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CONSUMER-DIRECTED PRESCRIPTION DRUG ADVERTISING:
EFFECTS ON PUBLIC HEALTH

WILLIAM E. HOLTZ,¹

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¹The author is a registered pharmacist in Virginia and Maryland (B.S. Pharmacy, University of Pittsburgh, 1995); J.D. candidate, Georgetown University Law Center, Washington, D.C.

I. INTRODUCTION

Over the past two decades, and to a greater extent recently, society has been increasingly exposed to prescription drug advertisements aimed directly at the consumer. The industry's gradual shift in focus from "physician-directed" to "consumer-directed" advertisements poses a threat to the public health because it may have the effect of misleading consumers by understating a drug's adverse reactions and overstating the benefits.

The increase in consumer-directed advertising has helped to foster a health care atmosphere in which it is the patient, and not the medical practitioner, who initiates a discussion regarding possible drug therapy.² Consumer-directed advertising also has a profound impact on the doctor-patient relationship and results in patients consuming drugs with attractive benefits and undisclosed possible adverse reactions. This creates an increased dependence on prescription drugs, and the falsified notion that there is a prescription drug to cure most any condition.³ The effects that consumer-directed advertising of prescription drugs have on the health care system warrant a thorough review and modification of the existing United States Food and Drug Agency (FDA) regulations in order to preserve the public health.⁴

To date, the FDA regulations have remained unresponsive to this change in advertising focus. In a draft guidance⁵ issued by the FDA, the agency has actually made advertising of prescription drugs easier by making disclosure requirements of

² See Bette-Jane Crigger, *Ask Your Doctor or Pharmacist*, HASTINGS CENTER REP., Mar.-Apr. 1998, at 47 (stating that prescription drug advertisements are simplistic and misleading, nurturing unrealistic expectations of benefit that physicians will not be able to counter effectively, and that this tension adds to the already fraying doctor-patient relationship when patients demand the medications they have seen advertised); Michie Hunt, *Direct-to-Consumer Advertising of Prescription Drugs*, NAT'L HEALTH POL'Y F., (Apr. 1998) (noting that most physicians are accommodating to patient drug requests).

³ In a recent survey, more than 40,000 consumers confirmed that prescription drug advertising had changed the way they took care of medical problems. See Abigail Zuger, *Drug Companies' Sales Pitch: 'Ask Your Doctor,'* N.Y. TIMES, Aug. 5, 1997, at C2. See also *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976). In his dissent, Justice Rehnquist noted that the general advertising of drugs may lead to the notion that there is a drug for every ill, whether real or imaginary. *Virginia State Bd. of Pharmacy*, 425 U.S. at 790.

⁴ See, Prescription Drug Product Labeling; Medication Guide Requirements, 60 Fed. Reg. 44,182 (1995) (to be codified at 21 C.F.R. pts. 201, 208, 314, 601) (proposed Aug. 24, 1995). The FDA believes that "inadequate access to appropriate patient information is a major cause of inappropriate use of prescription medications, resulting in serious personal injury and related costs to the health care system." *Id.* The FDA has proposed performance standards to define the acceptable levels of information distribution and quality that *accompanies* prescription drugs. *Id.* However, these standards do not affect prescription drug advertising. *Id.*

⁵ Draft guidances are FDA documents that represent the agency's current thinking on a particular subject. See 21 U.S.C. § 371(h)(1)(A) (1999). They do not create or confer any rights, and are not binding on the FDA or the public. *Id.*

adverse drug reactions⁶ less stringent for broadcast advertisements. The current regulatory system in place by the FDA⁷ is inadequate to deal with current issues surrounding consumer-directed advertising. This is due in large part because the regulations currently in effect were implemented in 1938 before the advent of this new breed of advertising.⁸ There is no doubt that the nature of advertising has changed significantly since that time and an updated version of regulations is needed to protect the public.

Consumers' quest for and access to information has been accompanied by an increase in the patient's role in his or her health care treatment.⁹ Prescription drug advertisements directed to the consumer have the potential to be excellent sources of consumer information and should therefore not be banned outright.¹⁰ Greater access to patient information certainly enables the patient to take a more active role in their treatment.

