

“Side Effects May Include Headache and Eye Strain” Talk to Your Doctor about Prescription Drug Advertising: A Suggestion for Revision of Prescription Drug Advertising Regulation

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Because of the protection of the learned intermediary doctrine and in light of reduced disclosure requirements for television and radio advertisements, advertisers of prescription drugs in print publications should not be required to print a full page of advisories and chemical information referred to as the “brief summary.” 21 C.F.R § 202.1 should be revised to lessen this burden.

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Within the last twenty years and increasingly in more recent years, patients have become interested and involved in their own medical treatment.² With the advent of WebMD.com and because of reforms in medical insurance plans that cause patients to change doctors more often, people now rely on a combination of several of sources of information to learn about common illnesses and particular symptoms, including information from drug companies, information from doctors, and information from the patient’s personal knowledge.

Whereas people in the past relied exclusively on the family doctor’s orders to remedy medical problems, people now also do their own research and take an active role in determining the course of action for their medical care. To be sure, this can be said for almost any decision a modern person makes. There is a popular embracing of the use of the Internet and popular media to find information on almost every aspect of life, from which stocks a person should buy, to whom they should vote for, to which schools they should send their children; a modern person is increasingly involved in attaining and discriminating

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² Marshall H. Chin, M.D., M.P.H., *The Patient’s Role in Choice of Medications*, 5 Yale J. Health Policy, L. & Ethics 771, 772 (2005).

about the information he or she trusts. While this patient involvement has been criticized for removing authority from the doctor, “the ultimate decision and whether or not the patient adheres to the treatment over time are influenced by the interaction between the patient and physician.”³

Because of this increase in the taking-in and filtering of information, the modern person is more critical of advertisements in general. The Food and Drug Administration (FDA) began to recognize this fact (and the cost of advertising) in reducing the disclaimer burden on prescription advertising in television and radio advertisements but as of yet has not similarly reduced the burden on print advertisements. While broadcast advertisements frequently end with a few seconds of warnings, print advertisements are still followed by two or three times as much technical information and warnings as there is advertising space.

The FDA and the courts have recognized the essential step of visiting a doctor to obtain prescription drugs in establishing the Learned Intermediary Doctrine.

In this article, I will argue that, because of the necessity of the learned intermediary – the doctor – in obtaining prescription drugs and noting the unequal legal burden on advertisers, the primary federal regulation for prescription drug advertisements, 21 C.F.R. § 202.1, should be revised to eliminate the requirement for a “brief summary” in print advertisements in favor of allowing advertisers instead to include a “major statement” of the relevant side effects as broadcast advertisers do.

The Current Regulation of Prescription Drug Advertisements

The Bases and Scope of Regulation

There are two bases for regulating advertisements, one unique to medicines and other things ingested, to ensure safe products, and the other common to all advertisements, to ensure fair competition. In 1962, Congress gave the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) concurrent jurisdiction over the regulation of prescription drug advertising.⁴ The FDA stepped forward to write preliminary regulations in 1975,⁵ fulfilling its mission to “promote the public health by... taking appropriate action on the marketing of regulated products in a timely manner.”⁶ Although both FDA and FTC regulations apply to advertising of prescription drugs,⁷ they focus on different aspects of the same advertisements to ensure truthfulness. The FDA ensures truth in medical claims and ingredients listed “to ensure that drug products purchased by consumers are safe and effective”⁸ and the FTC is concerned with the advertisement with regard to consumer protection in claims made.⁹ This is in keeping with the FDA’s mission to protect the health and safety of Americans by ensuring unadulterated foods and fair labeling¹⁰ and the FTC’s mission to ensure consumer protection and prevent unfair competition.¹¹ The agencies have the same roles in regulating the labeling and advertising of over-the-counter medications.¹²

³ Id. at 774.

⁴ 21 U.S.C.A. § 352(n) (2007).

⁵ Timothy S. Hall, *The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet*, 7 DePaul J. Health Care L. 1, 8 (2003).

⁶ 21 U.S.C. § 393(b)(1) (1998).

⁷ 21 U.S.C.A. § 352(n) (2007).

⁸ U.S. Food and Drug Administration, *Prescription Drug Marketing Act (PDMA)*, <http://www.fda.gov/cder/regulatory/PDMA/default.htm> (Accessed May 8, 2008).

⁹ 15 U.S.C. § 45(a)(2) (2000) as amended.

¹⁰ U.S. Food and Drug Administration, *What FDA Regulates*, <http://www.fda.gov/comments/regs.html> (Accessed April 25, 2008).

¹¹ Fed. Trade Commn., *About the Federal Trade Commission*, <http://ftc.gov/ftc/about.shtm> (Accessed April 25, 2008).

¹² Hall, 7 DePaul J. Health Care L. at 7.

