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(Article begins on next page)

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DTC Prescription Drug Advertising:

The History and Impact of FDA Regulation

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Harvard Law School

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Abstract: This paper traces the history of direct-to-consumer (DTC) advertising for prescription drugs in the United States, beginning with the enactment of the Federal Food, Drug, and Cosmetics Act in 1938 and continuing through the current state of FDA regulation. A detailed analysis of how the promulgation of DTC ads has affected a variety of groups (including consumers, the medical profession, pharmaceutical companies, the government, and advertisers) is followed by a brief look at a well-known DTC ad campaign (Schering-Plough's Claritin). The paper questions whether DTC ads are a constructive or a deconstructive element of the American healthcare system and concludes by offering an opinion on the current state of DTC advertising regulation and enforcement by the FDA.

I. INTRODUCTION

As clouds and balloons float across the screen and music plays in the background, a voice promises “nothing but blue skies from now on.” Joan Lunden shares that, while she used to suffer from severe allergies, today she is pollen-free, and you could be too. Mike Piazza swings at a pitch while telling you that he doesn’t have to worry about seasonal allergies anymore. For millions of Americans, these words, sounds, and images, all taken from the television and print ads for the prescription antihistamine Claritin, are some of the most familiar advertisements of the last five years. These pervasive sights and sounds have helped to make the Schering-Plough drug Claritin one of the most prescribed pharmaceuticals in the United States, and the same type of persuasive advertising has made blockbusters out of Prilosec, Viagra, Vioxx, Singulair, Zolofl and Lipitor as well, just to name a few.

To the average American consumer, prescription drug advertisements are such a staple of the modern media experience that it seems as though the ads have always been around. While prescription drugs were advertised occasionally in mainstream print publications prior to 1997, it has been only in the last five years that the broadcast ad campaigns with which we are so familiar today were affirmatively authorized by the Food and Drug Administration (FDA), the federal regulatory agency with authority over the marketing of prescription drugs.

In 1997, the Division of Drug Marketing, Advertising, and Communications (DDMAC), a sub-division of the Center for Drug Evaluation and Research (CDER), which is a division of the FDA, released guidelines which allow prescription drug manufacturers to comfortably satisfy the legal requirements for advertising their products to the general public. As a result, pharmaceutical companies have swelled their direct-to-

consumer (DTC) marketing budgets and provided the advertising industry with a profitable new line of products to promote. Since the regulatory change was announced, name-brand prescription drug use in the United States has increased, drug prices have gone up, a debate over the effects, efficacy and wisdom of DTC ads has ensued, and scores of health care issues that affect patients, doctors, insurers, and the federal government have risen to the surface.

This paper is an attempt to outline and update the development, success, and debate over DTC advertising. The starting point will be a review of DTC advertising history, the current DTC guidelines, and the FDA's enforcement of those guidelines. Next, the paper looks at the past, present and future impact of DTC advertising on the various groups associated with prescription drug promotion, groups such as consumers/patients, pharmaceutical companies, physicians, health insurers, advertising agencies, media, and the federal and state governments. After the rules are established and their impact fully explored, the paper will look at perhaps the most illustrative "case study" in DTC promotion: the Schering-Plough antihistamine Claritin. This case study will provide anecdotal evidence as to how DTC advertising has affected the pharmaceutical industry and its consumers. However, it should be noted that the Claritin case is not intended to be representative of *all* prescription drug DTC ad campaigns. The conclusion of this paper will attempt to answer one final question: Is DTC advertising a good thing for healthcare in America?

II. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The Federal Food, Drug, and Cosmetic Act (the Act) was passed by Congress in 1938 in an effort to federally protect the health and safety of the nation by regulating the food and medical supply.¹ Specifically, the Act

¹See Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq. (1994).

regulates the pharmaceutical industry to ensure the safety and efficacy of drugs produced and sold in the United States, and it gives the FDA authority to carry out its legislative directives. In 1962, Congress added the Kefauver-Harris amendments which, among other things, transferred regulatory authority for prescription drug “advertising” from the Federal Trade Commission (FTC), which exercises authority over general advertising, to the FDA.² With the addition of the 1962 amendments, the regulation of drugs became the most consuming, and at times the most controversial, aspect of all the FDA’s activities.³

In an effort to protect consumer reliance on the safety and efficacy of prescription drugs, Congress determined that the content of pharmaceutical advertising must be carefully monitored to avoid confusion, to protect against misinformation, and to provide for full and up-to-date disclosures of the drug’s risks and side effects.⁴

The Act requires that manufacturers who market prescription drugs to consumers with ads that mention the drug’s use and/or effectiveness must provide the following: the drug’s established name, the brand name (if any), the ingredients, and “information in *brief summary* relating to side effects, contraindications, and effectiveness.”⁵ This form of disclosure is referred to as the “brief summary” (an ironic term in light of the anything-but-brief requirements the statute imposes). If the ad appears in print form, it must also present the drug’s specific risks in more detail.⁶

If an advertisement is broadcast by television, radio, or over the telephone, it must include the brief summary as outlined above *unless* the ad contains language that gives “adequate provision for the dissemination of the approved package labeling.”⁷ This adequate provision requirement is intended as a compromise - a balance of the Act’s desire to fully inform a viewer or listener with the brief summary information *and* its recognition

²See Drug Amendments of 1962, 21 U.S.C. § 352(n) (1962). It should be noted that the only kind of “prescription drug advertising” contemplated by drafters of the Kefauver-Harris amendments was direct-to-physician, not direct-to-consumer. See S. Rep. 87-1744 87TH Cong., 2ND Sess. 1962, 1962 WL 4821 (Leg.Hist.), at 2895.

³PETER BARTON HUTT AND RICHARD A. MERRILL, FOOD AND DRUG LAW 13 (1991).

⁴See S. Rep 87-1744, *supra* note 2.

⁵21 C.F.R. § 202.1(e)(1).

⁶*Id.* As part of the FDA’s new drug application (NDA) approval process, pharmaceutical companies must fully disclose a drug’s specific risks on the drug’s package labeling. Labeling is a highly regulated drug information mechanism that is often connected to the policy and regulations for prescription drug advertising.

⁷21 C.F.R. § 202.1(e)(1).

of the inherent limitations of a 30-second TV or radio spot. Adequate provision allows a consumer to obtain necessary precautionary information while allowing the pharmaceutical company to effectively “market” the product.

A 1985 FDA interpretation of the Act that appeared in the Federal Register states that if an advertisement satisfies the adequate provision requirement, the brief summary may be reduced to a “major statement,” which is a disclosure of the product’s *major* risks in both the audio and any visual element of the ad.⁸ This reduction in what must be disclosed by the ad itself is the birthplace of DTC advertising – an issue that became a dominant one for both the FDA and the pharmaceutical industry in the 1990s.

Despite the wide enforcement authority generally given to the FDA, the Act expressly prohibits any requirement that pharmaceutical companies submit drug advertising content for FDA pre-market approval (except in extraordinary circumstances).⁹ This provision, grounded in First Amendment doctrine,¹⁰ has led to a regulatory regime that can only *offer* a pre-market approval process¹¹ and enforce compliance post-violation. This protection of the pharmaceutical company’s right to speak has occasionally led to the dissemination of harmful information - information that does not satisfy the Act’s “true statement” requirement that all advertisements present a “fair balance” of the drug’s benefits and risks.¹²

III. THE HISTORY OF DTC ADVERTISING UNDER THE ACT

⁸50 Fed. Reg. 36,677 (1985).

⁹21 U.S.C.A. § 352(n).

¹⁰A basic tenant of the First Amendment is the prohibition of prior restraint on speech. *See* Lovell v. Griffin, 303 U.S. 444 (1938); THOMAS EMERSON, THE SYSTEM OF FREEDOM OF EXPRESSION 506 (1970).

¹¹21 C.F.R. § 202.1 (j)(4). It is interesting to note, however, that this express prohibition of prior approval for ad content does not apply to other forms of pharmaceutical speech, such as the required pre-market approval of package labeling for prescription drugs. For more on this issue, see *infra* Part IV: Advertising Industry and the Media, at 58.

¹²*Id.* at (e)(5). A prescription drug ad is not a “true statement” if “it fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug. . . .” *Id.* at (e)(5)(ii).

For many years, the concept of advertising directly to consumers did not have much appeal for pharmaceutical companies. The very definition of “prescription drugs,” drugs that are distributed only under a doctor’s orders, casts the physician in the role of gatekeeper; if a drug manufacturer can persuade the doctor as to a drug’s effectiveness, it has won the consumer/patient by default. Drug companies spend a tremendous percentage of their marketing budgets on physician literature, free samples, gifts, conventions, and various other “incentives” that persuade doctors to prescribe the manufacturer’s products as often as possible.¹³

This traditional system of physician-focused information distribution has been facilitated by a pervasive theme in the US medical model: paternalism. Under this traditional model, the physician/patient relationship follows a role-play format, with the physician in the role of the knowledgeable, dominant doctor and the patient in the part of the obedient layman who trusts the doctor to act only in the patient’s best interest. Patients ask very few questions, perhaps due to intimidation or out of respect for the doctor’s experience and judgment; medical decisions involve complex and highly developed expertise that physicians are relied upon to provide.¹⁴ Some ethicists place an affirmative duty on the physician to communicate all of the information they have about a particular drug, its effects, and why the prescription is right for an individual patient. However, with time constraints and natural limitations on physician knowledge, this frank exchange is not as likely to occur as the “traditional model” seems to suggest.

One legal consequence that has developed as a result of the physician-as-gatekeeper model is the learned intermediary doctrine (the “doctrine”). The doctrine places legal tort liability on the “learned intermediary” (doctor) rather than the pharmaceutical company if harm arises out of a patient’s reliance on or use of misinformation about a prescription drug.¹⁵ Over the years, drug manufacturers have been able to shield themselves from consumer litigation so long as they comply with applicable label and physician disclosure

¹³Most of these physician-directed expenditures continue today, even as pharmaceutical companies have dramatically increased their expenditures for DTC advertising. See *infra* Part IV: Drug Manufacturers, at 34.

¹⁴See generally Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489 (1999).

¹⁵The doctrine, an effective legal liability shield, is discussed in more detail *infra* Part IV: Drug Manufacturers, at 41.

requirements.¹⁶ Considering the doctor’s role as an intermediary, the nature of the American medical model, and the drug manufacturers’ reliance on the doctrine, it is easy to see why companies believed for so many years that the most efficient and effective method of communicating with consumers was through their doctors.

In the 1960s, when a strong consumer movement began to sweep the US, patients began to express a greater interest in their health and in the decisions made about the treatments prescribed or recommended by their doctors. In 1970, the FDA responded to this increase in interest by requiring drug manufacturers to include “patient package inserts” (PPIs) in particular drug packages.¹⁷ This requirement was an FDA response to the growing consumer awareness of health issues, specifically consumer interest in the risks and potential side effects of prescription drugs. Despite the fact that PPIs are written in complex language, often too technical for the average patient to understand, their introduction began a process of direct communication between pharmaceutical companies and consumers that continued to expand during the 1970s and eventually evolved into an expectation that information traditionally reserved for physicians be made accessible to the ordinary consumer.

In the late 1970s and early 1980s, book publishers seized on this consumer interest by successfully marketing to consumers variations of “physician desk references,” an indication that the consumer demand for more information was palatable.¹⁸ “The surge of interest and information in prescription drugs also stemmed from the novelty and miracle of the drugs themselves” as more and more medications were formulated to treat diseases for which there was no previous “cure in a bottle.”¹⁹ Growing consumer expectations, the national enactment of consumer protection legislation, and the success of “miracle” pills precipitated the call for more

¹⁶ See 21 U.S.C.A. § 352. “Both FDA’s historical practice and court decisions have reinforced the proposition that information about prescription drugs – both indications for use and warnings about possible side effects and adverse reactions – is to be directed to physicians and other medical professionals.” HUTT & MERRILL, *supra* note 3, at 438.

¹⁷ See Pines, *supra* note 14, at 489.

¹⁸ See *id.* at 490 – 91.

¹⁹ *Id.* at 491.

consumer-directed medical information.

However, despite this burgeoning consumer interest, pharmaceutical companies continued to market and advertise their drugs strictly to physicians throughout the 1970s.²⁰ This decision was influenced not only by the medical profession's reliance on a paternalistic model of medicine and the industry's reliance on the learned intermediary doctrine, but also by the low level of comfort in knowing what would meet the Act's "brief summary" and "adequate provision" requirements. As a result, drug companies continued to direct most of their advertising to physicians in print literature, limited medical broadcast media, and other traditional methods of physician marketing.

In the early 1980s, this historical tide began to turn as the very first DTC prescription drug ads were developed by Boots Pharmaceuticals (for the ibuprofen drug Rufen) and Merck (for the pneumonia vaccine Pneumovax).²¹ These breakthrough ads triggered a new debate within the pharmaceutical industry, the medical profession, and internally at the FDA as to the efficacy, wisdom, and implications of advertising prescription drugs directly to the public. In a 1982 speech at the Pharmaceutical Advertising Council, then-FDA Commissioner Dr. Arthur Hull Hays, Jr. predicted "'exponential growth' in advertising directly to the consumer," a statement that, in the minds of the industry, was equivalent to a DTC endorsement.²² While neither Dr. Hays nor the FDA intended "to advocate for DTC advertising, nor even to passively support it," the industry reacted to the remarks by flooding the FDA with new proposals for DTC ads.²³

Many of the FDA's staff and physicians believed that drug ads directed at patients were "inappropriate" and would lead to confusion and misinformation. Based on this concern, the FDA, in September 1982, asked the pharmaceutical industry to cooperate in a voluntary moratorium on all DTC ads.²⁴ During the moratorium,

²⁰ See *id.*

²¹ *Id.*

²² *Id.* at 492.

²³ *Id.*

²⁴ See Caroline L. Nadal, *The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Con-*

various interested parties (the FDA, the CBS television network, and several pharmaceutical companies) conducted independent research on the issue of consumer education and DTC ads. Each study reported the same basic conclusion: consumers wanted more information about prescription drugs and were heavily in favor of DTC advertising.²⁵ However, those at the FDA continued to feel that the tight regulation of such ads was necessary to ensure that pharmaceutical companies provided full, rather than favorable, information to consumers.