The public health problems discussed in this Paper are undoubtedly caused by a number of concurrently occurring problems. The solution set out here is to construct a more stringent FDA regulatory scheme which seeks to minimize this problem, while acknowledging that it will not eliminate it.

This Paper will evaluate the effectiveness of the current FDA regulatory scheme regarding consumer-directed prescription drug advertising. Part II discusses the relevant history of consumer-directed advertising of prescription drugs which is a relatively new practice in the United States. Possible explanations are reviewed for why the change in focus from physicians to consumers as the targets of such advertising has occurred.

Part III explains the major classifications of consumer-directed advertising that the FDA has categorized and examines the differences existing among them.

Part IV focuses on the current FDA regulatory scheme and begins to expose some of the difficulties of applying the current regulations to consumer-directed advertisements.

⁶ WORLD HEALTH ORGANIZATION, TECHNICAL REPORT SERIES NO. 425, INTERNATIONAL DRUG MONITORING: THE ROLE OF THE HOSPITAL 6 (1969). According to the World Health Organization (WHO), an adverse drug reaction is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy. *Id.* This paper will not focus on contraindications (patients who should definitely not take a particular drug product) because they typically represent a more bright-line standard in risk decision-making.

⁷ One of the primary functions of the FDA is to regulate prescription drugs, and particularly prescription drug advertising. *See* 21 U.S.C. § 321 (1999). The FDA has sole jurisdiction of prescription drug advertisement regulation, while the Federal Trade Commission (FTC) has jurisdiction over OTC drugs. *Id.*

⁸ *Id.* The Federal Food, Drug and Cosmetic Act was enacted in 1938. *Id.*

⁹ Consumers can learn from advertising that all drugs (even over the counter drugs) have side effects. *See* John E. Calfee, *How Advertising Informs to our Benefit*, CONSUMERS' RES. MAG., Apr. 1998, at 13.

¹⁰ Consumer-directed advertising of prescription drugs is still prohibited in Canada and most of Western Europe. *See* Crigger, *supra* note 2, at 47.

Part V explores specific effects the FDA regulations have on our current healthcare system. These include: (1) downplayed adverse drug reactions; (2) inconsistent scope and quantity of adverse drug reactions advertised; (3) the increased cost to society; (4) deterrence; and (5) increased strain on the doctor-patient relationship.

Recommendations for effectively strengthening the FDA regulations are included in Part VI. These include a standardized percentage over which all adverse reactions must be reported to provide uniformity in the industry and to allow consumer comparison. In addition, all prescription drug advertisements should be in terms easily understood by the ordinary consumer. An illustration is included to demonstrate the proposed effectiveness of such increased regulation.

This Paper concludes that the time has come for the FDA to consider updating or amending the current regulations that affect advertising of prescription drugs, particularly those advertisements which are directed at consumers.

II. HISTORY OF CONSUMER-DIRECTED ADVERTISING

Drug manufacturers have "advertised" their products since the industry's inception. Until the early 1980's, however, drug manufacturers primarily relied upon promoting their products directly to medical practitioners.¹¹ This was in the form of scientific literature, mailings, and visits by representatives to speak directly to the practitioner.¹² These methods are still used today in conjunction with consumer-directed advertising.

Consumer-directed advertising first began to occur in response to a Federal Register notice in 1985 which stated that current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers.¹³ The Agency, in effect, indicated that existing standards created to regulate marketing of drugs to physicians would apply to consumer-directed advertising also.¹⁴ Thus, the FDA did not enact any specific regulations or requirements pertaining solely to consumer-directed advertising.

A possible explanation for the change in focus from prescribers to consumers may be due to the advent of managed care organizations.¹⁵ Many managed care entities such as health maintenance organizations (HMOs) have put consumer restrictions on access to certain prescriptions.¹⁶ Thus, through the use of drug formularies, due to direct contracts between HMOs and manufacturers, many patients and doctors are effectively denied a possible treatment because of payment

¹¹Hunt, *supra* note 2, at 3.