The FDA regulates for truthfulness the advertising of all medications, whether directed at customers or sent to medical professionals.¹³ “Advertising” in this case, defined by §202.1, includes “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems.”¹⁴ In addition to its work on advertising, the FDA regulates all drug labeling, which includes any written matter describing or marketing a drug. Any violation of the many standards of § 202.1 causes the drug to be considered “misbranded.”¹⁵ The FDA requires all marketing materials meant for medical professionals to be FDA-approved before dissemination. Disseminating these materials without approval constitutes misbranding, so manufacturers get this approval or correct advertisements as required to avoid regulatory action by the FDA.¹⁶ Materials meant for potential customers, however, are not required to be approved before they run. The FDA does request the opportunity to approve them. In practice, this request is a requirement. “FDA’s substantial enforcement authority functions to give the agency great *in terrorem* powers to ensure that even its ‘voluntary’ policies are followed.”¹⁷ There is little to no area for state regulation of drug advertisements.¹⁸

There are three major types of direct-to-consumer advertisements: product-claim, reminder, and help-seeking.¹⁹

Product-claim advertisements are the type with which consumers are most acquainted. These are ads that give the name of a drug and explain what it is for or which symptoms it might alleviate. On radio and TV, these are generally 30-second advertisements. These are the only ads that are regulated by the FDA, and the only ads to make claims.

Reminder ads are shorter than product-claim advertisements. These sound more like, “My allergy symptoms leave me in a fog. Talk to your doctor about how you can live Claritin clear.” There are no claims about the drug or what it does. Its purpose is to remind the potential customer of the full advertisement he or she saw before. They generally have the same look or theme as a product-claim ad.

Product-claim ads that list benefits of a drug must also list the contraindications, the side effects or risks, of the drug. Reminder ads do neither.

Help-seeking ads are less familiar to viewers. These advertisements look more like public service announcements in that their purpose is to bring light to a medical condition, generally by listing symptoms. They do not mention or hint at any prescription drug but encourage a viewer who recognizes symptoms to speak with a doctor about possible treatments. Because they contain no claims or references to prescriptions, they are not required to list any warnings. The FDA does not consider this type of ad to even be a prescription drug ad and so does not regulate them.²⁰

¹³ *Id.* at 7.

¹⁴ 21 C.F.R. § 202.1(l)(1) (2008).

¹⁵ William A. Dreier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 Rutgers L. Rev. 615, 629 (2006).

¹⁶ *Id.* at 636-37.

¹⁷ George W. Evans and Arnold I. Friede, *The Food and Drug Administration’s Regulation of Prescription Drug Manufacturer Speech*, 58 Food & Drug L.J. 365, 424 (2003).

¹⁸ Dreier, 58 Rutgers L. Rev. at 631.

¹⁹ Woodcock, Janet M.D., *Statement before Senate Special Committee on Aging* (Washington D.C., July 22, 2003) (available at 2003 WL 21701807) referencing FDA’s *Guidance for the Industry: “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* available at <http://www.fda.gov/cder/guidance/6019dft.pdf> (Accessed May 8, 2008). (Dr. Janet Woodcock was the Director for Center for Drug Evaluation and Research at the Federal Drug Administration at the time of this statement.) cited in Winkler, Student Author, *You Wanted the Best, You Got the Best! The Current Direct-to-Consumer Prescription Drug Advertisement Dilemma*, 26 Biotechnology L. Rep. 331 (2007).

²⁰ Josef Winkler, Student Author, *You Wanted the Best, You Got the Best! The Current Direct-to-Consumer Prescription Drug Advertisement Dilemma*, 26 Biotechnology L. Rep. 331, 336 (2007).

Requirements of 21 C.F.R § 202.1

The FDA's regulations of product-claim and reminder drug advertisements are detailed in 21 C.F.R. § 202.1. The statute requires that for "all advertisements for any prescription drug" an advertiser "shall present a true statement in brief summary relating to side effects, contraindications, and effectiveness."²¹ This "brief summary" – a misnomer – is the one or two pages of detailed medical information that magazine readers are so used to seeing after every prescription drug advertisement.

For print advertisements, this means including information about "each specific side effect and contraindication contained in required, approved, or permitted labeling"²² "limited to those pertinent to those indications for which the drug is recommended."²³ This information is the same as is found in the Physicians' Desk Reference, a universally-read comprehensive reference book for doctors of medications on the market.²⁴ If advertisers write the "brief summary" in consumer-friendly language, the disclaimer must also refer the reader to where the full physician-directed text may be obtained, usually a local pharmacy, library, or physician's office.²⁵

Advertisements broadcast through radio or television are permitted to have less information because of the difficulty of presenting the information and expense of broadcast presentation. These ads are required to include only "information relating to the major side effects and contraindications of the advertised drugs"²⁶ generally called the "major statement."²⁷ This information must be presented in the same format as the rest of the advertisement unless "adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."²⁸ Through the "adequate provision" requirement, advertisers must provide a means by which "most of a potentially diverse audience [would] have reasonably convenient access to the advertised product's approved labeling" (i.e. the brief summary).²⁹ Broadcast advertisers generally meet this requirement by providing the brief summary information through a toll-free phone number, a website, copies of a print advertisement in publicly accessible places, and a line in the advertisement reminding consumers that they can get the information from a doctor,³⁰ (Thus the common phrase- "Talk to your doctor about prescription [drug name].") and in doing so avoiding the requirement that the brief summary be included in broadcast. There is no equivalent set of options for print advertising.

Reduced Burden for Broadcast Advertising Since 1997

Where a broadcast advertisement is required only to air a major statement of the side effects and contraindications of a drug, the print version of the same ad must be accompanied by the entire brief summary.