In September 1985, the FDA lifted the voluntary moratorium by declaring that the restrictions historically applied to physician advertisements were applicable to consumer advertisements as well.²⁶ The notice included the FDA's assertion of jurisdiction over consumer prescription drug ads²⁷ and emphasized the importance of fair balance and the "brief summary" of risks.²⁸ The notice provided an exception to the brief summary requirement in broadcast ads by allowing for the substitution of a "major statement," but the FDA's continued insistence on the inclusion of "adequate provision" made it virtually impossible and too expensive for 30-second TV ads to fulfill the requirements of DTC.²⁹

As a result of this guidance, pharmaceutical companies began to market to consumers more than before, but they continued to focus their efforts primarily on print advertisements. Most of the ads were considered "help-seeking" ads - ads that do not name a product but rather encourage the consumer to seek help by identifying a particular disorder and suggesting that patients ask their physician about available treatments.³⁰ These ads became quite popular, and by 1989, DTC ad expenditures had risen from zero to \$12 million in little more than three years.³¹ The popularity of help-seeking ads continued to grow exponentially through

sumers Become the Learned, 9 J.L. & POL'Y 451, 479 (2001).

²⁵Pines, *supra* note 14, at 492.

²⁶50 Fed. Reg. 36,677 (1985).

²⁷While there is an argument to be made that the FTC rather than the FDA should have such jurisdiction, the two agencies have entered into a "Memorandum of Understanding" which gives the FDA authority over prescription drug ads and gives the FTC authority to regulate Over-the-Counter (OTC) ads. See Memorandum of Understanding, 36 Fed. Reg. 18,538 (1971).

²⁸50 Fed. Reg. 36,677 (1985).

²⁹*Id.*

³⁰Pines, *supra* note 14, at 493.

³¹*Id.*

the mid-1990s.

While the FDA continued to research the best regulatory policy for DTC advertising after lifting the moratorium, drug manufacturers continued to hold off on product-claim broadcast ads for fear of violating the Act's requirements. The industry particularly struggled with how to "fairly balance" the risk and side effect disclosure requirements with the positive promotion of the product's benefits. A temporary solution to this "fair balance" problem was found in extending "help-seeking" ads from print to broadcast and developing "reminder" ads "which call attention to the name of the drug product but do not include indications or dosage recommendations for use. . . ." ³² The first illustrations of these new approaches were seen in a help-seeking ad for Upjohn's hair restorer Rogaine (which provided consumers an 800 number for more information) and a reminder ad for Schering-Plough's Claritin (which omitted information about the purpose of the drug). ³³ Tamar Terzian cites three reasons pharmaceutical companies promulgated these new forms of DTC advertising before receiving more definitive regulations from the FDA: (1) the changing nature of the patient/physician relationships in the face of managed healthcare; (2) the ability to reach inaccessible patients; and (3) increased marketplace competition and the need to market a greater number of drugs. ³⁴ However, while the ball may have started to roll under the pressure of a changing marketplace, it remained clear that DTC ads were still a fairly limited form of consumer healthcare information.

In 1995, a pro-DTC ad movement began to grow within the FDA's DDMAC, with supporters hoping to clarify the agency's position on DTC ads and provide an outline for manufacturers to follow that would satisfy the statutory requirements. These DTC ad supporters were initially met with resistance from then-FDA Commissioner Dr. David Kessler who feared the ads would spark misinformation and confusion among consumers. However, upon his departure in 1995, the pro-DTC ad initiative took hold. After a continuous examination of drug advertising, its affect on consumers and the prescription drug market, and after

³²21 CFR 202.1(e)(2).

³³Pines, *supra* note 14, at 494.

³⁴Tamar V. Terzian, *Direct to Consumer Prescription Drug Advertising*, 25 AM. J. OF L. & MEDICINE 149, 157 (1999).

receiving numerous complaints about the vagueness of help-seeking and reminder ads, the FDA concluded that unless DTC broadcast ads were allowed to contain more information, they were of little to no help for consumers.

In addition to this internal pro-DTC ad movement, the FDA was under heavy pressure from the pharmaceutical industry and various media outlets, both of which stood to profit should the FDA make broadcast DTC ads easier for the industry to use.³⁵ It is also possible the FDA had considered the First Amendment problems its position on DTC advertising might face if challenged by pharmaceutical companies in court. The result of this internal re-evaluation was a guidance that dramatically changed the way pharmaceutical companies market their products in the US.

After issuing a temporary draft guidance in August 1997 (the “1997 draft guidance”),³⁶ the FDA finalized its release of the “Industry Guidance on Consumer Directed Broadcast Advertisements” in August 1999 (the “1999 guidance”) (Appendix 1).³⁷ “The purpose of this guidance is to describe an approach [to DTC ads] that FDA believes can fulfill the requirement for *adequate provision* in connection with consumer-directed broadcast advertisements for prescription drugs. . . .”³⁸ The guidance was designed to make it easier for manufacturers to run product-claim advertisements that include the drug’s purpose and effects while satisfying the statutory requirements and public policy goals. Even after the comment period, there were no substantial changes made to the guidance’s draft form, as research during the interim period left the FDA “unaware of any data supporting the assertion that the public health. . . is being harmed, or is likely to be

³⁵See Alexandra Marks, *A harder look at prescription-drug ads*, THE CHRISTIAN SCIENCE MONITOR, April 11, 2001 at 1.

³⁶62 Fed. Reg. 43,171 (1997).

³⁷See Guidance for Industry: Consumer-Directed Broadcast Advertisements [hereinafter “1999 guidance”] (1999) available at www.fda.gov/cder/guidance/1804fn1.htm (last visited April 18, 2002). By definition, a federal “guidance” only represents an agency’s thinking on a subject at a particular moment in time; a guidance does not have the power or authority of law, nor does it create or confer any rights or bind the agency or the public to its provisions. While the industry is warned that reliance on a guidance will not always prove successful, it is common practice to treat a guidance as if it were a promulgated rule or regulation.

³⁸*Id.*

harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising."³⁹

The 1999 guidance recommends that each of the following disclosures be made in broadcast product-claim advertisements:

- - the ad should disclose a toll-free telephone number for customers to call and request that approved package labeling either be sent to them by mail or read to them over the phone;
- the ad should announce the availability of packaging information in a print advertisement running concurrent with the broadcast ad and appearing in a publication that reaches an audience similar in scope to that of the broadcast ad;
- the ad should give an Internet address at which consumers may access the approved package labeling; and
- the ad should direct the consumer to contact his or her physician or pharmacists in order to gain more information about the advertised product.⁴⁰

While the FDA's 1999 guidance considers person-to-person telemarketing calls to be included in the "broadcast ad" category, it requires less disclosure because of the consumer's apparent willingness to receive the information (as demonstrated by taking the call). For these calls, the industry is only required to provide the drug's package label information to the consumer by mail or by reading it over the phone, and the marketer must indicate that a physician or pharmacist can provide additional information should the consumer have further questions.⁴¹

³⁹Food and Drug Administration, *Consumer-Directed Broadcast Advertisements Questions and Answers* (1999) available at www.fda.gov/cder/guidance/index.htm (last visited April 18, 2002).

⁴⁰*Id.*

⁴¹*Id.*

Upon issuance of the draft guidance in 1997, Nancy Ostrove, Ph.D., a former DDMAC public health analyst and FDA DTC expert,⁴² characterized the new approach as in the public's best interest, stating that "[b]y indicating how drug companies can ensure that consumers have convenient access to detailed product risk information, the new guidance should encourage ads that provide more specific information and promote consumer awareness of prescription drugs and their uses."⁴³ Ostrove promised the guidance was only "the first step of an intensive [FDA] review of concerns about the value of requiring extensive detailing of product risk information" in DTC ads.⁴⁴ To that end, the announcement of the 1999 guidance included a promise to study its provisions and the effects of DTC ads within two years. The results of this benchmark study, conducted in the Fall of 2001, are anticipated in late Spring of 2002.⁴⁵

In April 2001, the FDA solicited comment on a proposed new guidance allowing "the use [of] certain FDA-approved patient labeling to fulfill the requirement that prescription drug . . . advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure."⁴⁶ The new guidance provides that patient package labeling, when used word-for-word in print ads, satisfies the brief summary requirement if the ad includes the following: (1) contraindications; (2) warnings; (3) major precautions; and (4) other frequently occurring side effects that are likely to be drug-related.⁴⁷ The pharmaceutical industry has responded positively to the proposed new guidance, and it seems likely some form of the draft will be accepted in the year 2002.

⁴²Nancy Ostrove left her position at the FDA's DDMAC in March 2002 for a position with the pharmaceutical company Eli Lilly. *DDMAC's Ostrove Goes to Industry*, DTC PERSPECTIVES (March 29, 2002) at <http://www.dtcperspectives.com/content.asp?id=53> (last visited April 18, 2002).

⁴³Nancy M. Ostrove, Ph.D., *More understandable TV ads of Rx drugs on way*, NEWS ALONG THE PIKE, (FDA Interagency Newsletter) at 1, 11 (August 1997).

⁴⁴*Id.* at 11.

⁴⁵*FDA DTC Study Eagerly Anticipated*, DTC PERSPECTIVES (March 29, 2002) at <http://www.dtcperspectives.com/content.asp?id=52> (last visited April 18, 2002).

⁴⁶Guidance for Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements [hereinafter "New Guidance"] (2001) (proposed March 2001) available at www.fda.gov/cder/guidance/4114dft.htm (last visited April 18, 2002).

⁴⁷*See id.*

To enforce the pharmaceutical industry's compliance with the statute as interpreted by FDA in the 1999 guidance, the DDMAC has developed a DTC ad review procedure (Appendix 2).⁴⁸ This compliance review process may be initiated by any of three events:

- the applicant (manufacturer of the product) may request a review of either the product launch promotional materials or other communications;
- FDA/DDMAC officials may conduct surveillance and determine when particular communications need to be reviewed; or
- a complaint may be filed by an interested party (including members of the industry, competitors, health professionals, consumers or others) with regard to a particular product's communications.⁴⁹

The review process begins by assigning the request to the DDMAC reviewer responsible for that product or product class. The reviewer exercises his or her discretion in the initial fact finding and may choose to consult with one or all of the following: the DDMAC consultant on DTC advertising issues (a single FDA employee that consults on all compliance reviews to ensure consistency), a pharmaeconomics/managed care consultant, a medical consultant, or a statistical consultant from the FDA's CDER.⁵⁰ The reviewer may look

⁴⁸Food and Drug Administration, *Promotional Material Review Process*, available at www.fda.gov/cder/handbook/complain.htm (last visited April 18, 2002).

⁵⁰Food and Drug Administration, *Consultation*, available at www.fda.gov/cder/handbook/prconsul.htm (last visited April

to a product's previous promotional pieces or those of competing products and may request more information from the applicant or entity under review. After completing his or her investigation, the reviewer may choose whether to end the review by sending a "launch letter" to the applicant, effectively signaling a continuance of the ad campaign, or may present the matter at an "enforcement rounds" session, a weekly meeting of DDMAC officials to discuss enforcement issues. After rounds, the reviewer may re-visit the information, request additional information from the applicant, determine that no action is required, or may choose a method of enforcement.⁵¹

Enforcement of the 1999 guidance usually comes in the form of a "warning letter" that is sent to the manufacturer as notice that DDMAC considers a promotional piece to be in violation of the law. The letter gives the company 15 days to respond, and if prompt and appropriate measures are not taken, DDMAC promises further action without prior notification.⁵² For less serious violations, a reviewer may choose to send an "untitled letter" that requests a specific action be taken in order to bring the ad into compliance with the Act's requirements.⁵³ Other available methods of enforcement, those that the FDA is generally authorized to employ include seizure, injunction, or criminal prosecution.⁵⁴ To date, none of these more serious enforcement means have been used against DTC ad violations.

In the years since the guidance was released, the number of warning letters issued for non-compliance has significantly decreased. From August 1997 to August 1998, DDMAC issued 18 enforcement letters for more than half of the 35 products promoted by DTC broadcast ads.⁵⁵ However, the number of products subject

18, 2002).

⁵¹FDA, *Promotional Material Review Process*, *supra* note 48.

⁵²Food and Drug Administration, *Warning Letter*, available at www.fda.gov/cder/handbook/prwarlet.htm (last visited April 18, 2002).

⁵³Food and Drug Administration, *Untitled Letter*, available at www.fda.gov/cder/handbook/pruntlet.htm (last visited April 18, 2002).

⁵⁴21 U.S.C.A. § 331 – 37.

⁵⁵Pines, *supra* note 14, at 502.

to enforcement began to decrease in 1999, and in 2001, DDMAC only issued 13 letters, a small number in comparison to the number of prescription drugs currently advertised by DTC ads.⁵⁶

There are several possible explanations for this decrease in enforcement: (1) that the industry's increasing familiarity with the guidance and FDA expectations has led to fewer violations; (2) that the increased use by pharmaceutical companies of the voluntary pre-market approval process increases compliance; or (3) that the DDMAC has relaxed its discretionary review of DTC promotional materials. According to Nancy Ostrove, any measurable decline in FDA enforcement is most likely due to personnel turnover and/or the growing number of pre-launch reviews the agency conducts at the request of pharmaceutical companies.⁵⁷

However, some have argued that the decline in enforcement is actually due to budgetary constraints; that DDMAC cannot effectively enforce the regulations because it has not been given the resources it needs to keep up with the exploding growth of DTC ads. According to Dr. Sidney Wolfe of Public Citizen, "[t]he only plausible explanation for this dangerous decrease is that the police force DDMAC has not been strong enough in numbers of investigators along with a lack of adequate pro-enforcement leadership from top officials in FDA."⁵⁸ Wolfe suggests expanding the FDA's authority to assess monetary fines for DTC ad violations, stating that such action "might actually serve as a deterrent for companies who now just stop the violative ad when requested by the FDA, then create and massively disseminate a new one shortly thereafter."⁵⁹

While no one disputes the fact that enforcement actions have decreased, the FDA has continued to actively monitor DTC ads by accepting complaints and requests for compliance reviews from all interested parties. As recently as January 9, 2002, the pharmaceutical company Hoffman – La Roche was warned about a series of print and telephone broadcast ads that were misleading and lacked adequate provision.⁶⁰ The ads,

⁵⁶Food and Drug Administration, *Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, available at <http://www.fda.gov/cder/warn/index.htm> (last visited April 15, 2002).

⁵⁷*Direct to Consumer Advertising of Prescription Drugs Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism Senate Committee on Commerce, Science, and Transportation*, 107th Cong. (2001).

⁵⁸*Id.*

⁵⁹*Id.*

⁶⁰*See* Letter from Joseph A. Grillo, Regulatory Review Officer, DDMAC at FDA, to Mr. Murad Husain, Program Director,

which advertised the prescription drug Xeolda, an oral chemotherapy for colorectal cancer, were subsequently pulled by the company.

As consumers become more complacent toward DTC advertisements, it is possible the ads will begin to lose their effectiveness or their ability to grab a viewer's attention. If that happens, advertisers and manufacturers will be forced to find new ways of capturing the audience, perhaps pushing the envelope on the claims made in DTC ads. If this happens, it will be up to DDMAC to recognize the shift, and it will be up to the FDA to dedicate the resources necessary to ensure that the public is protected by the enforced compliance of DTC ad restrictions.