¹²*Id.*

¹³Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677 (1985). This lifted a voluntary moratorium placed on the industry by the FDA from the time consumer-directed advertising was pondered until the agency could research its likely effects. *Id.*

¹⁴*See* Hunt, *supra* note 2, at 3.

¹⁵*Id.* at 5.

¹⁶*Id.* (noting that this is especially true when a manufacturer is introducing a drug that cannot demonstrate significant therapeutic advances or cost savings over existing therapies).

restrictions. For example, doctors prescribing medications for patients in certain HMOs may have the option of only one or two drugs in a particular therapeutic class, instead of the full range of available drugs on the market. The resultant shift in marketing focus by the manufacturers has enabled pharmaceutical companies to regain control of the prescription drug market.¹⁷

Consumer-directed advertising began primarily in the print medium because of the ease with which advertisers could comply with FDA labeling requirements.¹⁸ As a practical matter, under current FDA regulations, there is no difference between a print advertisement in a physician's journal and a popularly circulated entertainment magazine.

More recently, manufacturers have tapped into the enormous market of broadcast advertising to promote their drug products.¹⁹ These advertisements are typically several-minute commercials on television and, to a lesser extent, on radio. Here, the FDA has issued a recent draft guidance²⁰ to instruct manufacturers on how they may comply best with existing regulations for drug advertising and how to apply them to broadcast advertising.

The computer realm of advertising on the World Wide Web seems to be the next target for drug manufacturers. The Internet poses many of the same issues surrounding print advertising with the additional dynamic of rapidly changing technology.²¹

III. TYPES OF CONSUMER-DIRECTED ADVERTISING

The FDA has classified consumer-directed advertising in three categories: (1) "product-claim" containing safety and efficacy statements; (2) "help-seeking" containing information about a condition and recommending that the consumer consults a medical practitioner (while not mentioning the name of the drug or

¹⁷ *Id.*

¹⁸ "Labeling" includes all written, printed, or graphic materials accompanying a regulated product. See 21 U.S.C. § 321(m) (1999). The Supreme Court has stated that this definition is not limited to information physically accompanying a product and that the textual relationship between the materials and the product is fundamental. *Kordel v. United States*, 335 U.S. 345, 349-50 (1948).

¹⁹ One manufacturer has recently experimented with a celebrity spokesperson. Schering-Plough used former *Good Morning America* host Joan Lunden to promote the fast-acting Claritin RediTabs allergy medication. See Melanie Wells, *Despite Star Power, Claritin Ads Falter*, USA TODAY, Sep. 28, 1998, at 8B. Consumer analyst corporation Ad Track has reported that it is among the least-liked consumer advertising campaigns since it began measuring prescription drug advertisements in 1995. *Id.*

²⁰ See Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (1997).

²¹ See David W. Opperbeck, *How Should FDA Regulate Prescription Drug Promotion on the Internet?*, 53 FOOD DRUG L.J. 47, 60 (1998) (addressing the unique problems raised by proposed regulation of prescription drug labeling and advertising on the Internet. For example, is a banner advertisement considered a "reminder advertisement" even though it is linked to a broader homepage?).

treatment); and (3) “reminder” containing the drug name and limited information, while excluding all representations about the drug.²²

A. Product Claim

Product claim advertisements contain safety and efficacy claims about a specific prescription drug product.²³ These advertisements are limited to one specific drug product and currently have not compared drugs, or classes of drugs, with each other.²⁴ Proponents of this noncomparative format argue that consumers do not have the contextual knowledge to evaluate such comparative claims.²⁵ Opponents contend that consumers can evaluate comparative claims that present a fair balance between benefits and adverse reactions.²⁶

B. Help-Seeking

Help-seeking advertisements encourage consumers with particular symptoms, conditions, or diseases to consult their doctor to discuss general treatment options, but do not mention the name of any specific drug products.²⁷ If there is only one available treatment for a condition, help-seeking advertisements may not be used because, by implication, they would be advertising for the product.²⁸ In such an instance, the FDA would regulate the help-seeking materials as product claim materials.²⁹

The FDA does not currently regulate help-seeking materials. Opponents to this stance feel that consumers are able to link a sponsoring manufacturer to a specific prescription drug.³⁰

C. Reminder

Reminder advertisements merely reinforce name recognition and brand loyalty.³¹ These advertisements have been traditionally targeted toward prescribers in an effort to increase the number of prescriptions by increasing the frequency that a prescriber recalls a drug’s name and its clinical function.³²

²² Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,581, 42,482 (1995).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. at 42,582.