All advertisements, including those broadcast, were originally required to carry the full brief summary until a 1997 FDA draft Guidance allowed ads to be broadcast with a major statement of the risk information instead.³¹ Airing the full summary, and prescription drug advertisers subsequent sole use of reminder ads to avoid airing the full summary, had been confusing to

²¹ 21 C.F.R. § 202.1(e)(1) (2008).

²² 21 C.F.R. § 202.1(e)(3)(iii) (2008).

²³ 21 C.F.R. § 202.1(e)(3)(iv) (2008).

²⁴ Dreier, 58 Rutgers L. Rev. at 630.

²⁵ Id. at 630.

²⁶ 21 C.F.R. § 202.1(e)(1) (2008).

²⁷ 21 C.F.R. § 352 (n) (2007).

²⁸ 21 C.F.R. § 202.1(e)(1) (2008).

²⁹ Corey Schaecher, Student Author, "Ask Your Doctor if this Product is Right for You", 26 St. Louis U. Pub. L. Rev. 421, 447 (2007).

³⁰ Id. at 447.

³¹ *Guidance for Industry: Consumer-Directed Broadcast Requirements*, Guidance for the Industry, accessible at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf>. (Accessed June 28, 2009.) (FDA Aug. 1999).

consumers.³² Under the FDA's final 1999 Guidance, "drug manufacturers are permitted to air product claim advertisements, so long as they also provide a statement in the advertisement itself of the major risks associated with the use of the drug, and the advertisement exhibits "fair balance" between the product claims and the risk disclosures."³³

Advertisements in print media, however, are required to include much more information to meet the requirement of "fair balance." The FDA recognizes this imbalance, but gives no reason for it.³⁴ As the equivalent regulation for broadcast ads was changed for being confusing to consumers and over the last ten years and the lessened burden on broadcast ads has not created problems so as to necessitate a reversion to the heightened disclaimer requirement still in place for print ads, there is no reason why the FDA should not similarly lessen the burden on print ads.

Effects of Current System of Regulation

Unjustified Financial Burden on Print Advertisers

Full-page prescription drug advertisements in popular magazines are commonly followed by one and sometimes two full pages of technical information required by federal regulation. These additional pages "d[o] get discounted" in some publications³⁵ at a rate that "varies depending on the advertiser and how many total pages they run with the magazine."³⁶ As this information is not commonly read and because the information is also found in the Physician's Desk Reference, there is no reason why this information needs to be included in print advertising. Since the major statement has been held to be adequate for broadcast advertisements, this requirement should govern print advertisements as well.

While statistics about the amount of money spent on printing brief summaries is difficult to come by,³⁷ there is substantial information available about the expenditures on direct-to-consumer advertising and the percentage of people who read them.

The U.S. Government Accountability Office found that \$4,200,000,000 (\$4.2 billion) was spent on direct-to-consumer prescription drug advertising in 2005 alone and that the amount of money spent on this advertising increased an average of 19.7% each year between 1997 and 2005. There is no update to this study as of publishing, but using this data, it can be extrapolated that approximately \$5 billion was spent in 2006, \$6 billion in 2007, \$7.2 billion in 2008, and \$8.6 billion will be spent in the calendar year 2009 on direct-to-consumer advertising for prescription drugs.³⁸ Because of the reluctance of the sellers of advertising to discuss the discount given to print pages of brief summary, there is no way to know what portion of this is spent on brief summaries.³⁹

The American Society of Health-System Pharmacists (ASHP) cites a 2002 FDA survey showing "41 percent of patients did not read any of the brief summary for a medication advertised in a print publication and about 32 percent of patients

³² Winkler, 26 Biotechnology L. Rep. at 336.

³³ Hall, 7 DePaul J. Health Care L. at 6.

³⁴ FDA, Keeping Watch Over Direct-to-Consumer Ads (2008), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm107180.pdf>.

("Drug companies are generally required to include all of a drug's risk information in a product claim ad. In print ads, this is usually done in a section called the 'Brief Summary.' Despite its title, this summary would take many minutes to read or scroll down a TV screen. This is where the long list of side effects in the TV ads comes into play.")

³⁵ At *People*, subsequent pages are discounted. At *Time*, they are not. Email correspondence with Andrew Meyerson and an advertising representative at *Time* who requested not to be named in this paper.

³⁶ Email from Andrew Meyerson, E. Advert. Dir. for People Mag. to Shannon Grace Stevens, 2L U. of Balt. Sch. of L., *Prescription Drug Advertising* (May 8, 2008) copy on file with Shannon Grace Stevens.

³⁷ Noting author's unanswered and vaguely answered queries to the advertising departments of *People* and *Time*.

³⁸ A U.S. Government Accountability Office study in 2005 found \$4.2B was spent on direct-to-consumer advertising in 2005 alone with a 19.6% average annual increase between 1997 and 2005. U.S. GOV'T ACCOUNTABILITY OFFICE, *PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING* (2006), available at <http://www.gao.gov/new.items/d0754.pdf>.