IV. EFFECT OF DTC ADVERTISING ON VARIOUS INTEREST GROUPS

DTC advertising affects the interests and policies of a number of various groups: consumers, pharmaceutical companies and their shareholders, physicians and other medical providers, broadcast and print media, health management organizations, health insurers, and both the federal and state government. Each of these groups has a stake in the use and regulation of DTC ads, and each has a different perspective on the pros and cons of the drug marketing technique. In order to truly assess the value and efficacy of the FDA's policy and DTC ads themselves, the issue should be examined from the points of view of all affected parties.

PATIENTS AND CONSUMERS

Drug Regulatory Affairs, Hoffman – La Roche, (Jan. 9, 2002) available at <http://www.fda.gov/cder/warn/2002/10521.pdf> (last visited April 15, 2002).

For the average consumer, it is difficult to remember what television commercial breaks were like before the FDA's 1997 draft guidance. DTC ads have become such an integral part of modern American culture that the mere mention of a prescription drug's name can trigger the mind to hear a catchy jingle, a catch phrase, or to see a familiar celebrity discussing their favorite medication.

But do DTC ads trigger more than the sounds and images of clever marketing? Do consumers retain any of the pertinent health information the ads provide, such as the drug's benefits, risks, or the condition it purports to treat? Surveys indicate that they do, and they remember these facts in remarkable numbers. "Prior to these ads, prescription drugs were a mystery with names we couldn't pronounce and side effects we didn't even try to understand. Today, consumers know the drugs they are taking, any potential side effects, even how they interact with other drugs."⁶¹ This heightened awareness of drugs can be partially attributed to the promulgation of DTC ads.

The primary argument made in support of DTC ads, an argument often made by prescription drug manufacturers and the FDA, is that they enable patients to exercise control over their own medical care by making them informed participants in healthcare decisions. The ads educate consumers about disorders of which they may have otherwise been unaware. Based on the results of several statistical studies, all of which indicate high consumer approval and retention of DTC ad information, it appears most consumers agree with this basic pro-DTC argument.

In November 2001, the Kaiser Family Foundation released the results of a survey in which over 1,800 people

⁶¹*Recent Developments which may impact Consumer Access to, and Demand for, Pharmaceuticals Hearing Before the Subcommittee on House of Representatives Health of the Committee on Energy and Commerce, 107th Cong. 15 (2001) (statement of Rep. Anna G. Ashoo).*

were questioned about the effect of DTC advertising on consumer behavior.⁶² The survey sample was broken into two groups: viewers and non-viewers of prescription drug television advertisements.⁶³ The study concluded that nearly 30% of Americans have acted upon information gained directly from a DTC ad, and that of that 30%, one in two was prescribed a particular medication after approaching their doctor with questions.⁶⁴ While the majority of the survey's DTC ad viewers reported "not learning" anything from the ads, they actually gave more correct responses than non-viewers when questioned about the details of the advertised drugs.⁶⁵ When asked how well they believe DTC ads disclose information about a drug's treatable condition or benefits, a high percentage of consumers rated the ads as "good or excellent." Only half believed the ads were successful in relating the potential side effects or dosage for the medication.⁶⁶

Those who oppose DTC advertising argue that consumers only retain information about the benefits of a drug and ignore information about risks or side effects. However, that claim is countered by the results of a 1999 FDA consumer/patient survey, results which were completed with the release of the 1999 guidance.⁶⁷ The survey, which focused on respondents who had seen a physician within the previous three months, indicated a 72% general recall level for information about products promoted with DTC ads. Eighty two percent of those who could recall only "some information" were able to recall the drug's risks, while 87% of those same patients were able to recall the drug's benefits. In print ads, 85% of respondents said they read

⁶²The Kaiser Family Foundation, *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising* (November 2001) available at <http://www.kff.org/content/2001/20011129a/> (last visited April 18, 2002). The Kaiser Family Foundation is not affiliated with the pharmaceutical company Kaiser-Permanente.

⁶³*Id.*

⁶⁴*Id.*

⁶⁵*Id.*

⁶⁶*Id.*

⁶⁷Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, *Attitudes and behaviors associated with direct-to-consumer (DTC) promotion of prescription drugs: main survey results* (1999) available at www.fda.gov/cder/ddmac/dtcindex.htm (last visited April 16, 2002).

all or almost all of the ad content if the ad was for a drug in which they were particularly interested.⁶⁸ This report of high consumer recall levels seems to answer many of the “poor information” arguments made by those who oppose the use of DTC advertising.

On the issue of consumer behavior, the FDA survey found that 27% of the patient respondents were prompted by a DTC ad to consult their doctor about a condition they had not previously discussed.⁶⁹ Half of those surveyed said they took other forms of action, usually by seeking additional information through product hotlines, magazine ads, or other sources. Eighty six percent of respondents said DTC ads helped to make them aware of new drugs, and 33% said that DTC ads had reminded them to refill their existing prescriptions on time, a spillover effect that DTC advocates often point out.⁷⁰

In addition to statistical surveys, a number of independent studies have indicated resolute consumer satisfaction with the growth of DTC ads. In January 2002, the National Health Council (NHC), a group comprised of volunteer health agencies, nonprofit organizations, professional associations, and healthcare businesses, released a report and position paper on DTC ads that endorses the practice as a consumer information device and approves of the current guidance structure.⁷¹ The paper called on the FDA to continue its research into the effects of DTC promotion, stating that “[b]oth the benefits and concerns related to DTC advertising deserve further thoughtful study in such areas as consumer perceptions and comprehension, the patient-doctor relationship, the impact on health outcomes, and the impact on health care costs based on integrated data and across components of care.”⁷² The NHC also urged the FDA to maintain a high level

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* For more on the pro-DTC ad “spillover effect” argument, see John E. Calfee, *What Consumer Surveys Show about Direct-to-Consumer Advertising of Prescription Drugs* (American Enterprise Institute) (May 7, 2001) at 18.

⁷¹ See The National Health Council, *Direct-to-Consumer Prescription Drug Advertising: Overview and Recommendations* (January 2002) available at www.nationalhealthcouncil.org/advocacy/dtc.htm (last visited April 16, 2002). It is important to note that this study was funded in part by Pfizer, a leading pharmaceutical company and member of the National Health Council.

⁷² The National Health Council, *National Health Council Statement: Direct-to-Consumer Prescription Drug Advertising* (January 2002), available at <http://www.nationalhealthcouncil.org/advocacy/dtc.htm> (last visited April 16, 2002).

of oversight and enforcement under the terms of the current guidance.

At the conclusion of its 1999 consumer survey, the FDA stated that it was unaware of any support for the proposition that “public health... is being harmed, or is likely to be harmed, by the [FDA’s] actions in facilitating consumer-directed broadcast advertising.”⁷³ However, not everyone agrees with this positive assessment of DTC promotion. As important as it is to consider what DTC ads say to consumers, it is equally important to consider what the ads do not say and the possible impact that such omissions may have. As Rep. Sherrod Brown (D-OH) noted during a recent House Health Subcommittee hearing, “[t]here are questions whether DTC ads fairly represent their products. It’s certain they don’t highlight the relative price of their product and how that relates to its efficacy. My guess is that if consumers had the full picture, DTC ads would be much less [successful] than they are today.”⁷⁴

An article by Dr. Sidney Wolfe of Public Citizen which appeared in the *New England Journal of Medicine* argues that the “marketing” information consumers receive in DTC ads is *not* the type of information that will empower them to participate in or take charge of their healthcare.⁷⁵ Wolfe states that “confusion arises when commercially driven promotional information is represented as educational,” and he calls for stronger regulation by the FDA to ensure that ads contain more useful information and less “sales” material.⁷⁶

In response to Dr. Wolfe’s article, Alan Holmer, president of the Pharmaceutical Research and Manufacturers of America (PhRMA), returns to the “informed patient” argument. He states that DTC advertising has played an important role in strengthening the healthcare system in favor of the informed patient, and that the true purpose of DTC promotion is realized when the ads facilitate a two-way conversation between doctor and patient. ⁷⁷ “Such discussions are beneficial — to the patient, who gains a better understanding

⁷³*Id.* at Appendix B7.

⁷⁴*Recent Developments which may impact Consumer Access to, and Demand for, Pharmaceuticals Hearing Before the Subcommittee on House of Representatives Health of the Committee on Energy and Commerce, 107th Cong. 5 (2001) (statement of Rep. Sherrod Brown).*

⁷⁵Sidney M. Wolfe, MD, *Editorial: Direct to Consumer Advertising – Education or Emotion Promotion?*, 346 NEW ENGLAND JOURNAL OF MEDICINE 524 (2002).

⁷⁶*Id.*

⁷⁷Alan J. Holmer, JD, *Direct to Consumer Advertising – Strengthening our Health Care System*, 346 NEW ENGLAND JOURNAL

of the physician's recommendation for treatment, and to the physician, who gains a better understanding of the patient's needs."⁷⁸

Despite the industry's argument that DTC ads produce better informed patients, Public Citizen and other consumer organizations have repeatedly called on the FDA to increase its funding for more efficient DDMAC enforcement, to lobby Congress for the authority to enforce monetary penalties, and to address what Public Citizen perceives as a growing problem of patient misinformation caused by DTC promotion.⁷⁹ Wolfe sees the promulgation of DTC ads as a direct threat to the most vulnerable consumers in the viewing audience: elderly patients.

In addition to Public Citizen, the National Consumers League (NCL) has expressed a concern that the FDA has inaccurately characterized the "information" in commercial advertisements as a positive, effective method of communication with patients. The NCL comment to the FDA's 2001 proposed new guidance included a summary of the organization's "Stakeholder Roundtable" events at which interested parties met to discuss DTC promotion. The participants at these events concluded that DTC advertising, in its current form, is an ineffective method of communicating risks to viewers and does not contain information that usefully contributes to patient participation in healthcare.⁸⁰ While NCL agrees with the FDA that DTC ads *could* be helpful tools in empowering consumers, the group believes that the current regulatory approach does not go far enough to ensure that only accurate information and full risk disclosures are presented in every DTC ad.⁸¹ NCL proposes that "the format for presenting risk information for prescription drugs be

OF MEDICINE 526 (2002).

⁷⁸ *Id.*

⁷⁹ See Wolfe, *supra* note 75.

⁸⁰ See Letter from National Consumers League to FDA (July 19, 2001) (on file with the author).

⁸¹ See *id.*

standardized, as it is for over-the-counter drugs, dietary supplements and foods.”⁸² They believe that a mandatory form of risk disclosure would more efficiently realize the potential benefits of DTC advertising.

Despite the overwhelming popularity of DTC ads among the general public, and aside from concerns expressed by consumer advocates as to the efficiency of DTC ads, a growing number of consumer advocacy groups express another objection: cost. These groups believe that DTC advertising harms the average consumer not only because of misinformation or partial disclosures but because they correlate the cost of DTC advertising with the rising cost of healthcare in America.⁸³ The pharmaceutical industry disputes any such correlation.

It is difficult to truly understand the impact DTC advertising has on consumers by reviewing this category of stakeholders in isolation. While consumers may feel as though they are empowered by DTC ads, as most statistical studies clearly suggest, an important indication of their ultimate effect may depend on how this “empowerment” translates from the living room to the exam room. How do DTC ads affect the patient/physician relationship, and are such effects really in the patient’s best interest?

THE MEDICAL PROFESSION

The 1999 FDA guidance opened up a whole new world to patients and their medical providers – one in which a patient questions the doctor about a particular prescription drug, questions a nurse about a particular disorder, or inquires at the pharmacy as to why they aren’t taking the drug advertised on TV as “the best” treatment available. Doctors and other medical professionals are being faced with patient demands

⁸²*Id.* at 3.

⁸³For more on the debate over the rising cost of prescription drugs, see *infra* Part IV: Drug Manufacturers, at ...

for particular prescription drugs popularized in DTC ads, drugs that sometimes cost twice as much as an alternative generic treatment or that treat a disease the patient does not have. The impact of DTC on the patient/physician relationship is one of the most volatile battlegrounds of the entire DTC issue, with many physicians claiming that this form of advertising strains their credibility with patients and reduces the position of authority they have been afforded under the traditional American healthcare model.⁸⁴

Historically, patients looked to their doctors for all the advice and information they needed about their health, their disease, and any possible “cure.” Today, the physician’s role has been changed by a new medical system in which intermediaries (such as HMOs) facilitate the doctor/patient relationship, and health information is available at the consumer’s fingertips. Physicians are no longer *the* primary resource for patients; rather, they are a bit further down a long list of informational tools. Based on these changes, it is not surprising that physicians and physician groups have been some of the most outspoken DTC ad critics. Studies have shown that DTC ads clearly affect patient behavior as patients consistently report questioning their doctors about prescription drugs to which they have been introduced on TV. It is estimated that 30% of Americans have approached their doctor about a DTC promoted drug at some point in the past five years.⁸⁵ Respondents to the 1999 FDA study reported that when they acted on information learned in a DTC ad (51%), 81% sought that information from their doctor.⁸⁶

Consumer respondents to the FDA study believe that DTC advertising has had a positive impact on their own doctor/patient relationships.⁸⁷ Of those consumers surveyed who had visited a doctor in the previous three months, 81% believed their doctor welcomed questions about products seen on DTC ads, 71% stated the doctor treated their question as a routine part of the visit, and 79% reported that their doctor followed their questions with a conversation about the drug.⁸⁸ Sixty two percent of respondents agreed that DTC

⁸⁴ See NHC, *Overview and Recommendations*, *supra* note 71, at 7.

⁸⁵ Kaiser, *DTC Survey Chartpack*, *supra* note 62, at 4.

⁸⁶ FDA, *supra* note 67.

⁸⁷ *Id.*

⁸⁸ *Id.*

ads have facilitated better communication with their physicians.⁸⁹

With so much consumer support for the impact DTC has had on the doctor/patient relationship, it seems difficult at first blush to see a problem. However, many medical professionals believe that some doctors are in fact pressured by these patient inquiries and that DTC ads may have a negative effect on physician prescribing behaviors.⁹⁰ “A recent study in New Zealand and the United States, the only two countries where DTC advertising is permitted, showed that 90% of doctors felt pressured to prescribe medications that consumers requested, 80% assented to their patients requests for certain drugs, and 31% prescribed drugs that were not their first choice. Physicians assent to patients demands for specific drugs because they cannot afford to lose patients in the modern managed care regime.”⁹¹ Other physicians express concern over the loss of faith and trust that some patients may experience should their physician not prescribe a medication in which the patient has become interested after watching and reading various DTC ads.⁹²

There is anecdotal evidence to support this notion of physician dissatisfaction with DTC ads. One doctor complains that patients are requesting prescription drugs they don’t need. “It used to be... that patients would feel an office visit wasn’t complete without them walking out with an Rx. Now they’re walking into offices and asking their physicians, ‘How come I’m not on *Claritin*?’ Well, how about because you don’t have an allergy?”⁹³ However, it is possible that, as patients become less enamored with DTC ads and physicians become more comfortable with patient inquiries, doctors will begin to soften their criticism over this form of marketing.