²⁹ *Id.*

³⁰ *Id.*

³¹ Direct-to-Consumer Promotion; Public Hearing, 60 Fed. Reg. 42,583.

³² *Id.*

The effect that reminder advertisements have on consumers has not yet been established since consumers are less likely to associate the clinical function of a drug and its brand name.³³

IV. THE CURRENT FDA REGULATION OF CONSUMER-DIRECTED ADVERTISING

As previously stated, the FDA has set forth one set of regulations for all prescription drug advertising.³⁴ There are three provisions of (the Code of Federal Regulations) section 202.1(e) of concern here: (1) the “brief summary” provision; (2) the “major statement” provision; and (3) the “adequate provision.”

A. The “Brief Summary” Provision

The regulations require all advertisements for any prescription drug to present “a true statement of information in brief summary relating to side effects, contraindications, and effectiveness.”³⁵ This is consistent with the Federal Food, Drug, and Cosmetic Act³⁶ which also requires advertisements to contain “information in brief summary relating to side effects, contraindications, and effectiveness.”³⁷

The provisions in section 202.1(e)(1) seem to conflict with other provisions of the same section. In section 202.1(e)(3), the regulations require that “information relating to side effects and contraindications shall disclose each specific side effect and contraindication contained in required, approved, or permitted labeling for the advertised drug dosage form(s).”³⁸ Advertisements in print medium have adhered to this more stringent requirement by including in an advertisement a copy of the official drug labeling. However, the presence of this information is not enough. The public health is not benefited by fine-printed labeling in highly scientific terms. Adverse event information is rendered effectively useless when surrounded by pharmacologic information such as metabolism and excretion, which the average consumer can not comprehend. Further, the accompanying product labeling frequently appears on the reverse side of the page of the original advertisement.³⁹

³³ *Id.* But cf. Zuger, *supra* note 3, at C2 (stating that there is some evidence that patients are fertile ground for cultivating brand awareness in the ever more competitive pharmaceutical market).

³⁴ See 21 C.F.R. § 202.1 (1999).

³⁵ See *id.* § 202.1(e)(i) (“When used in this section ‘side effects, contraindications’ include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.”).

³⁶ See 21 U.S.C. § 301 (1999).

³⁷ See 21 U.S.C. § 352(n) (1999).

³⁸ See 21 C.F.R. § 202.1(e)(3)(iii).

³⁹ The FDA regulations classify an advertisement as false, lacking in fair balance, or otherwise misleading if (1) it “fails to provide adequate emphasis for the fact that two facing pages are part of the same advertisement when one page contains information relating to side effects and contraindications,” or (2), if it “fails to include on each page or spread of an advertisement the information relating to side effects and contraindications or a prominent

This too renders it useless since a page-turning consumer is unlikely to even realize that a page of black and white text is intimately connected to a glossy color advertisement on another page.⁴⁰ The end result is that a consumer is unlikely to even attempt to read this detailed information.

B. The "Major Statement" Provision

The "major statement" provision is an instance in which the FDA has recognized a difference between print and broadcast advertising. This obvious difference is that it would be nearly impossible to name all of a drug's potential adverse reactions in a one minute broadcast advertisement, while at the same time it would be very easy and misleading to scroll the list of adverse reactions on a television screen. It is doubtful that either option would benefit the consumer or give effect to the FDA's intentions. The regulations state that "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."⁴¹ Thus, a broadcast advertisement may not simply scroll or flash a list of potential adverse reactions on the television screen.

C. The "Adequate Provision" Requirement for Broadcast Advertisements

The "adequate provision" requirement is, in effect, an alternative for broadcast advertisers. It allows the manufacturer to avoid the "major statement" provision if "adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation [and] shall contain a brief summary of all necessary information relat[ing] to side effects and contraindications."⁴² The most notable industry example is the usage of toll-free telephone numbers which the consumer may call to get the required drug information.