³⁹ Noting author's unanswered and vaguely answered queries to the advertising departments of *People* and *Time*.

read ‘a little’ of the brief summary.”⁴⁰ The ASHP website also quotes the former deputy director of the FDA’s Office of Medical Policy, Rachel Behrman, (current Director of Critical Path Programs at FDA) as she said,

It’s also worth noting that in a broadcast ad, it’s much easier to follow the less-is-more philosophy [adopted by the FDA]. [The ad is] very short, and in general the ads do a better job, if you will, of emphasizing just the key important points in a way that’s very understandable and a way that the information can be easily retained.⁴¹

Behrman and FDA Commissioner Mark McClellan “felt there was a significantly bigger problem [of false and misleading ads] in print” than in broadcast ads with a reduced disclaimer.⁴² So the question remains, how does printing an ad with a brief summary make a print advertisement more confusing to consumers than a broadcast ad without it? If a broadcast ad with a reduced disclaimer burden is more effective in emphasizing “just the key important points,”⁴³ it follows that a print ad with the same opportunity would do the same.

Proponents of the brief summary requirement for print ads generally cite consumer protection and an idea that brief summaries are printed to inform doctor-readers of magazines as opposed to average readers.⁴⁴ Both of these arguments are often refuted by those in favor of regulatory revision with facts that “consumers are not trained to understand” the brief summary, nor are they “able to obtain the products being promoted without their doctor’s intervention.”⁴⁵

The brief summary requirement is in sharp contrast to regulations for advertisements for other potentially-misused products, such as alcohol and tobacco. In sharper contrast is the complete non-regulation of “herbal remedies” and “vitamins.” These seeming holdovers from patent medicine have the ability to be just as unsafe as prescription drugs, alcohol, tobacco, and other products and yet are not restricted in advertising at all. Alcohol and tobacco advertisements are required only to use the “Surgeon General’s” warning in advertisements, a far less burdensome requirement than the pages of brief summary.⁴⁶

Litigation Risks for Print Advertisers

Advertisers have been willing to go along with increased advertising requirements because following the FDA’s advertising guidelines creates a rebuttable presumption of adequate warning.⁴⁷ Under the common law of products liability, a manufacturer of goods has a duty to produce a safe product and to adequately warn consumers of its associated risks.⁴⁸ This duty to warn has two intended functions: to inform consumers on proper usage in hopes of reducing injuries from misuse and to allow a customer to make an informed decision about whether to use the product at all knowing the risks.⁴⁹ The common law duty to warn extends to a product’s manufacturer, seller, distributor, dealer, wholesaler, and supplier, to all of the players in the chain of distribution to the final consumer.⁵⁰ The duty, as specified by the Second Restatement of Torts, requires manufacturers to warn consumers if the manufacturer knows that the product is dangerous, that the danger is not

⁴⁰ DONNA YOUNG, FDA ISSUES NEW GUIDANCE ON DRUG ADS, <http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=1488> (last visited June 28, 2009).

⁴¹ Id.

⁴² Id.

⁴³ Id.

⁴⁴ Timothy McIntire M.D., Student Author, *Legal and Quality of Patient Care Issues Arising from Direct-to-Consumer Pharmaceutical Sales*, 33 U. Mem. L. Rev. 105, 112 (2002).

⁴⁵ Evans and Friede, 58 Food & Drug L.J. at 423. Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 Wake Forest L. Rev. 97, 137 (2002).

⁴⁶ 15 U.S.C.A § 1333 (b) (2).

⁴⁷ *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. 1999).

⁴⁸ Schaecher, 26 St. Louis U. Pub. L. Rev. at 422.

⁴⁹ Id. at 423.

⁵⁰ Id. at 423.

obvious or readily discoverable by the user, and that the danger may accompany a normal usage of the product.⁵¹ Failure to warn leaves the manufacturer open to liability for damages under strict liability.⁵²

There is confusion in the courts and in learned discourse about whether the warnings required by the common law are to be given to doctors or to patients.⁵³ An official answer to this question would clear up many misunderstandings about what warnings are required in labeling and advertising and why they are required. If warnings are meant for prescribers of medications and not for the users, it may be that no warning should be required for prescription drug advertisements at all.

Drug manufacturers have the duty to warn consumers directly with regard to over-the-counter medications, even if a doctor recommends their use.⁵⁴

The key is the Learned Intermediary.

Reasons for Changing the Current System

The Learned Intermediary Doctrine

Unlike a consumer who decides to buy and take over-the-counter medications, a medical doctor prescribes prescription drugs in a specific dosage and form as a treatment for symptoms a patient reports. The doctor's necessary involvement in the process of obtaining and using taking prescription medications led to the development of the Learned Intermediary Doctrine. "Prescription drugs and medical devices are federally regulated products that are available to patients only through a learned intermediary. This will always distinguish prescription drugs and devices from other consumer products."⁵⁵

This doctrine relieves drug manufacturers of the duty to warn consumers directly when adequate warnings are provided to prescribing doctors. The doctor, who is educated in medicine and aware of medical interactions and effects with regard to the particular patient-consumer, has the duty to ensure that the prescription he or she writes will be safe for the patient-consumer and to warn that patient-consumer of the potential side effects or contraindications of which that patient should be aware.⁵⁶ Forty-eight states and the District of Columbia and Puerto Rico have recognized the Learned Intermediary Doctrine as an exception to the manufacturer's general duty to warn.⁵⁷ The Learned Intermediary Doctrine reflects the reality that doctors, not patients, make the ultimate determination of which drugs are used. Doctors weigh the product's relative risks and benefits and, hopefully after conversation of treatment options with their patients, make the decision whether to write a prescription.⁵⁸

⁵¹ Restatement (Second) of Torts § 388 (1965), cited by Schaecher, 26 St. Louis U. Pub. L. Rev. at 423 (2007). § 388 states:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

⁵² Schaecher, 26 St. Louis U. Pub. L. Rev. at 423.