A recent survey by Louis Harris Interactives and the Harvard University School of Public Health found that a growing number of doctors accept the benefits of DTC advertising. The report states that “initially

⁸⁹*Id.*

⁹⁰See Spurgeon D., *Doctors feel pressured by direct to consumer advertising*, 319 BRITISH MED. J. 1321 (1999).

⁹¹Yonni D. Fushman, *Case Comment: Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-to-Consumer Advertising Exception to the Learned Intermediary Doctrine*, 80 B.U.L. Rev. 1161, 1172 (2000).

⁹²See Anne B. Brown, *The direct-to-consumer advertising dilemma; prescription medication advertising*, 35 PATIENT CARE 22 (2001).

⁹³Robert McCarthy, PhD, *Rx Ads hit Consumer Bull’s Eye*, 10 DRUG BENEFIT TRENDS 23 (1998) available at <http://www.medscape.com/viewarticle/416807> (last visited April 18, 2002).

there was a sense of outrage among physicians. . . and a feeling that only they should talk to patients about prescription drugs,” but that doctors are recognizing the possibilities of DTC in growing numbers.⁹⁴ The Harris/Harvard poll reported that 49% of the physicians surveyed believed DTC had helped “educate and inform” patients, and 25% believed the ads had affected patient compliance with prescriptions they already used.⁹⁵ While these numbers do not suggest overwhelming physician support for DTC ads, they may reflect a growing trend of familiarity and acceptance of DTC promotion.

The physician’s role as an information and prescription drug gatekeeper is often seen as the ultimate protection against consumer harms caused by DTC ads. However, this protection only works if the gatekeeper maintains a steady watch. Dr. Sidney Wolfe recently questioned this traditional DTC ad defense by stating that “duped gatekeepers may not adequately resist patients’ exhortations to write a prescription.”⁹⁶ In response to changes in patient behavior, and to ensure physicians fulfill their role as the ultimate gatekeepers, a number of physician organizations have issued guidelines for physician response to patient inquiries about DTC promoted drugs.

For example, the American Medical Association (AMA) Council on Ethical and Judicial Affairs advises that, “[w]hen confronted with the influences of advertising, physicians should maintain professional standards of informed consent by denying requests for inappropriate prescriptions, educating patients as to why certain advertised drugs may not be suitable treatment options, and including, when appropriate, information on the cost effectiveness of prescription drug options.”⁹⁷ The Council set forth the following guidelines for all physicians to follow:

- (1) Work with the FDA to ensure effective policies and standards;

⁹⁴Pharmaceutical Researchers and Manufacturers of America, *Backgrounders and Facts: Direct to Consumer Advertising* (2000) at <http://www.phrma.org/publications/backgrounders/other/dtc.phtml> (last visited April 18, 2002).

⁹⁵*Id.*

⁹⁶Wolfe, *supra* note 75, at 525.

⁹⁷The Council on Ethical and Judicial Affairs of the American Medical Association, *Direct to Consumer Advertisements of Prescription Drugs*, 55 FOOD & DRUG L.J. 119 (2000).

(2) encourage studies on the impact DTC ads have on patient healthcare;

(3) maintain professional standards of informed consent when prescribing drugs after receiving a patient inquiry related to a DTC ad; and

(4) ensure that DTC advertising does not promote false expectations of any particular prescription drug.⁹⁸

The Council encouraged physicians to report any misleading advertisements to the FDA and to actively evaluate their own experiences with patients and DTC ads to ensure that patient health always comes first.⁹⁹

Medical organizations have not only advised their membership on how to respond to DTC ad inquires, but they have advised the FDA as to their opinions of the current DTC ad regulations and their suggestions for possible DTC ad reform. Prior to the 1997 draft guidance, the AMA developed a set of standards by which it believed DTC ads should be regulated. The organization's comment to the 1997 draft guidance expressed concern over the possibility that an "adverse impact... on the patient-physician relationship and the potential for negative public health and economic outcomes" might occur.¹⁰⁰ In a 1999 report by the AMA's Board of Trustees, the organization clarified its position on DTC ads by reconfirming the standards it developed in 1997 and calling for the continued assessment of DTC ads and their impact on consumer healthcare. The AMA requested that the FDA continuously research the effects and benefits of DTC, and it asked that its own standards be incorporated into the FDA's regulatory regime (a request that was not honored).¹⁰¹ The AMA urged strict enforcement of DTC ad regulations and encouraged the pharmaceutical

⁹⁹ *Id.*

¹⁰⁰ Memorandum from AMA Board of Trustees to Reference Committee E, *Report of the Board of Trustees*, B OF T REPORT 38 -A-99, at 3 (1999).

¹⁰¹ *Id.*

industry to update its research as to the effect DTC ads have on the physician/patient relationship.¹⁰² While the AMA position could be characterized as somewhat cautious, it serves as an important endorsement of DTC ads in the prescription drug trade.

The American College of Physicians – American Society of Internal Medicine (ACP-ASIM) has taken a more critical position on DTC ads, suggesting that the FDA pre-screen all DTC ads rather than rely on post-hoc complaints or requests for review.¹⁰³ Doctors affiliated with the group complain that the current FDA review system is too lenient and must be revised to ensure that patients receive only the highest quality of balanced, fair information.¹⁰⁴ The ACP-ASIM disputes reports which suggest that DTC advertising has resulted in more patient visits to see their doctors. The organization believes that higher *prescription* levels, which are in fact quantifiable, do not necessarily indicate a higher number of *doctor visits* since patients can call in for prescriptions or order drugs off of the Internet.¹⁰⁵ The ACP-ASIM argues that the dangerous nature of such practices, including the possibility that some patients purchase prescription drugs for self-diagnosed symptoms when they actually suffer from more serious conditions, must be considered when developing DTC ad regulations.¹⁰⁶

The American Academy of Family Physicians (AAFP) issued a statement in 1999 arguing that DTC ads are appropriate only when they comply with FDA regulations, the information is accurate, balanced and objective, the ad adequately highlights adverse reactions and side effects, and the consumer is clearly urged to seek consultation with a physician.¹⁰⁷ The organization also stressed that, “if advertisements direct the consumer to a physician, referral should be to the consumer’s personal physician,” rather than a doctor

¹⁰² See AMA Report of Council on Medical Service, *Report No. 9: Costs and Benefits of Pharmaceutical Use in the United States* (1999) at www.ama-assn.org/meetings/public/interim99/downloads/cmsrep.pdf.

¹⁰³ *Facing off: Prescription Pitches*, THE NY TIMES, August 21, 2001, at F7. For a discussion into why this suggestion violates the Constitution, see *infra* Part IV: Advertisers and the Media, at 56.

¹⁰⁴ *Id.*

¹⁰⁵ American College of Physicians – American Society of Internal Medicine, *Direct to Consumer Advertising for Prescription Drugs* (1998) at www.acponline.org/hpp/pospaper/dtcads.htm (last visited April 16, 2002).

¹⁰⁶ *Id.*

¹⁰⁷ American Academy of Family Practitioners, *Proprietary Practices: AAFP Policies and Positions related to Proprietary Practices* (1999) at <http://www.aafp.org/policy/x1794.xml> (last visited April 16, 2002).

referred by the advertisement or the pharmaceutical company.¹⁰⁸

Pharmacists, much like physicians, have been placed in a somewhat precarious situation as a result of higher consumer awareness of brand name prescription drugs, often confronted with questions about a drug the patient has seen advertised. However, pharmacists are not the prescribing professional and can thus refer these inquiries to the patient's doctor. As time passes and heavily advertised prescription drugs begin moving to the OTC shelves,¹⁰⁹ pharmacists may face a new wave of questions from consumers about the efficacy and expense of highly popular and often more expensive drugs.

It is likely, due to the heightened concerns over the cost of drugs in America, that pharmacists will be asked by the FDA or Congress to step up their role as patient advisors. Pharmacists must be prepared to face many of the same questions doctors are finding so difficult today – questions about expensive drugs that are made popular by advertisements but are often no more effective than similar, less expensive medication. However, this “challenge” is a familiar one for experienced pharmacists who have always faced questions about OTC drugs and newly switched prescription medications. The only difference DTC marketing makes for these professionals is the increase in consumer awareness of particular name brands. The pharmacists' traditional role as a patient advisor makes them particularly well suited to accurately answer consumer questions and effectively assist the physician in balancing the effects of high name recognition and influential DTC advertising.

As the medical community and consumers become more familiar with and complacent toward DTC ads, and as changes continue to occur in doctor/patient relationships, it is likely that the negative reaction most doctors initially had toward DTC ads will fade. However, any increase in physician comfort may be conditioned on the perception that the FDA will continue to ensure, through research and strict enforcement, that DTC ads fairly present both the benefits and the risks of heavily promoted prescription drugs.

¹⁰⁸ *Id.*

¹⁰⁹ For example, Schering-Plough announced in March 2002 that Claritin would soon be moving to OTC status. For more on this, see *infra* Part V: The Effect of DTC on a Representative Drug: Claritin, at 63.

DRUG MANUFACTURERS

The introduction of the FDA guidance that ensured compliance with broadcast DTC ad regulations was a real turning point for the prescription drug industry. These manufacturers and their shareholders have been clear winners in the influx of DTC advertising, and so far, the companies have found a friend in their traditional adversary, the FDA. The agency's research and the statements of its leadership have continued to support the use of DTC ads because, according to Dr. Janet Woodcock, director of the FDA's CDER, the agency has recognized that even though DTC ads are driven by commercial goals, they "have the potential to increase awareness among consumers and patients of. . . conditions and the availability of treatment."¹¹⁰ This faith in the benefit of DTC advertising has resulted in a cooperative enforcement relationship between the FDA and pharmaceutical companies, a relationship in which the companies have thrived. Will the successes of DTC ads continue to grow, or was the marketing boom of the late 1990s a limited chance to make the most out of a "gift" from the FDA?

Immediately following the release of the 1997 draft guidance, the pharmaceutical industry began to invest heavily in DTC ad efforts. In 1997, the industry spent a total of \$1.07 billion on DTC marketing, an increase of 35.3% over the 1996 expenditure of \$791 million.¹¹¹ That figure rose to \$1.32 billion in 1998 and \$1.85 billion in 1999. In the year 2000, pharmaceutical companies spent \$2.5 billion on direct-to-consumer ads for prescription drugs.¹¹² Of that \$2.5 billion, TV ads accounted for \$1.4 billion, the largest portion (57%) and an increase of 27.3% over the industry's 1999 TV expenditures.¹¹³

To place these DTC ad expenses in context, it should be noted that they represent a relatively small per-

¹¹⁰ *Recent Developments which may impact Consumer Access to, and Demand for, Pharmaceuticals Hearing Before the Subcommittee on House of Representatives Health of the Committee on Energy and Commerce, 107th Cong. 34 (2001)* (statement of Janet Woodcock, M.D., FDA).

¹¹¹ National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising, 2000*, at 5 (2001) available at www.nihcm.org/mainframe.html (last visited April 16, 2002).

¹¹² *Id.*

¹¹³ *Id.* at 2.

centage of most pharmaceutical companies' marketing budgets. For example, in 2000, a total of \$15.7 billion was spent on marketing prescription drugs, the majority on doctor promotions and only 16% on DTC.¹¹⁴ However, if the *retail* value of the drug samples provided to doctors is reduced to the drug company's actual cost value, DTC ads account for a higher, and perhaps more accurate, 31.8% of the industry's total marketing budget.¹¹⁵ While DTC is not the leading marketing tool for pharmaceuticals, it does account for the most significant portion of most companies' *advertising* budgets.

Despite the extraordinary advertising expenditures by drug manufacturers, the shareholders of these pharmaceutical corporations have had nothing to complain about. In 2000, industry wide sales of the 50 most heavily promoted prescription drugs brought in \$41.3 billion, a 31.9% increase over 1999 sales figures; in comparison, total sales for all prescription drugs yielded \$131.9 billion, an increase of only 13% over 1999.¹¹⁶ This data indicates that DTC marketing works. Since 1997, similar increases in sales have raised both the revenues of pharmaceutical companies and their stock prices.

However, despite these past successes, the long term economic benefits of DTC marketing are beginning to come into question. "The sales growth of 8 of the 10 most heavily advertised drugs, nearly all of which have annual sales of more than \$1 billion, slowed in the third quarter of 2001, compared with the period in 2000. . . ,"¹¹⁷ and for the first time in recent memory, some drug companies announced zero growth for the Fourth Quarter of 2001.¹¹⁸ As a result, Wall Street lowered share prices by an average of 18% in 2001, and the S&P Index declined 13 % for the eight largest drug manufacturers.¹¹⁹ It is possible that these downturns were simply the result of the general market decline in late 2001. However, it should be considered that, along with an overall slowdown in the market, lower sales figures for the most heavily promoted prescription

¹¹⁴*Id.* at 6.

¹¹⁵*Id.*

¹¹⁶*Id.* at 2.

¹¹⁷Milt Freudenheim and Melody Petersen, *The Drug-Price Express Runs Into a Wall*, THE NY TIMES, December 23, 2001, at Sec. 3, 1.

¹¹⁸See Amy Tsao, *Big Trouble in Biotech City?*, BUSINESSWEEK ONLINE, January 25, 2002 at http://www.businessweek.com/bwdaily/dnflash/jan2002/nf20020125_2250.htm (last visited April 18, 2002).

¹¹⁹Freudenheim and Petersen, *supra* note 117.

drugs could be due in part to the declining impact and effectiveness of DTC advertising.

The phenomenal success of DTC ads over the past five years has been realized primarily by the large pharmaceutical companies – companies with a bevy of established products and available capital to spend on advertising campaigns. Due to the high cost of running a successful DTC campaign, small drug manufacturers, including one-product start up ventures, cannot initially afford to compete with the name brands that DTC ads have made so popular. For example, Sepracor Inc., a small New England drug maker, has been readying a launch for Soltara, its version of a non-sedating antihistamine. In order to make it, Soltara will have to compete in the most competitive drug market today – antihistamines – and against such pharmaceutical giants as Schering-Plough’s Clarinex, Pfizer’s Zyrtec, and Aventis’ Allegra.¹²⁰ While Sepracor’s executives have faith that the product’s effectiveness will eventually sell itself, they must first overcome the market saturation and name brand familiarity its competitors currently enjoy.¹²¹

According to Robert Hazlett, a pharmaceutical market research analyst for Robertson Stephens, this task is not impossible. He cites Allegra’s 16% market share gain in just one year as proof that a comprehensive DTC campaign, accompanied by customer dissatisfaction with competing products, makes it possible.¹²² The problem for small pharmaceutical manufacturers is that such large-scale advertising requires a tremendous investment of front-loaded capital – money that is usually available only to large pharmaceutical companies with proven records of success. This hurdle presents the dangerous possibility that innovation and development by small research firms may be discouraged due to the costs associated with any profit realization

¹²⁰Naomi Aoki, *A challenge that’s not to be sneezed at: Its new allergy drug will pit tiny Sepracor against goliaths*, THE BOSTON GLOBE, January 9, 2002, at C1.

