meeting, the AMA House of Delegates approved a new policy on DTC advertising, advocating that advertisements prominently display the language, "Your physician may recommend other appropriate treatments."[145]

D. *Pharmacists*

In 1988, the American Pharmaceutical Association (APhA) stated its support for state and federal legislation that would allow DTC advertising, as long as a specific brand name was not used.[146] This position was rescinded in 1999, and a new position following DDMAC guidelines for advertising was adopted.[147] Specifically, APhA supports DTC advertisements that are "complete, comprehensive, and understandable . . . [that] inform consumers of potential benefits and risks of the product"; it opposes "false or misleading" advertising.[148] APhA encourages the utilization of pharmacist services, and would like DTC advertisements to be viewed by pharmacists prior to general release, so that pharmacists may address questions and concerns from the general public that result from DTC advertising.[149]

In testimony before the Senate HELP (Health, Education, Labor, and Pensions) Committee, a spokesman for both CVS Pharmacy and the National Association of Chain Drug Stores (NACDS) commented that DTC advertising may encourage the over-utilization of drugs.[150] He stated that the most heavily promoted drugs often are the biggest

[139] American Medical Association, Report of the Council on Medical Service: Pharmaceutical Spending in the United States, CMS Report 3-I-00.

[140] *Id.*

[141] D. West, *Doctor's Report: Questions Over DTC Cost Deepen AMA Rift*, PHARMACEUTICAL EXEC. (Mar. 1999).

[142] *Id.*

[143] *Id.*

[144] *Id. See also* American Medical Association Report, *supra* note 139.

[145] F-D-C. REP. ("The Pink Sheet"), June 25, 2001, at 15.

[146] American Pharmaceutical Association, 1998-1999 Policy Committee Report: Direct to Consumer Advertising, *available at* http://www.aphanet.org/govt/direct.html (last visited Oct. 22, 2002).

[147] *Id.*

[148] *APhA Sets Policy on Telepharmacy, DTC Ads, Unions*, 56 AM. J. HEALTH SYS. PHARM., No. 8, at 706-07 (1999).

[149] *Id.*

[150] *Prescription Drug Costs: What Drives Increases: Hearing Before the Senate Comm. on Health, Education, Labor and Pensions*, 106th Cong. (1999) (statement by Carlos R. Ortiz, Director of Government Affairs, CVS Pharmacy, and the NACDS).

sellers.[151] His suggestion to remedy the imbalance was that Congress review FDA policies toward DTC advertising, "to determine its implications for consumers' health and the healthcare delivery system."[152]

E. *Consumers*

In 1996, *Consumer Reports* evaluated prescription drug advertisements directed towards consumers for accuracy, and found that many of those advertisements omitted important information, and that less than half were forthright about efficacy.[153] *Consumer Reports* further stated that rules governing prescription drug advertising should not be relaxed, pointing out that the purpose of advertisements is to sell products.[154]

During FDA's 1997 to 1999 solicitation of comments on its proposed draft guidelines, consumer groups voiced their ideas on FDA's policy. Public Citizen's Health Research Group filed comments stating that the public is not protected from deceptive advertising practices, and that consumers do not have access to objective information that presents the risks and benefits in such a way as to allow informed decisions.[155] The Group also voiced concerns about the objectivity of the physician gatekeepers themselves, claiming that advertising and marketing can exert a biased influence upon some physicians.[156] In addition, the Group supported a strong research role for FDA, saying the agency was in the best position to conduct valid and valuable research that was free of the conflicts of interest present in privately contracted research.[157]

Other groups possess a more favorable attitude. The National Consumers League Direct-to-Consumer Promotion of Prescription Drugs Roundtable stated in a consensus report that DTC promotion is an effective tool in encouraging consumers to seek health information from their healthcare professionals.[158] Promotion, however, can present only a limited picture of medications because of time and space restrictions. Therefore, the report also emphasized that additional information sources are essential for a balanced assessment of safety and effectiveness.[159] One suggestion for print advertisements was that a more consumer-friendly presentation could be used as an alternative to the brief summary.[160] Also, standardized information messages that included information on efficacy, compliance, risk, contraindications, and food/drug interactions were desirable.[161] The fair balance requirement was also favored.[162] Finally, the report concluded that research into DTC promotion and its effects was necessary.[163]

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[151] *Id.* "For example, the Director of the PACE program for the elderly in Pennsylvania recently told me that just one DTC advertised product (Prilosec) accounted for 20 percent of their total budget for pharmaceutical expenditures." *Id.*

[152] *Id.*

[153] Matthew Hollon, *Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand*, 281 JAMA 383 (Jan. 1999) (citing *Drug Advertising: Is This Good Medicine?*, 6 CONSUMER REP. 62 (June 1996); Public Citizen Health Research Group, Re: Direct-to-Consumer Promotion [Dkt No. 95N-0227], 1996, *available at* http://www.citizen.org/publications/release.cfm?ID=6596 (last visited Oct. 22, 2002).