⁵³ See Garbutt and Hofmann, 58 Food & Drug L.J. 269 (2003); Dreier, 58 Rutgers L. Rev. at 615 (2006). Compare *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. 1999) (holding that drug manufacturer had a duty to warn consumer, not doctors, directly of side effects of contraceptive capsules that were surgically implanted under the skin and that the Learned Intermediary Doctrine does not apply to DTC marketing of prescription drugs) with *In re Meridia Products Liability Litigation*, 328 F.Supp.2d 791 (N.D. Ohio July 7, 2004) (declining to follow *Perez*, holding that the Learned Intermediary Doctrine shields drug manufacturers from liability when prescribing doctor is adequately warned) as shown in *In re Norplant Contraceptive Products Liability Litigation*, 215 F.Supp.2d 795 (E.D. Tex. Aug 14, 2002) (recognizing the disagreement in the courts, holding that manufacturers were not liable for adverse reactions included in manufacturer's physician labeling).

⁵⁴ Garbutt and Hofmann, 58 Food & Drug L.J. at 280.

⁵⁵ Dabney J. Carr IV and Bryony H. Bowers, *Recent Developments in Learned Intermediary Doctrine*, 31-WTR Brief 20, 24 (2002). (*The Brief* is a trade publication for the Section of Tort & Insurance Practice of the American Bar Association.)

⁵⁶ Schaecher, 26 St. Louis U. Pub. L. Rev. at 427; Carr and Bowers, 31-WTR Brief at 20; Hall, 7 DePaul J. Health Care L. at 25.

⁵⁷ Schaecher, 26 St. Louis U. Pub. L. Rev. at 434.

⁵⁸ Carr and Bowers, 31-WTR Brief at 20.

Courts have decided that the Learned Intermediary Doctrine applies even in an environment of direct-to-consumer prescription drug advertising.⁵⁹ “Dissemination through the media concerning the drugs does not increase the patient's ability to acquire the drugs because a prescription is still required.”⁶⁰

Writers opposing this position in learned discourse argue that direct-to-consumer advertising causes patients to force doctors to write desired prescriptions based on information patients gain from advertising at the risk of losing that patient to medical forum shopping. Physicians, however, are under no obligation to write prescriptions “when that drug, in the physician's considered professional judgment, is not clinically indicated at that time for that patient.”⁶¹ Doctors are at an “enormous educational advantage over the average consumer”⁶² and so have an obligation to use that expertise to the patient's actual advantage, even if pressured by patients as the opponents say. Doctors should take into account that patients know their own symptoms best but do not necessarily understand the chemical implications of medication. “As a central component of the ideal informed, shared decision making process, the physician is obliged to assist patients in evaluating health-related information obtained through direct advertising.”⁶³ A 2007 article in the *American Journal of Medicine* affirmed this point, concluding, “It is important to understand that patient questions and inquiries do not necessarily represent expectations for a particular drug, but rather are opportunities to strengthen the provider-patient bond. This bond remains the foundation of optimal medical care.”⁶⁴

Advertisers and drug manufacturers rely on the doctor's informed decision-making to ensure that the drugs that they put to market are used safely. Conversely, doctors would be lost without many of the new drugs that have been developed and manufactured by these companies.⁶⁵ Drug manufacturers use the scope of protection of the Learned Intermediary Doctrine when deciding whether to introduce drugs to the market in over-the-counter strengths and sometimes choose not to if the doctor's expertise is necessary in ensuring the safe use of these drugs.⁶⁶

The information required to be included in a brief summary is essentially the same as that information provided to doctors in the Physicians' Desk Reference. This technical information is essentially illegible to the average consumer.⁶⁷ Advocates of the brief summary requirement contend that it is in the best interest of consumers to have this information to make informed decisions. However, “while mandating that every promotional communication for a drug essentially replicate the operative labeling might conceivably check harmful prescribing practices, all of the relevant information already is available to prescribers – and there is some indication that doctors already consider the operative labeling, not promotional pieces, to be their standard reference tool.”⁶⁸ Because of doctors' involvement in prescribing prescription medications, the brief summary is not necessary or useful as attached to consumer advertisements. This principle should apply equally to advertisements in broadcast media as to those in print.⁶⁹ Because broadcast advertisements are considered fairly balanced

⁵⁹ See *Martin by Martin v. Ortho Pharmaceutical Corp.*, 661 N.E.2d 352 (Ill. 1996) (holding that drug manufacturer had no duty to warn consumers directly of contraceptive's dangerous side effects under the Learned Intermediary Doctrine), *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254 (Ia. 2002) (upholding lower court's finding of adequate warning where doctor was warned of potential side effects and patient did not promptly return to doctor's office for required testing).

⁶⁰ Schaecher, 26 St. Louis U. Pub. L. Rev. at 444.

⁶¹ Marshall B. Kapp, J.D., M.P.H., FCLM, *Drug Companies, Dollars, and the Shaping of American Medical Practice*, 29 S. Ill. U. L.J. 237, 245 (2005).

⁶² Hall, 7 DePaul J. Health Care L. at 25.