¹²¹*Id.* at C4.

¹²²*Id.*

from a resulting product.

The most recent debate over the pharmaceutical industry's use of DTC advertising involves the growing perception that the money drug companies spend on DTC ads contributes directly to the rising cost of pharmaceutical drugs. That drug prices have increased over the past ten years is an undisputed fact – it is the source of that increase that is of interest to a variety of groups, including consumer advocates, members of Congress, and particularly the third party payers who are often stuck with the bill for higher prescription drug costs.

A report by the Kaiser Family Foundation found that “manufacturer price increases have contributed a growing proportion of the total rise in prescription drug spending - 19% from 1993-1997, and 24% from 1997-2000.”¹²³ In a 1999 report, the Health Insurance Association of America (HIAA) forecast a continued increase in prescription drugs expenditures, higher health insurance premiums, and more consumer spending over the next ten years.¹²⁴ HIAA cited several contributing factors to higher drug costs, including faster FDA approval of expensive treatments, higher demand for expensive medication due to the growth in third-party payment, and the aging of Americans. However, HIAA stated that, in its opinion, the most significant contributing factor to higher drug prices was “the expansion of DTC advertising.”¹²⁵

The pharmaceutical industry and other supporters of DTC strongly dispute any suggestion that the increase

¹²³Kaiser Family Foundation, *News Release: Survey: Nearly One in Three Adults has Talked to a Doctor and One in Eight has Received a Prescription in Response to a Drug Ad* (November 29, 2001) at 2, available at www.kff.org/content/2001/20011129a/Release%20Final.pdf (last visited April 16, 2002).

¹²⁴Brown, *supra* note 92, at 22.

¹²⁵*Id.*

in DTC ad expenditures is contributing to the rising cost of prescription drugs. In 2001, Dr. Richard Manning and Dr. Alison Keith issued a report which found no causal connection between consumer drug costs and pharmaceutical ad budgets.¹²⁶ While the report admits the possibility that DTC advertising has increased the *use* of prescription drugs, Manning and Keith draw a clear distinction between use and *price*. The report explained that “there is no theoretical reason to expect that advertising will cause higher prices. While advertising presumably will increase demand for a product, the cost of that advertising would usually be recouped through increased sales volume rather than through higher prices.”¹²⁷ The report also argues that advertising in a particular market will eventually lead to *lower* prices over time due to heightened competition among producers and market based retailers.¹²⁸

A common explanation pharmaceutical companies give for any increase in drug prices is a corresponding rise in their own Research and Development (R&D) costs. While opponents argue against this assertion by citing lower drug costs in neighboring Mexico and Canada, drug manufacturers claim that because the additional R&D costs are incurred in the US, they are rolled into US prices.¹²⁹ Pharmaceutical companies also cite the FDA’s prolonged drug approval process as a contributing factor to higher prices because it shortens the amount of time in which companies can market a drug under an exclusive patent; the price must be higher in order to recoup their initial development costs.¹³⁰ The manufacturers warn that reducing the amount they recover for a drug while it is under patent will dramatically reduce the both the incentives

¹²⁶Richard Manning, Ph.D. and Alison Keith, Ph.D., *Prescription Drug Advertising: Empowering Consumers Through Information: The Economics of Direct to Consumer Advertising of Prescription Drugs*, 2 ECONOMIC REALITIES IN HEALTH CARE POLICY 3 (2001). It is important to note that this report was funded by Pfizer, a leading pharmaceutical manufacturer.

¹²⁷*Id.* at 7.

¹²⁸*Id.* One problem with this argument, however, is that DTC ads are not limited to products with a competitor in the marketplace. For drugs without any competition, it is impossible for ads to lower prices – they are the only drug on the shelf.

¹²⁹When US drug prices are compared to the cost of the same drugs in both Canada and Mexico, US prices are almost always higher. For more on this issue of price discrepancy, see David E. Rosenbaum, *Health Insurance Provides Buffer to Rising Drug Prices for Most Americans*, THE NY TIMES, June 1, 2000.

¹³⁰Patents are granted for a period of twenty years at the beginning of the drug development process, often leaving only seven to ten years of exclusive marketing privileges after development and FDA approval.

and available funding for investment in future R&D.¹³¹ Pharmaceutical profits should be viewed, they argue, as a necessary condition for the development of healthcare.

Another industry explanation for the rising cost of prescription drugs is the steady increase in usage and changes in the types of drugs most often prescribed.¹³² In 1998, the average American consumer took 10 prescriptions, one more than in 1996 and three more than 1992.¹³³ “The type of drugs people are taking is also getting more costly as new, more expensive drugs replace older, less expensive drugs, such as generics.”¹³⁴ Patients are also taking drugs for conditions not previously treated by medication. According to the industry, all of these factors contribute to higher usage and the correlating increase in overall drug expenditures that insurers and HMOs have experienced in the past few years.

In the end, DTC ad supporters conclude that not only is the cost of DTC advertising not affecting the price of drugs, but that the ads may actually *lower* the price of prescriptions. They claim that higher levels of consumer awareness, information and demand will eventually give rise to a more competitive market that will lower the cost of prescription drugs.¹³⁵ This point raises a new charge by consumer advocates: if DTC advertisements are not *causing* the price of prescription drugs to increase, are DTC ad budgets *benefiting* from this market-based increase in profit? Are pharmaceutical companies applying these profits to their DTC ad expenditures rather than using the funds for research and development? Drug manufacturers and DTC proponents say no, arguing that the increase in profits is being applied to R&D in an effort to develop their next blockbuster drug.¹³⁶ Consumer groups and DTC ad opponents disagree, but their disagreement lacks any substantial proof.

Despite the arguments in favor of DTC ads, consumer groups and insurers continue to believe that the

¹³¹Gregg Easterbrook, *The Drug Wars*, THE INDUSTRY STANDARD, May 29, 2001 available at www.biohope.org/media/article_print.cfm?articleid=1277 (last visited April 16, 2002).

¹³²See Sarah A. Webster, *Pill ads raise drug costs*, THE DETROIT NEWS, May 6, 2001 at 13.

¹³³*Id.*

¹³⁴*Id.*

¹³⁵Merrill Matthews, Jr., PhD., *Answering Critics of the Pharmaceutical Industry*, IPI IDEAS (Institute for Policy Innovation), March 21, 2001 at 5.

¹³⁶*Id.*

correlation between the high cost of DTC advertising and the increase in prescription drug prices is more than coincidence. They counter the industry's R&D explanation by citing a larger allocation of dollars to marketing and administrative budgets than to R&D budgets.¹³⁷ "The drug industry's top priority increasingly is advertising and marketing, [increasing] almost 40% a year since . . . 1997. Moreover, the Fortune 500 drug companies dedicated 30 percent of their revenues to marketing and administration in the year 2000, and just 12 percent to R&D."¹³⁸ DTC ad critics also argue the implausibility of the industry's statement that a prolonged FDA approval process has contributed to higher prices. In fact, they say, the average time for FDA approval has *decreased* since the guidance was issued in 1997.¹³⁹

Moving beyond the financial implications of DTC ads (a profitable success that has fulfilled drug companies' fiduciary duties to their shareholders), and considering that drug manufacturers are an integral part of the American healthcare system, some commentators have argued that drug manufacturers have an ethical duty to consider patient interests when developing DTC ad campaigns. In a *Washington Post* editorial, Harvard Medical School professors Marcia Angell and Arnold Relman argue that pharmaceutical companies have a fundamental duty to serve patient interests because "[p]rescription drugs are not like discretionary consumer products. For millions of patients, they are necessary to health and even survival."¹⁴⁰ Drs. Angell and Relman believe the true "purpose" of DTC advertising is education, not marketing, and that DTC ads should be approached as such by the drug companies. While this imposition of an ethical duty might provide fodder for patient activists and physicians groups, it is not likely to have much bearing on the FDA's legal

¹³⁷Public Citizen, *Massachusetts Consumers Pay More for Prescription Drugs while Pharmaceutical Profits Soar*, October 11, 2000 available at http://www.citizen.org/congress/reform/state_rx_price/articles.cfm?ID=812 (last visited April 18, 2002).

¹³⁸Public Citizen, *Rx R&D Myths: The Case against the Drug Industry's R&D 'Scare Card'*, September 6, 2001 available at www.citizen.org/publications/release.cfm?ID=7065 (last visited April 16, 2002).

¹³⁹For more on the FDA's innovations to speed up the drug approval process, see <http://www.fda.gov/cder/fdainnovate.htm> (last visited April 18, 2002).

¹⁴⁰Marcia Angell and Arnold S. Relman, *Editorial: Prescription for Profit*, THE WASHINGTON POST, June 20, 2001 at A27.

approach to DTC ad requirements.

Despite the past successes of DTC promotion, there is a frightening change in the legal landscape looming for pharmaceutical companies – a change that could alter the way companies approach the advancement of DTC ads and other forms of consumer communication. Recent decisions in several state courts suggest that there may soon be a break down in one of the most stringent modern-day liability shields: the learned intermediary doctrine (the “doctrine”).

According to the doctrine, drug manufacturers are required to provide adequate warnings about the prescription drugs they produce to physicians and other health care providers who in turn prescribe the medication to patients. Manufacturers are *not* required to communicate such risks directly to consumers because the prescribing physicians are required to give the patient all of the information regarding risks, side effects, and contraindications. The health care provider who prescribes the drug is the “learned intermediary,” and liability for patient harms that are a result of inadequate risk information lies with the prescribing doctor rather than the manufacturer.

The policy behind the doctrine is based on the theory that physicians, as experts, are in a better position than the consumer or the drug manufacturer to adequately assess the drug’s particular effects on the individual.¹⁴¹ In many states, the doctrine has been incorporated into a product liability statute. Through the years, state courts and legislatures have developed some limited exceptions to the doctrine, including cases where large numbers of patients were misinformed in association with mass immunizations or FDA-mandated patient disclosures.¹⁴²

A 1999 New Jersey Supreme Court decision threatens to add one more important limitation to the doctrine.

¹⁴¹ See Nadal, *supra* note 24, at 454.

¹⁴² Jack E. Karns, *Direct Advertising of Prescription Drugs: The Duty to Warn and the Learned Intermediary Rule*, 3 DEPAUL J. HEALTH CARE L. 273, 278 (2000).

In *Perez et. al. v. Wyeth Laboratories Inc.*,¹⁴³ the Court held that:

The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product. The FDA has established a comprehensive regulatory scheme for direct-to-consumer marketing of pharmaceutical products. Given the presumptive defense that is afforded to pharmaceutical manufacturers that comply with FDA requirements, we believe that it is fair to reinforce the regulatory scheme by allowing, in the case of direct-to-consumer marketing of drugs, patients deprived of reliable medical information to establish that the misinformation was a substantial factor contributing to their use of a defective pharmaceutical product.¹⁴⁴

The *Perez* case involved a DTC print campaign for the contraceptive Norplant that began appearing in women's magazines (*Cosmopolitan*, *Glamour*, and *Mademoiselle*) in 1991. Wyeth Laboratories, Inc., the manufacturer of Norplant, did not warn readers of any risks or side effects in the ads, assuming instead that the doctrine transferred the responsibility for such warnings to the prescribing physician.¹⁴⁵ Wyeth Labs *did*, however, contact physicians, advising them as to the ad campaign and preparing them to receive patient inquiries about the product.¹⁴⁶

In *Perez*, the court considered the affect of DTC on patient behavior and concluded that Wyeth did not do enough to warn patients considering the direct nature of their communication. The court found that, "as a result of direct advertising, patients now enter their physician's office with preconceived expectations about their treatment,"¹⁴⁷ thereby reducing the influence a physician's warnings will have on patient perceptions. This ruling excludes pharmaceutical companies from the doctrine's protection under the New Jersey Product Liabilities Act *unless* the company complies with all FDA regulations governing consumer communication.¹⁴⁸

While the *Perez* decision is based on state tort law and is therefore limited to lawsuits filed in New Jersey, the decision has received tremendous notice and has been followed in the 2nd, 3rd and 7th Circuits and

¹⁴³734 A.2d 1245 (NJ 1999).

¹⁴⁵*Id.* at 1248.

¹⁴⁶*Id.*

¹⁴⁷Karns, *supra* note 142, at 286 – 87.

¹⁴⁸*Id.* Because the Norplant ad campaign occurred prior to the release of the 1997 draft guidance, there was no DTC ad blueprint for Wyeth to follow in 1991.

in the states of Connecticut and Nebraska.¹⁴⁹ However, the *Perez* decision was accompanied by a very strong dissent, and the ruling is in direct conflict with a 5th Circuit finding in a similar Norplant case that no additional duty is created by the use of DTC.¹⁵⁰ “After reviewing the *Perez* opinion, it is difficult to determine who was the true winner. On one hand, consumers of prescription drugs will... receive the benefit of the protections provided by FDA regulations, especially in DTC advertising, as *Perez* demands and rewards FDA compliance. On the other hand, prescription drug manufacturers receive the conclusive presumption of an adequate warning by complying with FDA standards. Arguably both sides can claim a somewhat tainted victory.”¹⁵¹ While the extension of *Perez* to other jurisdictions is not inevitable, the threat of extensive liability exposure on ad campaigns that are released without pre-market approval by the FDA may cause pharmaceutical companies to more carefully weigh the benefits and rewards of DTC advertising.

Pharmaceutical manufacturers have benefited enormously from the FDA’s guidance on DTC ads, reaping the rewards of consumer activism and capitalizing on the opportunity to “provide useful healthcare information” to the general consumer. However, despite any sincere intention to contribute to the public health, it cannot be disputed that pharmaceutical companies are in no way duty-bound to make decisions based solely on the public’s best interests. Corporations have legal responsibilities to shareholders that require them to put profit ahead of other considerations despite their legitimate intention to “do the right thing.” The FDA, physicians, and most importantly consumers must keep in mind that the ultimate impetus behind DTC advertising is profit, and the FDA approach to monitoring DTC ads should always consider the understandably biased motives of the industry.

¹⁴⁹See *Vitanza v. Upjohn Corp.*, 214 F.3d 73 (2d Cir. 2000); *RTC v Fidelity & Deposit Co.*, 205 F.3d 615 (3d Cir. 2000); *Eve v. Sandoz Pharm. Corp.*, 2001 US Dist. LEXIS 4531 (S.D. Ind. Mar. 7, 2001); *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001); *Freeman v. Hoffman – La Roche*, 618 N.W.2d 827 (Neb. 2000).