The FDA has stated that this provision can be met by providing an effective mechanism by which the majority of a potentially diverse audience can receive the product's approved labeling.⁴³ However, this audience will inevitably include persons with limited access to technologically sophisticated outlets (e.g., Internet access and personal fax machines) and persons who hesitate to actively request additional product information.⁴⁴ The FDA recommends including the following mechanisms to communicate to these patients:

reference to its presence and location when it is presented as a distinct part of an advertisement." 21 C.F.R. § 202.1 (e)(7)(ix), (xii).

⁴⁰ See Editorial, *Pushing Ethical Pharmaceuticals Direct to the Public*, 351 LANCET 921 (1998) (stating that the closely packed black and white listing of drug information following a colorful print advertisement will not likely be read).

⁴¹ See 21 C.F.R. § 202.1(e)(1).

⁴² *Id.*

⁴³ Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. at 43,171.

⁴⁴ See *id.*

1. The Toll-Free Telephone Number

The toll-free telephone number is acceptable to the FDA as long as the caller is given the choice of having the information read to them over the phone or sent to them in a timely manner by fax or mail.⁴⁵

The logic here is faulted because it is unlikely that a person who would not otherwise seek out information would make an active effort to do so after seeing a television commercial or hearing a radio advertisement. Furthermore, a consumer must either immediately call the number or write it down for future usage. This adds to the unlikelihood that a person will seek this information actively rather than simply asking their physician, or not asking anyone at all.

2. Statement to “Ask Someone Else”

The FDA has included in its recommendations that a broadcast advertisement include a statement that pharmacists and/or physicians (and/or veterinarians in the case of animal drugs) may provide additional information to consumers.⁴⁶

This provision almost signs the doctor or pharmacist on to the advertising campaign of the manufacturer. One may certainly argue that it is an essential function of doctors and pharmacists to respond to patient questions; however, here it is foremost benefiting the manufacturer. The patient is only benefited when the particular therapy is appropriate for them.

To be sure, a recent survey concluded that ninety-nine percent of physicians said they would prescribe or consider prescribing a drug that a patient requested.⁴⁷

3. Statement to “Look Elsewhere”

The FDA has recommended that manufacturers instruct the viewer of a consumer-directed advertisement that additional product information is provided in print advertisements appearing concurrently in publications that reach the exposed audience or in brochures located in a variety of public places.⁴⁸

This provision also provides a problem for the consumer who does not actively pursue information. Even if a sufficient number of brochures were located in local pharmacies, doctor offices, libraries, and grocery stores, a consumer may very well never access them or have access to them.

⁴⁵ *Id.* An example of this practice is an advertising campaign created by ad agency Leo Burnett for Prozac (manufactured by Eli Lilly Co.) which doesn't mention Prozac by name, but rather encourages consumers to call a toll-free number to learn more about depression and prescription medication for it. See Melanie Wells, *First Prozac TV Ads Air on Cable*, USA TODAY, Sep. 15, 1998, at 2B. The voiceovers in the commercial state “treatment that has worked for millions is available from your doctor.” *Id.*

⁴⁶ See Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. at 43,171.

⁴⁷ See Zuger, *supra* note 3, at C2.

⁴⁸ See Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. at 43,171.

4. Internet Web Page (URL)

An Internet web page with access to the product labeling may be provided in the broadcast or via the toll-free telephone number.⁴⁹

The same technical objections apply here, as mentioned above, for those without access to the World Wide Web. In addition, this is hardly an improvement over the current status since virtually all drug product information is currently available at multiple Internet web sites.

V. EFFECTS OF CONSUMER-DIRECTED PRESCRIPTION DRUG ADVERTISEMENTS ON THE CURRENT HEALTH CARE SYSTEM

The advent of consumer-directed advertisements has contributed to some unique problems and tensions which did not exist before its inception. It is important to realize the extent to which consumer-directed advertising contributes to these modern problems when deciding how to best deliver health care in the United States.