⁶³ Kapp, 29 S. Ill. U. L.J. at 246.

⁶⁴ Ziad F. Gellad & Kenneth W. Lyles, *Direct-to-Consumer Advertising of Pharmaceuticals*, 120 Am. J. Med. 465 (2007).

⁶⁵ Ozlem A. Bordes, J.D., LL.M., *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising*, 81 U. Det. Mercy L. Rev. 267, 284 (2004).

⁶⁶ Garbutt and Hofmann, 58 Food & Drug L.J. at 281.

⁶⁷ Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 Wake Forest L. Rev. 97, 137 (2002).

⁶⁸ Evans and Friede, 58 Food & Drug L.J. at 420.

⁶⁹ Carr and Bowers, 31-WTR Brief at 24.

with an appropriate and fair major statement and adequate provision, §202.1 should be revised to make this the standard for print advertisements as well.

Benefits of Direct-to-Consumer Drug Advertising

A lot of good comes from direct-to-consumer (DTC) advertising: undiagnosed conditions come to light, medical innovations are increasingly used, patients are more informed, and patients and doctors are able to make decisions together.

Writers in opposition to prescription drug advertising cite increased spending on prescription drugs since 1997 as a problem caused by the advertising of new drugs. They blame the ads for causing people to take unnecessary drugs at the benefit of prescription drug manufacturers.⁷⁰ What these writers fail to recognize, however, is that the amount spent on prescription drugs in countries that do not allow DTC advertising has also increased in that time period.⁷¹ It is more likely that this increase is caused by a growing number of patients diagnosed with pharmacologically-treatable conditions than by an increase in people taking unnecessary medications.⁷²

Through prescription drug advertisements, patients discover that symptoms they have are tied to a treatable condition and that they should talk to a doctor about what they are experiencing. This recognition and treatment of symptoms is the aim of prescription drug advertising and is beneficial not only to drug manufacturers, but also to patients and doctors who may not have discussed the symptoms otherwise. These discussions have been especially seen in traditionally-undiagnosed conditions such as erectile dysfunction and clinical depression. Seeing an advertisement recognizing embarrassing or unexplained symptoms as a treatable condition has encouraged many patients to seek out doctors specifically to discuss these symptoms and the information the patient has learned.⁷³

DTC advertising has become one more piece of information used by patients and doctors to discuss medical issues, just as personal beliefs, experiences of family members and friends, medical education, and scientific discovery are all brought to a doctor-patient conversation.⁷⁴ Diagnoses and treatment, even if begun with DTC advertising, lead to better quality of life for patients, which is everyone's goal.⁷⁵

The U.S. system of protection for new technologies through patent law highly rewards those who create new products and methods to benefit the public. These valuable new technologies are introduced to the public through DTC advertising. Through broadcast and print advertisements, people learn that symptoms might be associated with medical conditions and that treatments are available for those conditions. DTC advertising brings this information to wide and varied populations in accessible media, especially benefiting rural populations – both patients and physicians – who are traditionally slower to accept developments in modern medicine.⁷⁶

Finally, in an era where health care economics inhibit doctors' ability to discuss alternative treatment options with their patients, prescription drug advertising in the mainstream media helps patients enter a doctor's office with specific questions. As people frequently have to change doctors when their insurance changes and doctors have more patients than ever, it is important for patients to become true partners in their treatment, discussing with their doctor: values, interests, and willingness to use different types of medications. Patients can better express their desires when they understand the options

⁷⁰ Hall, 7 DePaul J. Health Care L. at 14.

⁷¹ Id. at 14.

⁷² Id. at 14.

⁷³ Chin, 5 Yale J. Health Policy, L. & Ethics at 776.

⁷⁴ Id. at 773.

⁷⁵ Id. at 773.

⁷⁶ Jaclyn Carole Hill, Student Author, *The Learned Intermediary Doctrine and Beyond*, 72 Def. Couns. J. 362, 376 (2005).

available. DTC advertising is by no means the only method a patient can get this information, but it is one way that the average person can learn about medical advances and possibilities. When patients play an active role in making medical decisions, doctors have seen “improved patient compliance with treatment regimens as well as health outcomes.”⁷⁷

The Problem and Possibility of the Internet

As in all areas of the law, a major problem of the Internet is that no one knows its jurisdiction. In the area of advertising of prescription drugs, an additional problem is deciding how much pharmaceutical manufacturers should be able to claim, and how much they should be required to disclose, on websites. Controversy over the First Amendment rights of pharmaceutical manufacturers and advertisers is widely discussed in courts and learned discourse.⁷⁸ Web advertising is a clear and attractive choice for manufacturers because of relatively low start-up costs and the lack of space constraints when comparing to broadcast or print advertising.