¹⁵⁰In re Norplant Contraceptive Products Liability Litigation, 165 F.3d 374 (5th Cir. 1999).

¹⁵¹P. Terrence Gaffney, *NJ High Court Scuttles Learned-Intermediary Rule*, 22 THE NATIONAL LAW JOURNAL B11, May 22, 2000.

INSURERS, HMOs, AND THIRD PARTY PAYERS

Over the past two decades, the American healthcare industry has seen a dramatic shift in the way medical services are delivered to consumers. The development of Managed Care Organizations (MCOs) has altered the physician/patient relationship by inserting a third party payer into the medical decision-making process, thereby affecting the way doctors communicate with patients about healthcare options and inevitably affecting the choices that are made. It is this third party payer system, which often leaves the patient feeling removed from his or her healthcare, which the pharmaceutical industry cites as evidence of the need for DTC advertising.

According to drug companies, insurers are making consumer engagement in their own healthcare more difficult by imposing approved lists and expense limitations for prescription drugs. Insurers, MCOs, Health Management Organizations (HMOs), and other third party payers exercise a great deal of control over what medications are available under the patient's or employer's health plan, often creating tension when the physician or the patient wishes to deviate from those standards. Insurers answer this allegation by citing the rising cost of prescription drugs, thereby shifting the blame for limited patient access to the pharmaceutical companies.

Recent statistics have shown that MCO pharmacy costs increased between eight and twenty percent in 1998,¹⁵² and prescription drugs make up approximately 17% of every health care dollar the average MCO plan spends, up from only 9.2% in 1990.¹⁵³ Many third party payers believe that the enormous expense of running a DTC ad campaign has an ultimate effect on the cost of providing heavily promoted drugs to their membership. "According to one integrated health system executive, 'a major factor is precisely those drugs

¹⁵²Terzian, *supra* note 34, at 160.

¹⁵³Timothy F. Dickman & Howard R. Veit, *Consumerism and Escalating Drug Costs: A Volatile Mix*, 13 DRUG BENEFIT TRENDS 48 – 52 (2001) available at www.medscape.com/viewarticle/409975 (last visited April 16, 2002).

being advertised; they are the ones showing the greatest per-member/per-month increases.”¹⁵⁴

In response to the increased cost of prescription drugs, many employers are feeling the squeeze as their benefit premiums continue to rise. As a result, “[e]mployers, frustrated by seeing little return for managing employee health benefits, are trying to shift increasing costs back onto employees.”¹⁵⁵ Employers, in an effort to lower their own costs, are reducing the healthcare benefits their employees receive. These cutbacks, a direct result of the employer’s desire to reduce overhead, ultimately leave the consumer holding the bag. In addition to employee benefit cutbacks, HMOs have begun to reduce prescription expense allowances in their benefit plans. The new plans actively encourage and reward the use of generic drugs, with some even excluding very popular drugs that are heavily promoted by DTC ads (drugs which are often more expensive than other medications). While patients and pharmaceutical companies may see this as a potentially dangerous reduction in patient care, many third party payers blame the changes on the rising cost of prescription drugs and the effect DTC ads on consumer expectations; they say the ads manipulate consumers into believing that they need the most heavily advertised, often more expensive drugs.¹⁵⁶ Atheer Kaddis, director of pharmacy services at Michigan’s Blue Cross, says that “the medication that’s being advertised is portrayed as the best possible therapy. That may not necessarily be true.”¹⁵⁷

As employers and insurers begin to reduce the amount they are willing to pay for prescription drugs, often citing DTC as a contributing factor, the ultimate price for these drugs may eventually fall to the consumer, thereby creating a whole new debate for the pharmaceutical industry. The possibility exists that a continued resistance by healthcare plans to pay for “brand name” drugs will reduce the initial return on investment drug manufacturers expect from DTC advertising. In the alternative, “DTC advertisements may increase physician and patient pressure on MCOs to ensure that the drugs they want are included”¹⁵⁸ in their health-

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ See Webster, *supra* note 132.

¹⁵⁷ *Id.*

¹⁵⁸ Terzian, *supra* note 34, at 159 – 60.

care coverage. “If there is enough pressure from both physicians and patients, these third party payers will be forced to consider including popular, yet expensive, drugs or risk losing subscribers to other plans that do.”¹⁵⁹ Only time will tell which way the pendulum will swing.

FEDERAL GOVERNMENT

Since the FDA issued the 1997 draft guidance, the agency has conducted two studies on the effectiveness of DTC advertising and the impact it has on consumers. The most recent study, undertaken in 2001, has not yet been released, but if the findings are similar to those issued in 1999, the pharmaceutical companies will continue to find refuge in the FDA’s statistical support for the use of DTC ads. However, regardless of “consumer satisfaction,” and despite the FDA’s traditional support of the practice, changes to the current state of DTC ads may be brewing in the halls of Congress.

In July 2001, Rep. Pete Stark (D – CA), the ranking member of the House Ways and Means Health Subcommittee, introduced H.R. 2352, the Fair Balance Prescription Drug Advertisement Act (the “Fair Balance bill”).¹⁶⁰ The Fair Balance bill requires the compliance of pharmaceutical companies who elect to take a tax deduction for advertising expenses with the following: all DTC advertisements must contain a “balanced presentation” of benefits and risks as measured by an “equal allocation” of broadcast air time or “equal typeface” on the same or a facing page in print advertisements.¹⁶¹ Rep. Stark states that the impetus for this bill is two-fold: his concern that consumers clearly understand the risks of an advertised drug, and his belief that the increasing effect ad expenditures are having on the cost of prescription drugs must be stymied.¹⁶² He believes the bill will “decrease the economic incentives for DTC advertising by taking away

¹⁵⁹*Id.*

¹⁶⁰HR 2352, 107th Congress (2001).

¹⁶¹*Id.*

¹⁶²Rep. Pete Stark, *Unbalanced drug ads delude the customer*, THE HILL, July 18, 2001 available at www.biohope.org/media/article_print.cfm?articleid=1808 (last visited April 18, 2002).

tax deductions for ads that are not fairly balanced.”¹⁶³

Rep. Stark states that “[p]harmaceutical companies know that the demand they are creating with their advertising allows them to charge almost any amount for their products,” and he correlates their “soaring advertising expenditures” with the rising cost of drugs.¹⁶⁴ He also cites the impact drug advertisements have on patient requests to their doctors, stating a belief that “doctors should prescribe and insurance companies should pay for those medications that are deemed necessary and appropriate for patients, and that doctors should make those decisions outside the influence of advertising campaigns.”¹⁶⁵ The bill’s standard of compliance does not rely in any way on the FDA or its regulatory process, an omission that could perhaps be interpreted as a direct affront to the current state of regulation. On July 16, 2001, the bill was referred to the Ways and Means Committee and the House Energy Committee. It has gained ten sponsors in the ensuing months, but the bill has yet to be acted upon.

For a number of reasons, it is highly unlikely that this legislation will ever emerge from the Health Subcommittee. First, the bill is not very effective in altering the content or reducing the use of DTC advertising – its vague requirements would either be easily met or scarcely enforced, and pharmaceutical companies will do everything in their power to ensure that their tax deductions are safe. The bill is also of debatable First Amendment Constitutionality as it presents a direct regulation of the content of speech with little correlation to its purported goal.¹⁶⁶ The strong consumer support for DTC ads and the lack of any apparent legislative priority for DTC ad regulations also weigh against the success of this bill. However, its mere proposal sends a message to pharmaceutical companies that some members of Congress are willing to connect the dots between the rising cost of drugs and the promulgation of DTC ads. If costs continues to rise and the use of DTC ads continues to grow, it seems likely that more proposals like the Fair Balance bill will be offered in

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ For more on the Constitutionality of commercial speech, see *infra* Part IV: Advertising Industry and the Media, at 56.

the years to come.

In addition to Rep. Stark's proposed legislation, Congress has conducted two hearings within the past year to discuss the rising cost of prescription drugs and the effect of DTC advertising on that change. In June 2001, the House Energy Subcommittee for Health heard from a panel that included Dr. Janet Woodcock of the FDA, Gregory J. Glover, an attorney with Ropes & Gray on behalf of PhRMA, Thomas Geiser, General Counsel of Wellpoint Health Networks, and Jane Delgad of the National Alliance for Hispanic Health.¹⁶⁷ On the Senate side, the Commerce, Science and Transportation Committee's Subcommittee for Consumer Affairs held a hearing on July 24, 2001. Those testifying included Nancy Ostrove of the FDA, Dr. Sidney Wolfe of Public Citizen, Dr. Michael Shaw of EthicAd, and Mr. Christopher Malineaux of PhRMA.¹⁶⁸ At both hearings, Congress expressed an interest in monitoring any possible connection between prescription drug costs and the rise in DTC advertising. While no action has yet been taken on the basis of these discussions, the hearings sent a clear message: Congress is not yet convinced that DTC ads are necessarily the best answer for consumers or third party payers.

STATE GOVERNMENT

While the regulation of prescription drugs is an entirely federal matter, the issue of DTC advertising has not bypassed the states. In the past year, several state legislatures have proposed various forms of legislation, all of which attempt to monitor the impact DTC ads have on drug prices within their states. According to mid-2001 numbers, almost 60 bills addressing DTC advertising were up for consideration across the country, with several other states already having enacted legislation.¹⁶⁹ Interestingly, none of these bills include the imposition of any substantive requirements for DTC ads; rather, the bills primarily establish systems for

¹⁶⁷*Recent Developments which may impact Consumer Access to, and Demand for, Pharmaceuticals Hearing Before the Subcommittee on House of Representatives Health of the Committee on Energy and Commerce, 107th Cong. (2001).*

¹⁶⁸*Direct to Consumer Advertising of Prescription Drugs Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism Senate Committee on Commerce, Science, and Transportation, 107th Cong. (2001).*

¹⁶⁹*Scott-Levin announces states take aim at Direct to Consumer drug ads, BUSINESS WIRE, June 26, 2001.*

monitoring the relationship between ad expenditures and prescription drug costs. The impetus behind these bills is the states' concern with the cost of providing medication to patients on state Medicaid rolls – a price that is ultimately borne by the taxpayer. As a result of this cost-control focus, none of the proposals attempt to ensure or protect the real value of DTC ads: the “fair balance” presentation of important healthcare information direct to consumers.

In West Virginia, the legislature passed a resolution entitled “The Prescription Drug Cost Management Act,” which “require[es] prescription drug manufacturers to disclose to the state expenditures for advertising, marketing and promotion, as well as for provider incentives and research and development efforts. . . .”¹⁷⁰ The bill also creates a state program to complement and/or counteract these marketing efforts by educating consumers as to the costs and benefits of particular prescription drugs.¹⁷¹ In Pennsylvania, a bill introduced last year would permit the state’s Health Care Cost Containment Council to “collect data and provide reports on prescription drug advertising and promotional activities.”¹⁷² The bill provides for the disclosure of all advertising and promotional money spent inside the state, with the data to be organized by which health care provider and/or audience was targeted by the promotion.¹⁷³ In Massachusetts, Senate bill No. 1979 places the blame for rising drug costs squarely on the shoulders of ad and marketing expenses.¹⁷⁴ The bill’s sponsors claim that Massachusetts, due to its role as a “major purchaser of prescription medication,” must monitor the associated rising costs, and the bill requires broad reporting of all aggregate advertising and promotional costs directed at managed care plans, HMOs, benefits management groups, professionals, hospitals, and consumers through Massachusetts media outlets.¹⁷⁵

¹⁷⁰W. Va. Code § 5-16C-9(4) (2001).

¹⁷¹*See id.* at (9)(5).

¹⁷²*See* PA S.B. 127 (2001). The Bill was introduced on January 29, 2001 and referred to the Senate Committee on Public Health and Welfare, where it has remained.

¹⁷³*Id.*

¹⁷⁴MA S.B. 1979 (2001), available at <http://www.state.ma.us/legis/bills/st01979.htm> (last visited April 18, 2002).

¹⁷⁵*Id.*

Other states have debated resolutions which ask the federal government to regulate DTC ads and drug pricing simultaneously and to fund state-based programs that do the same – all in an effort to control the increasing price of drugs.¹⁷⁶ The attempts by these states to require the disclosure of any relationship between advertising expenses and the price of prescription drugs sends a message to drug manufacturers: states, as third party payers, are not pleased with the rising cost of drugs and are actively searching for creative ways to keep prices low. However, none of these state proposals or laws would have any substantive effect on the promulgation or distribution of healthcare information via DTC advertising.

ADVERTISING INDUSTRY AND THE MEDIA

With all the dollars being spent on DTC ads by pharmaceutical companies, it is not surprising that the direct benefactors of those large marketing budgets, the advertising agencies and media outlets, are strong supporters of DTC ads and the FDA's 1999 guidance. Currently, DTC prescription drug advertising is the sixth largest ad category in the United States.¹⁷⁷

Advertising agencies and print publications benefited somewhat from prescription drug print ads before the 1997 draft guidance was issued, a benefit not shared by the broadcast media. Pharmaceutical companies invested only \$595 million in television DTC ads in 1996, which was a 212% increase over the previous year.¹⁷⁸ However, with the issuance of the 1997 draft guidance, those numbers began to increase in dramatic fashion as drug manufacturers and ad agencies became comfortable with the FDA's DTC advertising blueprint.

The FDA's new approach to DTC ads generated a niche for advertising agencies and mainstream media outlets. In 1998, the first full year under the draft guidance, the top prescription drug advertisers spent 44%

¹⁷⁶ See Scott-Levin, *supra* note 169.

¹⁷⁷ The American Advertising Federation, *AAF National Conference Video Archive* (2001) available at www.aaf.org/calendar/aac.video.html (last visited April 17, 2002).

¹⁷⁸ See Terzian, *supra* note 34, at 164.

more on DTC ads than on physician directed materials (\$665 million vs. \$462 million).¹⁷⁹ By the year 2000, the drug industry's DTC ad expenditures topped more than \$2.5 billion, filling the pockets and portfolios of advertising executives, broadcasters, and the media.¹⁸⁰ For example, CommonHealth, the top ranking advertising agency that focuses primarily on healthcare, reported a gross income of \$158.7 million in 2000, up 16.3% from 1999.¹⁸¹

Many ad industry organizations, including the American Advertising Foundation (AAF) and the Coalition for Healthcare Communication (CoHealthcom), have spent hundreds of hours and thousands of dollars lobbying members of Congress and the FDA to dismiss consumer groups' calls for more restrictions on DTC advertising. The advertisers assert the "consumer benefit" argument of their pharmaceutical clients, stating that further regulations would reduce consumer participation in health care by reducing the amount of direct information they receive. Most of these advertising groups accept the current guidance, and most support the idea of federal regulatory oversight, but several believe the current adequate provision requirement is too prohibitive of speech and too difficult to satisfy in a 30-second spot. There are even some industry groups that go so far as to call for a change in *who* regulates prescription drug advertisements.