[154] *Id.*

[155] Public Citizen Health Research Group, Comments on Food and Drug Administration: Attitudinal and Behavioral Effects of Direct-to-Consumer Advertising of Prescription Drugs [Dkt. No. 98N-0748] (submitted Sept. 28, 1998), *available at* http://www.citizen.org/publications/release.cfm?ID=6658 (last visited Oct. 22, 2002).

[156] *Id.*

[157] *Id.*

[158] THE NATIONAL CONSUMERS LEAGUE, THE NATIONAL CONSUMERS LEAGUE DIRECT-TO-CONSUMER PROMOTION OF PRESCRIPTION DRUGS ROUNDTABLE II CONSENSUS REPORT (Sept. 1998).

[159] *Id.*

[160] *Id.*

[161] *Id.*

[162] *Id.*

[163] *Id.*

VII. IMPLICATIONS FOR THE FUTURE OF DTC ADVERTISING

At present, FDA is working to administer or enforce its guidance on broadcast advertisements,[164] while attempting to meet the spirit of the guidance and encourage truthful, balanced, and useful information for consumers.

In addition to statutes, regulations, and policies, other forces are being brought to bear on pharmaceutical advertising. These forces may have a direct impact on DTC prescription drug advertising, specifically as it relates to the First Amendment of the U.S. Constitution.

In a five-to-four opinion in *Thompson v. Western States Medical Center*,[165] the Supreme Court struck down a provision in the FDA Modernization Act (FDAMA) that prohibited pharmacies from advertising compounded products.[166] The provision was not a direct ban on advertising per se, but a type of "safe harbor" for compounded drugs in the form of an exemption from the FDCA's "new drug" requirements.[167] In addition to other restrictions, compounded drugs qualified for the exemption as long as the pharmacy, licensed pharmacist, or licensed physician compounding the drug did not advertise or promote the compounding of any particular drug, class, or type of drug.[168]

FDA argued in defense of the ban on advertising of compounded products, stating that the ban served three important government interests: 1) to protect the public health by protecting the effectiveness and integrity of FDA's new drug approval process; 2) to preserve the availability of compounded drugs for patients who, for particularized medicinal reasons, cannot use commercially available products approved by FDA; and 3) to achieve the proper balance between these two competing interests.[169]

The majority of the Court rejected the view that people will make bad decisions if given truthful information. The Court stated that this argument already had been rejected in *Virginia Board of Pharmacy v. Citizens Consumer Council, Inc.*[170] In that case, the state feared that if people received price advertising from pharmacists, they would choose the low-cost, low-quality service, thus driving the "professional" pharmacist out of business and destroying the pharmacist-customer relationship by causing patients to go from one pharmacist to another. The Court in *Virginia Board of Pharmacy* found these fears insufficient to justify a ban on such advertising, and emphasized that the First Amendment allows lawful information to reach the public.

The *Western States* court applied the four-part *Central Hudson* test for determining whether a particular commercial speech regulation is constitutionally permissible.[171] With respect to *Central Hudson*'s threshold step one, FDA conceded that the speech was not unlawful or misleading. All parties recognized that the government interests were substantial (*Central Hudson*'s step two). Therefore, the issues before the Court focused on whether the ban on advertising of compounded products served the articulated government interests, and whether the ban was the least restrictive way to achieve those interests (*Central Hudson*'s steps three and four, respectively).

The majority in *Thompson v. Western States* said that a ban on all advertisements for compounding was too restrictive because it would prevent useful speech, such as a

[164] Food and Drug Administration, Guidance for Industry, *supra* note 62.

[165] 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002).

[166] Compounding is the process by which pharmacists specially prepare drugs, pursuant to a physician's prescription, that are tailored to a specific patient's medical needs.

[167] 21 U.S.C. § 355 (1976); 21 C.F.R. § 314 (1982).

[168] Food and Drug Modernization Act of 1997, § 503A (21 U.S.C. § 353a(c)).

[169] *Thompson v. Western States Medical Center,* 122 S. Ct. at 1504.

[170] 425 U.S. 748, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976).

[171] *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 65 L. Ed 2d 341, 100 S. Ct (1980).

pharmacist telling doctors with patients with special needs about the availability of alternative compounded drugs. The Court said other less restrictive methods could be used to prevent compounding from occurring on such a large scale as to undermine the new drug approval process.[172]

When the Supreme Court in *Western States* declared the ban on advertising compounds unconstitutional, it was invalidating an indirect restriction on commercial speech on First Amendment grounds. It is unclear, given this ruling, whether proposed legislation that would limit pharmaceutical companies' annual tax deductions for marketing and promotional expenses also will be viewed as unacceptable indirect restrictions on truthful advertising.[173] *Western States* is one of a number of cases challenging legislation that seeks to place limits on commercial speech.[174] In response to the *Western States* ruling, FDA published a request for comments on May 16, 2002, to seek public input regarding FDA's authority to regulate commercial speech and other related issues.[175] All comments and responses were due by October 28, 2002.[176]

Considering recent case law, industry practices, and FDA's authority, the issue of DTC prescription drug advertising will continue to develop for some time.