Pharmaceutical manufacturers and advertisers, especially those that specialize in anti-depressants and allergy medicines, are increasingly aware of the benefits of advertising online – the unlimited space, the constant availability to the public, and the chance to inform people about new medicines available and the intended uses for them. These websites sometimes include patient decision aids in the forms of quizzes and other interactive features.⁷⁹

Writers in learned discourse in opposition to direct-to-consumer advertising through websites argue that the role of the doctor is undermined by these increasingly interactive websites. They say that a patient will rely more on the website and fail to properly inform their doctor. This is another reason they cite for arguing that the Learned Intermediary Doctrine should not apply to pharmaceutical advertisers.⁸⁰ A doctor is still needed to determine whether a particular drug is right for each individual patient and if so, what dosage would be effective and safe for him or her. A doctor will also be able to discuss several treatment options with each patient and determine which would best suit that patient. These websites are useful informative and teaching tools for those interested in learning about treatment options in addition to discussing these options with a doctor. As a patient cannot receive a prescription for medication through a website, there is little danger that the patient will be able to disregard a doctor’s decision about the fit of that drug for him or her. In any case, Internet advertising will either need to be addressed by the governing agencies as separate from either broadcast or print advertising or will need to be regulated in one category or another.

A pharmaceutical manufacturer’s website, accessible by doctors and the public, without space restrictions, and immediately updateable, is a good alternative to the brief summary requirement for print advertisements. It is important for members of the public to be able to get to drug side effect and risk information if they want it. Many doctors already instruct patients to research medical procedures a doctor and patient are considering for treatment of a patient’s medical condition; having this information from a reputable source would make this process increasingly useful and simple. If this information is available for not only medical procedures but also for all prescription drugs, it would enhance the ability for doctors and patients to make medical decisions together as patients would be able to look up drugs a doctor has suggested before deciding

⁷⁷ Hall, 7 DePaul J. Health Care L. at 25.

⁷⁸ See Christopher D. Zalesky, *Pharmaceutical Marketing Practices*, 39 J. Health L. 235 (2006); Josef Winkler, *You Wanted the Best, you got the Best! The Current Direct-to-Consumer Prescription Drug Advertisement Dilemma*, 26 Biotechnology L. Rep. 331, 336 (2007); George W. Evans & Arnold I. Friede, *The Food and Drug Administration’s Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 Food & Drug L.J. 365, 424 (2003); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (holding the Food and Drug Administration Modernization Act unconstitutionally broad in disallowing any advertising of compounded drugs); *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976) (overruling state statutory ban on advertising prescription drug prices).

⁷⁹ April L. Foreman, Student Author, *Web of Manipulation*, 35 J. Marshall L. Rev. 97, 109 (2001).

⁸⁰ *Id.* at 110.

to take them. Having information available in this searchable and optional format is a much better way of providing it to the public than by including the information with all print advertisements.

There are concerns with using the Internet as a way to disseminate medical information. Websites may be hacked and altered but as Internet security continues to evolve this danger may be lessened. Websites are easily changeable by the owner. This may be a problem in that drug manufacturers may add new information or change the product risk information on the website and expect the world to be on notice. However, a requirement to notify doctors when information is changed or a continuation of use of the Physicians' Desk Reference updating mechanism may remedy this concern. There is also the fact that the Internet is not universally accessible. People without Internet service or computers in the home, however, should have Internet access at their local public library.

Suggested Resolutions

General Suggestions for Revision of Prescription Drug Advertising

No matter which method is used, regulation of print DTC advertisements needs to be changed to match the same advertising in broadcast media. It is simply unfair that print advertising, a common method of increasing the knowledge and awareness of new medications, to the benefit of doctors and patients, should be so highly burdened by unnecessary legal requirements. There are several ways that this goal can be accomplished. The FDA should not, however, continue to force advertisers to print brief summaries in an "attempt to duplicate the doctor's communicative role through compelled speech in DTC ads that cannot realistically achieve the desired effect."⁸¹ As the FDA has reduced the burden to disclaim placed on broadcast advertising to requiring a major statement of side effects and contraindications and an adequate provision for customers to obtain the full brief summary, so should the FDA do for print advertisements. Having a brief summary in print is less effective even than the same information was in broadcast- a person can flip past a page of technical information in less time than he or she would have to wait for a television program to come back from a commercial.

The FDA is regulating to ensure that drug manufacturers and advertisers follow the letter of the regulation and not the intent. The justified intent of requiring the brief summary was to ensure consumers had adequate access to information balancing the persuasiveness of an advertisement. The effects that have resulted are burdens on manufacturers and wasted space, paper, and money in magazine advertisements.

The desired effect would be much better served if the FDA were to require a major statement and adequate provision for print advertisements. Advertisements under this rule would include a disclaimer similar to those currently heard at the ends of broadcast commercials; for example "FLOMAX is not for people with certain conditions. Only a doctor can tell if you have BPH, not a more serious condition like prostate cancer. Avoid driving and hazardous tasks for 12 hours after your first dose or an increase in dose, as a sudden drop in blood pressure may occur, rarely resulting in fainting. If considering cataract surgery, tell your eye surgeon that you've taken FLOMAX. Common side effects are runny nose, dizziness or a decrease in semen."⁸² This kind of written disclaimer, paired with a website, phone number, and copies of the entire brief summary in a publicly accessible place (the general way broadcast advertisers meet the adequate provision requirements) would be a better way to ensure that consumers have access to the brief summary information if they choose to read it.

⁸¹ Evans and Friede, 58 Food & Drug L.J. at 428.

⁸² Boehringer Ingelheim Pharmaceuticals, Inc., *How FLOMAX can help*, <http://www.4flomax.com/doctor/tv.jsp> (Accessed April 27, 2008).

Other writers on this subject have suggested a disclaimer stating that the advertised drug is available only by prescription, that all prescription drugs carry risks, and that consumers should consult their doctors for more information.⁸³ Giving readers the option to find more information for drugs that relate to them would be much more effective in creating an informed consumer base than distributing it to everyone in this haphazard way.