A. Enhanced Benefits/Downplayed Adverse Reactions

Under the current regulations, an advertisement does not satisfy the “true statement” of the “brief summary” if it fails to present a fair balance between adverse reactions and information relating to effectiveness.⁵⁰

Current consumer-directed drug advertisements, like most advertisements with increased product sales in mind, have a tendency to focus on the benefits of the particular medication. The problem with this approach in relation to prescription drugs is that it may create a notion to patients that the drug is safe for use specifically by them. This calls to question two related issues: the physician’s role as a gatekeeper to dangerous medications which certain patients should not use, and the ability of ordinary consumers to understand risk information. Both of these issues will be visited below.

Further, the regulations fail to take into account the visual portions of an advertisement when suggesting “fair balance.” The regulations clearly forbid the use of blatantly false or misleading statements,⁵¹ but the actors in a commercial or the graphic material accompanying a print advertisement are not weighed in this balancing. For example, a commercial may show allergy-suffering actors enjoying allergy-sensitive activities while mentioning the benefits of the particular drug for all but the last ten seconds when the three major side effects are listed. Since images have traditionally been considered speech for relevant First Amendment analysis, an FDA regulation addressing the role of images would be beneficial in achieving “fair balance.”

This brings to question which side effects and contraindications are significant enough to be included in the “brief summary.”

⁴⁹ *See id.*

⁵⁰ *See* 21 C.F.R. § 202.1(e)(5)(ii).

⁵¹ 21 C.F.R. § 202.1(e)(3)(ii).

B. Scope and Quantity of Adverse Events

Adverse drug reactions are a major cause of hospitalization, prolonged hospital stays, and frequently death in the United States.⁵² Recent studies have placed deaths due to adverse drug reactions among the top ten causes of death in the United States.⁵³ For these reasons, public health authorities such as the FDA should consider regulation of the prescription drug industry more stringently.

The current FDA “brief summary” requirements are unspecific and give pharmaceutical manufacturers too much control over the amount and content of adverse reaction and contraindication information. The result is a downplaying of adverse information and an increase in patients taking unnecessary medications. In addition, medications which may be necessary are never fully explained to the patient in understandable terms.

Under the current regulations, manufacturers typically list the top three to five adverse effects of the advertised drug. Adverse effects such as headache and nausea, for example, are almost always included.⁵⁴ It is true that these are included because they are among the leading side effects of most drugs; however, it is important to ascertain the extent to which they may be displacing side effects which consumers may place more importance upon such as increased risk of stroke or blurred vision.

Presumably the average consumer knows that headaches and nausea can be caused by a stressful day, spicy food, etc. To know the extent to which a drug causes these frequently occurring side effects is not necessary here. It is just important to realize that the inclusion of these in prescription advertisements in the “top three” will necessarily remove more informative risk information from the advertisement. It may even be appropriate to inform consumers that any foreign substance ingested into one’s body may cause headaches, nausea, etc. This will allow room for more definitive adverse risk information so a consumer may make a more educated decision.

C. The Cost of Adverse Drug Reactions and the Impact of Advertising

The market for prescription drugs in the United States is enormous, with annual drug sales exceeding eighty billion dollars.⁵⁵ There is no doubt that advertising is in

⁵² See, Yvonne Bukstein, Comment, *Drug Products Liability: Duty to Warn*, 49 U. PITT. L. REV. 283 (1987).

⁵³ Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies*, 279 JAMA 1200, 1202 (1998) (finding that in 1994, an estimated 2 million hospital patients had a serious adverse drug reaction and about 100,000 patients had a fatal adverse drug reaction). Although this study involved only hospitalized patients due to ability to record data, it is suggestive of the population at large. *Id.* at 1201. In fact, the researchers have admitted to being “conservative” in their approach. *Id.* at 1204. This suggests that the out-patient problem is far worse due to a less controlled atmosphere involving multiple doctors without knowledge of other concurrent medications and less patient monitoring. *Id.*

⁵⁴ For this reason, it is important to include the relevant placebo-associated risk information as well.