In CoHealthcom's Position Statement on DTC ads, the organization states that "... the functions of approving new drugs and monitoring the marketing of existing drugs should be separated in order to eliminate the implicit threat of withholding drug approval where there is a disagreement over marketing questions."¹⁸² This statement questions the FDA's competence to regulate DTC ads; however, no such accusation of biased conduct has ever been reported. It seems CoHealthcom, an ad industry coalition formed specifically to urge support for DTC ads, is willing to make any argument it can in an effort to remove DTC ad regulation

¹⁷⁹ *Mercedes Yanks \$100M Account from Lowe*, ADVERTISING AGE, February 11, 1999 at 36.

¹⁸⁰ AAF, *supra* note 177.

¹⁸¹ *Top 25 Healthcare Agencies*, ADVERTISING AGE available at www.adage.com/page.cms?pageId=401 (lasts visited April 17, 2002). CommonHealth, located in Parsippany, New Jersey, is the agency responsible for the Claritin account.

¹⁸² Coalition for Healthcare Communication, *The Coalition's Positions: FDA Reform*, (2001) available at www.cohealthcom.org/pages2/positions.html (last visited April 17, 2002).

from the FDA. Why would an ad industry coalition take up such an unlikely initiative? There are several possibilities.

It is possible the advertising industry would prefer to streamline its dealings with the federal government by placing all of their “regulators” in one agency – the FTC. It is also possible that the industry believes the FDA simply knows too much about the drugs that are advertised. By removing the regulation of “drug ads” from the “drug regulator,” it is possible that DTC ad restrictions would mirror more closely the less-restrictive regulations placed on other types of products. However, despite CoHealthcom’s position, the initiative will likely stall with their statement. No such proposal has been made, and any chance of success is practically inexistent.

The AAF, apparently resigned to the FDA’s regulatory authority over DTC ads, recently hosted a workshop at their annual meeting entitled “Direct-To-Consumer Advertising of Prescription Drugs.” The panel, which included advertising professionals, pharmaceutical representatives, and an academic, addressed the growth, benefits, regulation and ethics of DTC advertising. The discussion focused primarily on strategies for such advertising and whether the ads actually arm consumers with accurate and useful information about disease and the risks of certain drugs.

The AAF panel indicated that drug manufacturers are currently looking for ways to expand their campaigns to new “media outlets” – the Internet, sporting stadiums, etc. - and to find new “consumer connection points” for each drug’s target audience.¹⁸³ As Kim B. Rotzol, dean of the College of Communications at the University of Illinois-Champaign, pointed out, this initiative is necessary because the current American healthcare system doesn’t allow enough access to or time with a doctor to provide patients with everything they need to know.¹⁸⁴ Rotzol admits that DTC ads can at times seem intrusive, raising very personal issues in very public ways. However, he says this approach “may be the strongest ethical pillar that DTC ads have

¹⁸³ See AAF, *supra* note 177.

¹⁸⁴ *Id.*

to rely upon. . . . [They give] consumers the opportunity to think about whether they have an untreated illness” about which they should consult a doctor.¹⁸⁵

Rotzol cautioned that pharmaceutical companies and their ad agencies should remember the weaknesses of DTC ads and account for them in ad content; specifically, these ads often target vulnerable populations (the elderly), are just a one-sided communication, and assume a rational marketplace that isn’t always present.¹⁸⁶

Nick Cannistraro, president and general manager of Newspaper National Network, stated that by keeping in mind the point of DTC advertising – consumer empowerment – advertisers can ethically yet persuasively present truthful information in accordance with the FDA guidance. Total disclosure, he says, is a method that both captures and informs the audience while benefiting manufacturers as well.¹⁸⁷

In addition to advertng agencies, the media - newspapers, magazines, and broadcasters - have a substantial financial stake in continued FDA support for DTC ads. The Newspaper Association of American and the Magazine Publishers of America recently teamed up to submit an official comment to the proposed 2001 new guidance.¹⁸⁸ The letter posits that the continued use of DTC ads will “reward consumers’ efforts to learn more about prescription pharmaceuticals” and foster continued consumer involvement.¹⁸⁹

While the interest of all media in the promulgation of DTC ads would seemingly be aligned, it is interesting to note that most DTC ad money is spent on television ads, thereby suggesting a schism in interest between print and broadcast media. However, because one of the elements in the 1999 guidance’s “adequate provision”

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ Letter from Newspaper Association of America and the Magazine Publishers of America to FDA (July 23, 2001) (on file with the author).

¹⁸⁹ *Id.*

requirement is reference to a concurrent print ad, it is actually in their best interest for the print media to support the growth of broadcast DTC ads. Not only will print publications benefit from the DTC ads run in their own material, but they benefit from ads that air in the broadcast media as well.

One very strong argument that the media, advertisers, and pharmaceutical companies have on their side of the DTC advertising debate is the First Amendment's protection of commercial speech. This fundamental right, which has been extended to advertisements in numerous court opinions, makes it difficult for regulators to impose heavy restrictions on commercial speech. The ultimate authority in this area, *Central Hudson Gas & Electric Corp. v Public Service Commission*,¹⁹⁰ provides a four-prong test for determining the constitutionality of government restrictions on commercial materials. The court must consider whether (1) the speech is misleading or concerns unlawful activity; (2) the government has shown a substantial interest in restricting such speech; (3) the government has shown that the regulation directly advances the interest it asserts; and (4) the restriction is not more extensive than necessary to reach the governmental interest.¹⁹¹ In the case of prescription drugs and the FDA, the government has successfully argued in previous cases that its interest in protecting public health and safety and in limiting misleading claims satisfies the *Central Hudson* test. However, it should be reiterated that the absolute preemption of speech is not only disfavored by the courts, but it is strictly prohibited by the Act itself.¹⁹²

The courts have also addressed attempts by state legislatures to circumvent the FDA prescription drug ad regulations. In *Knoll v Sherman*,¹⁹³ a district court invalidated a state statute that prohibited the advertising of federally scheduled drugs even if the ad satisfied the FDA's established guidelines. The court applied the *Central Hudson* test to find that the statute did not materially advance the state's objective of preventing drug abuse.¹⁹⁴

¹⁹⁰447 U.S. 557 (1980) [hereinafter "Central Hudson"].

¹⁹¹*Id.* at 566.

¹⁹²*See infra* Part II: The Food, Drug, and Cosmetic Act, at 5.

¹⁹³57 F.Supp.2d 615 (N.D. Ill. 1999).

¹⁹⁴*Id.*

The protections that *Central Hudson* and *Knoll* offer to pharmaceutical manufacturers is difficult to refute – the protection of speech and the freedom to truthfully promote a product is vital in an open market society. However, it is interesting to note that *Central Hudson* and *Knoll* do *not* prevent the FDA from strictly regulating the speech content of package labeling for prescription drugs. Is there a reason why labels and DTC ads should be treated differently under a First Amendment test?

The answer lies in the degree and likelihood of harm that would result if the government did not closely monitor the content of each type of communication. If prescription drug labels do not fully disclose all of the information a patient needs to accurately treat their illness, great harm could be done to the patient. The government restrictions on this type of potentially-harmful speech clearly satisfy *Central Hudson's* “substantial interest” and “no more extensive than necessary” requirements. DTC advertisements, on the other hand, are less likely to cause such direct and serious harm simply because the ad’s content is something less than what the FDA would have chosen if it had the authority to script DTC ads. The physician’s role as a prescription drug gatekeeper serves as protection enough, making any pre-emptive regulations “more extensive than necessary” to realize the FDA’s protective goals.

Despite the First Amendment’s limitations on what the FDA can require of pharmaceutical advertisers, it still seems as though the very nature of prescription drugs should impose a greater duty on companies who market them to the general public. Prescription drugs are not just another product; rather, they have the power to both save and destroy lives. Advertisers must be aware of the potentially harmful effects their ad campaigns could have on the health of consumers. If the advertising and pharmaceutical industries take this charge seriously, and if the FDA fulfills its responsibility by continuing to enforce regulations that protect consumer health, DTC ads can be a powerful tool for informing patients and medical providers while also

serving their intended purpose: to sell prescription drugs.

V. THE EFFECT OF DTC ADVERTISING ON A REPRESENTATIVE DRUG: CLARITIN

In order to better understand the impact of DTC promotion on consumer behavior and the pharmaceutical market, it may be useful to consider the history of the most famous DTC advertising campaign to date: Schering-Plough's Claritin. Whether it was timing, innovative advertising, or just sheer luck, Schering-Plough saw industry-breaking records in the late 1990s with an ad campaign that began with the simplicity of blue skies.

Patented in 1981 and introduced in 1993, Schering-Plough marketed Claritin (loratadine) as the antihistamine for the future by promoting its ability to relieve allergy symptoms without the usual side effects (drowsiness). However, despite its reputation as a breakthrough drug, Claritin was not the first non-sedating antihistamine to be created. It was, however, the first of its kind to make it all the way through the FDA's approval process.¹⁹⁵

In 1995, the same year the FDA announced its intention to proceed with new guidelines on broadcast DTC advertising, Schering-Plough began running a series of "reminder ads" on national television. The ads mentioned only Claritin's name and advised consumers to "talk to their doctors" about the drug. For consumers, this form of advertisement was incredibly frustrating – they wondered: what is Claritin? What is it for? Should I go to the doctor and find out what this is? Should I try to get a prescription? This response to the Claritin reminder ads was an example of the "irrational marketplace," lending support to

¹⁹⁵Stephen S. Hall, *Prescription for Profit*, THE NY TIMES MAGAZINE, March 11, 2001, 40 – 45, 59, 91 – 92, 100. The antihistamines that preceded Claritin faced FDA opposition because of harmful side effects, and they were therefore never marketed to physicians.

the position that “more is more” when it comes to the disclosure of prescription drug information.

When the FDA released its 1997 draft guidance, Claritin was the first drug to run a full product-claim advertisement under the new regulations. The campaign, entitled “Claritin Blue Skies,” first aired in prime time on August 15, 1997, and Schering-Plough president Richard W. Zahn stated: “Under the old FDA guidelines, it was difficult for TV viewers to understand that Claritin is indicated for the treatment of seasonal allergies. . . . With new informative Claritin DTC advertising, consumers will have a clearer understanding of the benefits of Claritin.”¹⁹⁶

Unfortunately, the company’s much awaited launch was short lived. Schering-Plough chose not to submit their ads to the DDMAC for approval prior to their broadcast, and on August 19, 1997, the FDA issued the first in a series of “warning letters” regarding the Blue Skies TV commercials.¹⁹⁷ Schering-Plough’s advertising agency responded quickly to correct the numerous violations cited in the letters, violations which included a misleading major statement of risks.¹⁹⁸ The FDA responded with one follow up letter and another “informal” criticism before the campaign was free of violations.¹⁹⁹ Despite their tangles with the DDMAC, Claritin’s DTC ads had a definitive impact as sales began to soar. However, those sales came with a hefty price tag as Schering-Plough’s cost of sales increased dramatically.²⁰⁰

DTC opponents often claim that, as the cost of sales and advertising increased for Schering-Plough, so did the cost of Claritin. In 1994, prior to the release of the FDA 1997 draft guidance, the price of Claritin was \$2.35/pill. That price rose to \$2.83/pill by 1998 – a 20% increase.²⁰¹ In comparison, between 1993 and 1998, the price of the average prescription drug rose only 12% per year.²⁰² Today, the price of Claritin is lower

¹⁹⁶ *Schering Laboratories to Release New Claritin(R) TV Advertising Campaign*, PR NEWSWIRE, August 14, 1997.

¹⁹⁷ See Letter from FDA to Ronald J. Garutti, M.D., Director, Marketed Products Support, Worldwide Regulatory Affairs, Schering Corp. (August 19, 1997) available at www.fda.gov/cder/warn/aug97/5738.pdf (last visited April 17, 2002).

¹⁹⁸ See *id.*

¹⁹⁹ See Letter from FDA to Alexander R. Giaquinto, Ph.D., Senior Vice President, Worldwide Regulatory Affairs, Schering Corp. (September 8, 1997) available at www.fda.gov/cder/warn/sep97/5760.pdf (last visited April 17, 2002).

²⁰⁰ For a detailed look at the cost of sales and net sales for Schering-Plough and Claritin, see Appendix 3.

²⁰¹ *Hearing Before the House Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary* (May 21, 1998) (testimony of Mr. Bruce Downey, President and CEO of Barr Laboratories).

²⁰² Generic Pharmaceutical Association (December 1999) available at <http://www.gphaonline.org/about/> (last visited April

that in 1998, averaging \$2.66/pill, but so is the cost of sales for Schering-Plough.

DTC ad opponents also point to the fact that, as Claritin's popularity and price continued to grow, a considerable difference between Claritin prices in the US and Claritin prices in neighboring countries began to emerge. For example, a one month supply of Claritin in the US today costs an average \$80; in Canada and Mexico, where Claritin is sold OTC, the cost averages only \$10-15 per month.²⁰³ The difference, say opponents, is that Mexico and Canada do not allow DTC marketing of prescription drugs.

Pharmaceutical companies, including Schering-Plough, attribute all price increases and any cost differentials to a variety of political and economic factors (inflation, rising R&D and regulatory expenses, more healthcare price control by the governments of other countries). However, critics of DTC ads continue to correlate the growth of expensive DTC advertising with the increasing cost of the drug in the US and the lower cost in other countries.

Despite the company's obvious profits, it is possible that Claritin's clever marketing efforts worked *too* well for Schering-Plough, reaching beyond what the drug itself was capable of delivering. Steve Hall, a writer for *The New York Times Magazine*, reports that when Claritin did not work for him, he asked his doctor if other patients had experienced similar dissatisfaction. The doctor noted anecdotally that, in his experience, only 30-40% of patients (an estimate he characterized as "generous") found that Claritin actually worked to relieve their allergies.²⁰⁴ Yet despite reports of dissatisfaction among patients and doctors, Claritin remained one of the most prescribed prescription medications of the late 1990s. Hall's anonymous doctor's estimate is clearly an arguable one; even his own partner in practice disputes the figure by estimating that 50-55% of his patients were helped by the drug.²⁰⁵ It is likely that these anecdotal estimates of effectiveness are equally as low for other brand name allergy medications – medications simply do not work for everyone. However,

28, 2002).

²⁰³Hall, *supra* note 195, at 40.

²⁰⁴*Id.* at 40.

²⁰⁵*Id.*

the assessment made by Hall's physician common enough to generate a class action lawsuit that questions the efficacy of Claritin.