Other possible changes that would achieve the effect of the regulation would be to increase the requirement of consumer labeling on packages of prescription drugs themselves, much like the printed information that comes with prescriptions filled by some pharmacies, detailing accepted uses and risks of the drug.⁸⁴ This would certainly be more effective and focused on the target audience than magazine advertisements as manufacturers can be sure that this information will reach those who will be taking the drug. The downside of this option is that the consumer will only have the information after speaking with a doctor and getting a prescription filled. Offering the information in this way instead of the print brief summary would not deter patients from speaking with doctors about advertised products and would be simpler to read while still meeting the FDA's intent to inform consumers about the drug. "Consumers need better information not only about the risks, but also about the benefits of the drug and the factors that limit the usefulness of the drug."⁸⁵ Information can be of most use when fairly balanced and directed to those who actually need it.

One last possibility is the option for the FDA to reshape the brief summary requirement into an optional safe harbor.⁸⁶ This would allow drug advertisers more flexibility in deciding how to ensure the fairness and truthfulness through the ad and bring the FDA within the bounds of the First Amendment.⁸⁷ This solution would further the FDA's aims while reducing the number of unnecessary pages printed and paid for by drug advertisers, but has the strong possibility of not changing anything at all. If advertisers are complying with the brief summary requirement for the legal protection it provides, none will want to be the first to step outside of the known boundary of protection. The comparative advantage is simply not there for cutting the ad from three pages to two pages (hypothetically one page of ad and one of disclaimer as opposed to two pages of disclaimer) would not be worth the legal costs of litigation over whether the advertiser met the safe harbor requirements. This change in name only would not solve the problem but might make legislators and rulemakers think the situation has been remedied and keep them from making the necessary changes that would actually change something.

Rewriting 21 C.F.R. § 202.1

The best solution to the imbalance of regulation for prescription drug advertisements in broadcast media and in print is also the simplest- to recognize the problem as an imbalance and to change the print advertisement regulations to match those of broadcast ads. The guiding regulation for prescription drug advertising, 21 C.F.R. § 202.1, currently sets out a rule that "all advertisements for any prescription drug... shall present a true statement of information in brief summary relating to side effects, contraindications... and effectiveness,"⁸⁸ and an exception to it:

Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation

⁸³ Evans and Friede, 58 Food & Drug L.J. at 428.

⁸⁴ Margaret Gilhooly, *Heal the Damage*, 38 J. Health L. 1, 39 (2005).

⁸⁵ *Id.* at 39.

⁸⁶ *Id.* at 422.

⁸⁷ *Id.* at 422.

⁸⁸ 21 C.F.R. § 202.1 (e) (1).

shall contain a brief summary of all necessary information related to side effects and contraindications.⁸⁹

The best correction to this problem would be to change this section of the regulation to:

Advertisements shall include information relating to the major side effects and contraindications of the advertised drugs in the audio, audio and visual, or visual presentation, not including presentations made over the Internet, and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the presentation shall contain a brief summary of all necessary information related to side effects and contraindications. Presentations made over the Internet or in websites, not including presentations that use Internet connectivity but take the shape of television, radio, or telephone presentations at the sending and the receiving of the message which are to be regulated as television, radio, or telephone presentations respectively, shall include a brief summary of all necessary information related to side effects and contraindications. All manufacturers of prescription-strength medications shall maintain a website which includes readily-available recognizable product names and advertising themes and these websites shall include a brief summary of all necessary information related to side effects and contraindications.

This regulation, in encompassing all forms of advertising, ensures fairness among methods used and eliminates the wastefulness of requiring brief summary information in every print advertisement while ensuring that consumers have access to brief summary information, should they chose to read it, in the form of a manufacturer's website. If consumers are currently not harmed by broadcast advertisements only airing a major statement of side effects and contraindications with an adequate provision for obtaining the full brief summary if they so choose, they should not be harmed by reading the same. There is no reason for the law to be as out-of-date as it is or for it to cause such waste in public advertising as it does today.

Conclusion

The system of regulation currently in place for prescription drug advertising is clearly flawed. It is inequitable, inconsistent, and illogical. Current regulation mandates unjustified expenditures on the part of prescription drug manufacturers and advertisers, at the risk of tort liability for failure to warn, without taking into account the doctrine of law already in place to prevent this duplicity, the Learned Intermediary Doctrine. Learned intermediaries have always and will always be a necessary part of the provision and use of prescription drugs. The FDA should rely on these educated individuals to do what is best for their patients and remove the requirement for prescription drug advertisers to include the brief summary in print advertisements as it did more than a decade ago for broadcast advertisements. Direct-to-consumer advertising has had a major beneficial impact on the way doctors and patients jointly identify problems, make decisions, and ensure patients' health. To maintain this interaction, lessen the possibility of consumer confusion, and reduce unnecessary expense, the FDA should bring the antiquated 21 C.F.R. § 202.1 into line with regulation of broadcast prescription drug advertising and make use of the benefits of the Internet. With so many alternatives, this regulation is no longer the best, or even a good, method of ensuring consumer protection in an area where consumers are already well-protected by a qualified professionals, their doctors.

⁸⁹ Id.