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[172] The dissent in *Thompson v. Western States* argued that FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put consumers who did not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway. The dissent emphasized that the doctor-patient relationship—not an advertisement—was the proper source for the demand for a individualized compounding prescription, and that the FDAMA restrictions aimed to ensure that demand for a compounded drug was generated doctor-to-patient-to-pharmacist, not pharmacist-to-ad-to-patient-to doctor. In support of this argument, they cited a 1999 National Institute of Health study, which provided evidence that consumer-oriented advertising will create a strong consumer-driven demand for a particular drug.

[173] *Paxil TC Ad Case Could Produce Ruling on FDA's Authority to Regulate Ads*, F-D-C REP. ("The Pink Sheet"), Aug. 12, 2002, at 29.

[174] A class action was filed Friday, Sept. 14, 2001, in the U.S. District Court for the Central District of California in Los Angeles by plaintiffs who allege that antidepressant Paxil's® "not habit forming" claim in TV advertisements was false and misleading. The plaintiffs, who claim to have suffered withdrawal reactions to the antidepressant, sought a court order requiring the manufacturer to pull its television commercials that claim Paxil® is non-habit-forming, and to pull its promotional brochures from doctors' offices that make claims that the drug does not cause dependency and causes only mild side effects. On Aug. 16, 2002, U.S. District Court Judge Mariana R. Pfaelzer entered an injunction against drug maker, GlaxoSmithKline, enjoining the company from claiming in a national advertising campaign that Paxil® was not "habit-forming." *In re Paxil*, Civ. No. 01-07937 MRP (C.D. Cal Aug. 16, 2002). On August 22, 2002, Judge Pfaelzer stayed her injunction and ordered the parties and FDA, a nonparty to the class action, to submit briefs. FDA was asked to submit specific information about what it considered when it allowed GSK to include the language "Paxil is non-habit forming" in its television advertisements and the precise reasons FDA had concluded that this language should be allowed. On Sept. 4, 2002, the FDA submitted its brief to the Court in which it urged the Court to reconsider the injunction.

[175] 67 Fed. Reg. 34,942 (May 16, 2002). To view comments submitted to FDA on First Amendment issues, go to http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n0209.doc (Dkt. No. 02N-0209).

[176] In response to requests for an extension, FDA extended to Sept. 13, 2002, the comment period for original comments, and extended to Oct. 28, 2002, the comment period for responses to those comments relating to FDA's original Request for Comment on First Amendment Issues, published in the *Federal Register* of May 16, 2002. *See* 67 Fed. Reg. at 34,942.

APPENDIX: CHRONOLOGY OF EVENTS SURROUNDING DTC ADVERTISING

- 1906: Pure Food and Drugs Act (the "Wiley Act")—first federal legislation governing food and both prescription (Rx) and over-the-counter (OTC) drugs; addressed labeling.
- 1914: Federal Trade Commission (FTC) Act—gave FTC jurisdiction over advertising.
- 1938: Federal Food, Drug, and Cosmetic Act (FDCA)—repealed the Wiley Act; gave FDA jurisdiction over labeling of all drugs, both Rx and OTC.
- 1938: FTC Act—amended to give jurisdiction of all drug advertising to FTC.
- 1951: Durham-Humphrey Amendments to the FDCA—required drugs that are not safe for use except under medical supervision to be dispensed only by prescription of a licensed practitioner.
- 1954: Working agreement between FDA and FTC—designed to eliminate duplication of effort.
- 1962: Kefauver-Harris Drug Amendments to the FDCA—transferred jurisdiction of prescription drug advertising from FTC to FDA, but left OTC regulation with FTC.
- 1968: FDA required patient package insert for isoproterenol inhalation products.
- 1970s: FDA required patient package insert for birth control pills, and other drugs.
- 1979: FDA proposed regulation requiring patient package inserts for all prescription drugs.
- 1981: First U.S. prescription drug advertisement by Boots Pharmaceuticals for American subsidiary's ibuprofen product, Rufen.
- 1982: FDA asked the pharmaceutical industry for voluntary moratorium on DTC prescription drug advertisements.
- 1985: FDA issued regulation for DTC; moratorium lifted.
- 1995: FDA conducted public hearings on DTC advertising.
- 1997: FDA released Draft Guidance on Direct-to-Consumer Broadcast Advertisements.
- 1999: FDA released Guidance on Direct-to-Consumer Broadcast Advertisements.