Prescription Access Litigation (PAL), a Boston-based non-profit organization, was established in 2001. Its mission is to develop and pursue class action litigation in the hope of raising public awareness of prescription drug "misinformation campaigns" (DTC ads), the ineffectiveness of such drugs over generic alternatives, and the effects of DTC promotion on the cost of medication.²⁰⁶ PAL sees favorable monetary judgments for such claims as a down payment in return for the millions of dollars PAL believes consumers and third party payers have "overpaid" for name brand prescription drugs.²⁰⁷

In August 2001, PAL filed a lawsuit in New Jersey Superior Court against Schering-Plough, alleging that Claritin advertising was deceptive under the New Jersey Consumer Fraud Act.²⁰⁸ PAL claims that Claritin is essentially ineffective, serving no better purpose than a sugar pill (a seemingly difficult claim to make based on Claritin's NDA approval from the FDA in 1993). The PAL lawsuit also alleges that the "false, deceptive and misleading advertising for Claritin has artificially inflated consumer demand. . . . In our view, that elevated demand, in turn, has permitted Schering to price-gouge purchasers of Claritin by sustaining the inappropriately elevated prices charged in the United States for the drug."²⁰⁹ Due to PAL's belief that misleading DTC ads present an imminent harm to public health, they are requesting a permanent injunction to "prevent future illegal advertising of Claritin."²¹⁰

The PAL lawsuit is pending, yet there is little chance their claims will succeed based on the available defenses Schering-Plough has in its corner (FDA NDA approval and compliance with DTC ad regulations). However, regardless of its success or failure in New Jersey, it seems probable that PAL will continue to pursue these

²⁰⁶Prescription Access Litigation, *About Us*, at www.prescriptionaccesslitigation.com/html/about.html (last visited April 17, 2002).

²⁰⁷Prescription Access Litigation, *Frequently Asked Questions: Claritin Lawsuit*, at www.prescriptionaccesslitigation.com/html/claritin_faqs.html (last visited April 17, 2002).

²⁰⁸*Id.*

²⁰⁹*Id.*

²¹⁰*Id.*

actions in states across the country to continue what it characterizes as a necessary “awareness campaign.” Despite the defenses available to pharmaceutical companies, it seems possible that even the smallest risk of tort liability for deceptive practices could encourage companies to *more* carefully screen DTC advertisements for compliance. However, if the primary goal of PAL’s lawsuits is to reduce the amount of money spent on DTC ads, they are likely to fail. So long as companies are in compliance with all FDA regulations on DTC ads, there is a total defense against such claims and little chance of a reduction in use.

Schering-Plough announced in early 2002 that it would submit a request for a change in Claritin’s status from prescription to Over-the-Counter, marking the end of its current patent period. In the company’s 2001 10-K filed with the SEC, the company disclosed to its shareholders the impact this change in status and the end of the patent is likely to have on Schering-Plough’s financial status:

Management believes that either the introduction of generic prescription or OTC loratadine or OTC Claritin in the U.S. market would likely have a rapid, sharp and material adverse effect on the Company’s results of operations beginning at the occurrence of such an event and extending for an indeterminate period of time thereafter.²¹¹

Waiting in the wings to take Claritin’s place at the top of the antihistamine race is Clarinex, the new Claritin “incarnation.” Schering-Plough hopes to switch loyal patients over to Clarinex before Claritin hits the OTC shelves, thereby maintaining consumers at the higher prescription-price level. Whether or not Clarinex will produce the same blockbuster results will depend on a host of factors, but one similarity has already been proven: Schering-Plough has pulled out all the stops for an intensive media campaign to help launch the product in the Winter/Spring of 2002.

VI. CONCLUSION

Is it possible, after reviewing the history, impact, and debate over DTC ads, to draw a conclusion as to the value and efficacy of such advertising? The benefits of DTC promotion are many. The ads are an efficient method of reaching a wide audience in an effort to spread important information about healthcare options. DTC ads arguably encourage consumers to visit their doctors, discuss possible ailments and treatments, and open a dialogue in a medical environment that has not always welcomed patient initiative. DTC ads give the consumer a sense of empowerment, enabling them to take control of their own medical destiny, and they put more information into the marketplace for prescription drugs that will later be offered OTC, after which time there is very little disclosure required. It is also important to remember that commercial speech and advertising is a protected First Amendment right, and any regulation of such must be carefully tailored to achieve a substantial and distinct public interest. To date, the FDA has tailored its enforcement approach to account for this important speech protection while also maintaining a vigilant watch over the content of the ads.

On the flip side, the negatives of DTC advertising are easy to note. DTC ads can at times be misleading before the FDA can correct the problem, giving viewers a false perception of the drug's benefits and de-emphasizing its risks. The ads have caused tension in the doctor/patient relationship when patients demand drugs that, in the opinion of the physician, they do not need. Unfortunately, some doctors cave in to these patient pressures, resulting in a potentially dangerous health situation for the patient. There is a risk that consumers will forget that DTC advertising is just that – advertising – and that advertisements are fundamentally intended to sell a product, not to empower the consumer. Finally, there is perhaps the most controversial negative of DTC promotion: the rising cost of prescription drugs and the correlative increase in pharmaceutical company expenditures for DTC ads.

Under the current FDA guidance, DTC advertising has been a boom for the pharmaceutical industry, advertising agencies, and the media. However, the long-term effects of DTC ads have yet to be seen, including what happens to a company's financials when a "blockbuster" drug, such as Claritin, loses its exclusive marketing under a valid patent. If Wall Street doesn't see something profitable in the pipes, the loss of a product that was made all the more profitable by DTC ads could spell disaster for a pharmaceutical company. Just ask Schering-Plough. However, it should also be noted that, regardless of whether a drug has been promoted by DTC advertising, the loss of a patent will always cause financial hardship for a pharmaceutical company. This was most recently illustrated by the dramatic declines experienced by Eli Lilly with the expiration of the Prozac patent in August 2001.

Are consumers more informed of their healthcare options because of DTC ads? Probably. Are they more aware of the signs and symptoms of particular diseases? Perhaps. Are direct to consumer advertisements the most *impartial* method of disseminating vital health information to consumers? Probably not. However, the ads are effective in reaching a wide audience, consumers respond positively to their inclusion in the mainstream media, and physicians seem to be adapting to their widespread use. DTC advertising even seems to be winning over some of its most strident critics as Americans become more accustomed to the idea of advertising prescription drugs on television.²¹²

So long as DTC ads continue to be a profitable exercise, pharmaceutical companies are likely to continue using them regardless of whether "causation" can be established. If the measured positive impact of the ads slows, so too will their presence in our daily lives. Why? Because despite the serious impact prescription drugs have on people's lives, the manufacturers who produce these drugs are first and foremost *businesses*

²¹²See Raja Mishra, *Ex-FDA Chief Recants on Drug Advertising*, THE BOSTON GLOBE, April 17, 2002, at A2. Dr. David A. Kessler, a staunch DTC opponent while head of the FDA in the mid 1990s, announced he had changed his position on this issue while speaking at the DTC National Convention. "I was wrong. . . . On the whole, I think there is a lot of educational benefit." *Id.*

that are required by law to place the interest of shareholders (and therefore profit) above other considerations.

Before DTC promotion exploded onto the scene in 1997, many consumers found it difficult to get basic information from a source other than their doctors. With the ensuing changes to the modern healthcare system, consumers take relief in knowing that, while at times annoying, DTC ads are a constant source of information on health and available treatment. However, consumers MUST be reminded that DTC ads are fundamentally a form of promotion, and while they benefit greatly from their use, consumers must balance DTC ad information with alternative, traditional, and perhaps more complete sources of information.

The current approach taken by the FDA toward DTC advertising is the most balanced, fair, sensible, yet protective approach possible for an efficient continuation of regulatory monitoring. Some consumer groups have called for pre-market approval of DTC advertisements, a suggestion made impossible by current First Amendment doctrine. Some pharmaceutical organizations have called for fewer restrictions and the elimination of the adequate provision and major statement requirements, suggestions which should be dismissed out of hand. If DTC advertisements are to be trusted by the medical community and consumers alike, they must present as much information about the risks of a particular drug as they do about the benefits. The true value of DTC advertising lies in its ability to educate an otherwise ignorant public as to the possibilities of drug therapy for diseases they may not even know exist. If this is to be realized, the FDA must continue to demand "fair balance," DDMAC must continue to ardently enforce the guidance requirements, and physicians must be willing to intervene when a patient is on the wrong track as to which prescription medication might be right for him. If each of the interested and affected parties keeps in mind the true purpose and public value of DTC ads, consumers should continue to benefit from their promulgation well into the future.

APPENDIX 1

Guidance for Industry

Consumer-Directed Broadcast Advertisements

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Center for Biologics Evaluation and Research (CBER)

Center for Veterinary Medicine (CVM)

August 1999

DDMAC

GUIDANCE FOR INDUSTRY¹

Consumer-Directed Broadcast Advertisements

I. INTRODUCTION

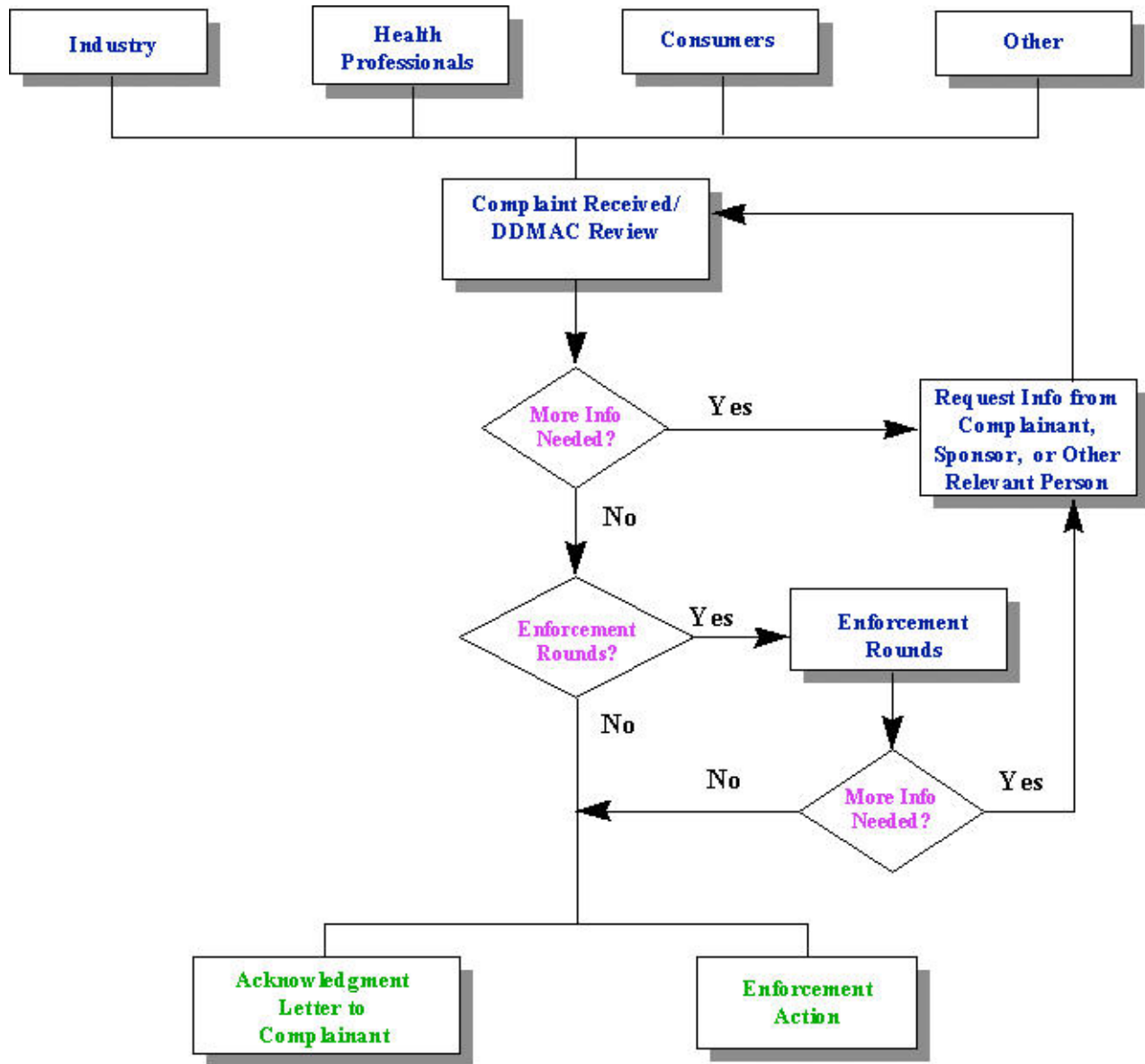
This guidance is intended to assist sponsors who are interested in advertising their prescription human and animal drugs, including biological products for humans, directly to consumers through broadcast media, such as television, radio, or telephone communications systems.²

II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, the Act requires advertisements to contain information in brief summary relating to side effects, contraindications, and effectiveness (21 U.S.C. 352(n)). The resulting information disclosure is commonly called the *brief summary*. The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Print advertisements must include the brief summary, which generally contains each of the risk concepts from the product's approved package labeling. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the *major statement*. This guidance does not address the major statement requirement. Sponsors of broadcast advertisements are also required to present a brief summary or, alternatively, may make adequate provision... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation (21 CFR 202.1(e)(1)). This is referred to as the *adequate provision* requirement. The regulations thus specify that the major statement, together with adequate provision for dissemination of the product's approved labeling, can provide the information disclosure required for broadcast advertisements. The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for *adequate provision* in connection with consumer-directed broadcast advertisements for prescription drug and biological products. The approach⁶ presumes that such advertisements:

- Are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.
- Present a fair balance between information about effectiveness and information about risk.
- Include a thorough *major statement* conveying all of the product's most important risk information in consumer friendly language.

APPENDIX 2
FDA DDMAC Promotional Material Review Process
(Complaints)



APPENDIX 3

The following chart shows Schering-Plough's net sales and cost of sales (advertising expenses, including DTC and other promotional activities) from 1996 through 2001. The financial information contained in this chart was taken from Schering-Plough's annual and periodic filings with the Securities Exchange Commission and are available via search engine at www.sec.gov.

<i>Information taken from Schering-Plough SEC Filings</i>	Schering-Plough Cost of Sales	Schering-Plough Net Sales	Cost of Sales attributed to Claritin	Net Sales attributed to Claritin
1996	\$1,078,000,000	\$5,656,000,000	N/A	\$1,200,000,000
1997	1,308,000,000	6,778,000,000	\$ 90,000,000	1,700,000,000
1998	1,601,000,000	8,077,000,000	182,900,000	2,300,000,000
1999	1,800,000,000	9,176,000,000	137,100,000	2,700,000,000
2000	1,902,000,000	9,815,000,000	99,700,000	3,000,000,000
2001	2,078,000,000	9,802,000,000	N/A	3,200,000,000