⁵⁵ IMS Global Services, *Managed Care, New Product, and OTC Efforts Drive Utilization*, (visited Dec. 2, 1997) <http://ims-america.com/communications/pr_dtcsurvey.html>.

the best interest of a pharmaceutical company's bottom line. The market for some new drug therapies has been estimated to be in the billions of dollars.⁵⁶ Therefore, it is extremely attractive for manufacturers to increase their market share through consumer-directed advertising.⁵⁷

Adverse drug reactions contribute to an increase in the number of hospitalizations.⁵⁸ Studies have shown that this increase in hospitalizations, due to adverse drug reactions, has an estimated direct cost to society of \$1.56 to \$4 billion in the United States.⁵⁹

Since the relaxing of the regulations regarding consumer-directed broadcast advertising,⁶⁰ the industry has spent considerably more each year on consumer-directed advertising.⁶¹ The industry spent \$500 million in 1996 and \$844 million in 1997.⁶² This is due to the fact that it costs much more to advertise on television and radio than in print.

Together with the increased costs of hospitalization and advertising, these costs will likely be passed on to the consumer directly through a rise in the price of drugs, or indirectly through insurance hikes.⁶³ It may be possible that manufacturers would absorb the cost through an increase in sales;⁶⁴ however, it is more likely that advertising would remain on the cost side of a budget and income derived would remain on the profit side.

⁵⁶ See Thomas N. Riley & Jack DeRuiter, *New Drugs: A Review*, 23 U.S. PHARMACIST 115, 120 (1998) (stating that the potential market for leukotriene inhibitors and antagonists for the treatment of asthma is estimated to be several billion dollars).

⁵⁷ When popular allergy medication Seldane (Hoechst Marion Roussel) was removed from the market in 1997, other manufacturers raced to advertise their allergy medications to potential consumers who could no longer acquire Seldane. See, Yumiko Ono, *Drug Makers Try to Win Over Seldane Users*, WALL ST. J., Jan. 31, 1997, at B1.

⁵⁸ See Lazarou et al., *supra* note 54 at 1202.

⁵⁹ See Classen et al., *Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality*, 277 JAMA 301, 304 (1997); Bates et al., *The Costs of Adverse Drug Events in Hospitalized Patients*, 277 JAMA 307, 311 (1997).

⁶⁰ See *Pushing Ethical Pharmaceuticals Direct to the Public*, *supra* note 40, at 921.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.* (stating that whether public or private insurance foots a nation's drug bill, in the end it is always the public who pays).

⁶⁴ See Steven W. Kopp, *Direct-to-Consumer Advertising and Consumer Prescription Prices*, 30 DRUG INFO. J. 59, 61 (1996) (stating that consumer-directed advertising tends to lower the price of advertised drugs relative to other drugs.); *but cf.* Hunt, *supra* note 2 at 11. (stating that this is in line with the dual-stage economic theory which forces all drug retailers to price advertised drugs competitively with other retailers. Also, retailers may offset prices by taking a loss on advertised drugs and increasing the prices on other drugs. Therefore, the impact of advertising on the overall prices of prescription drugs is still not known).

Therefore, the current FDA regulatory system fosters a drug market where the drug product made by a manufacturer with an enormous advertising budget may displace a product with considerable cost savings and a superior therapeutic profile.

By making the FDA regulations more stringent, there is no additional cost to the manufacturer over present conditions. The manufacturers already have the required information on adverse events. In order to get prescription drug approval from the FDA, all manufacturers must accumulate clinical trial information that must be included in the application for a new drug (NDA).⁶⁵

However, if a more stringent policy leads to a decrease in sales, many manufacturers may make claims that their freedom of expression is being curtailed. Whenever regulations involving restriction of speech are proposed, the First Amendment necessarily comes into play. The speech of concern here is certainly commercial speech since the main purpose of the speech is to increase revenue.⁶⁶ The Supreme Court has held that a lesser degree of free speech protection applies to purely commercial speech.⁶⁷ Furthermore, if the goal of a regulation that prohibits or curtails commercial speech is legitimately to protect consumers' public health, then it will more likely withstand a constitutional challenge.

Here, the FDA has a legitimate interest in protecting the public health. There is no doubt that the preservation of public health is among the most important functions of government.⁶⁸ Therefore, a court applying the Supreme Court's four-part test from *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York* and *44 Liquormart, Inc. v. Rhode Island*⁶⁹ would likely find that a substantial legitimate governmental interest exists for which this type of commercial speech may be regulated. Strengthening FDA regulations to encourage disclosure of the dangerous propensities of drugs also directly advances the FDA's interest in protecting the public from dangerous drugs. For these reasons, a Constitutional challenge under the First Amendment would not likely be successful.

⁶⁵ The FDA requires the accumulation of very specific clinical trial information as part of the prescription drug approval process.

⁶⁶ See *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942). The Court defined commercial speech as speech towards endorsing and selling a particular product.

⁶⁷ See *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 498 (1996). The Court slightly changed the four-part test from *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980) that should be used in determining if a commercial speech restriction can be upheld: (1) Does commercial speech concern lawful activity and is it otherwise not misleading?; (2) Is asserted governmental interest in regulating interest substantial?; (3) Does regulation of commercial speech directly advance governmental interest?; and (4) is regulation no more expansive than necessary to serve governmental interest? *Id.* at 528. *But cf. Virginia State Bd. of Pharmacy*, 425 U.S. 761. The Court indicated that "speech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another." *Id.*

⁶⁸ See *Jacobsen v. Massachusetts*, 197 U.S. 11, 25 (1905). The Court states that the protection and preservation of the public health is among the most important duties of [state] government. *Id.* Here, the federal government (FDA) is vested with the duty to protect consumers in the case of drug advertising because advertising occurs on a national level. *Id.*

⁶⁹ See *44 Liquormart, Inc.*, 517 U.S. at 498.

It may become apparent that more substantial listing of adverse reactions is so burdensome and impracticable on manufacturers that it effectively denies the right to advertise in certain mediums (i.e. broadcast). It is necessary to realize that there are other alternative means available and that all advertising would not be banned. Any means that would disclose the required adverse reactions in an understandable way should be permitted. This may require utilizing new forms of consumer-directed prescription advertising such as the "info-mercial."

It is important to note here again that the FDA should not ban this type of commercial speech, but rather regulate the quality and context of the information that is disseminated in a way that balances the manufacturer's right to advertise and the governmental (FDA) interest in protecting public health.

More stringent regulations will likely affect the content and appearance of drug advertisements and effectively deny some manufacturers the right to advertise their product. By requiring manufacturers to list a minimum percentile of side effects, for more "dangerous" drugs this may include upwards of forty side effects. Manufacturers will have to decide if advertising will actually benefit their product sales or hurt them.

D. Deterrence

A strong argument may be made that certain patients will actually be deterred from taking necessary medications because of fear of disclosed adverse effects. It is logical to think that consumers bombarded with adverse drug reactions may elect to not participate in a particular drug therapy.⁷⁰ This would be primarily from fear that they would be among the percentage of sufferers of a particular adverse reaction. This would in turn directly affect the public health; arguably, worse than the above mentioned effects from inadequate adverse reaction information.

Physicians are certainly the best suited to determine the appropriateness of prescription medications for their patients. It is difficult to strike a balance between this thinking and the allowance of consumer-directed advertising of prescription drugs. If patients began refusing, out of fear, prescriptions ordered by physicians, there would undoubtedly be a decrease in the overall public health status. This begs the question of whether consumers are better off being over-medicated or under-medicated?

It would be reasonable to assume that patients who are prescribed medication that is deemed "life-saving" or absolutely necessary to the preservation of their current health status would follow their doctor's orders and take the medication regardless of adverse events learned through advertising. For example, this would include medication for high blood pressure or diabetes (interestingly, conditions for which treatments are not usually advertised since they are not "self-diagnosing" conditions). The problem of deterrence lies most heavily with precisely the type of medications which seem to be frequently advertised.

Keeping with the above example (assuming a patient will most always take necessary blood pressure-reducing medication), a patient who avoids an antihistamine/decongestant product for treating their seasonal allergies because they

⁷⁰ See Yumiko Ono, *More Drug Ads Ticking Off List of Health Risks Expected on TV*, WALL ST. J., Aug. 11, 1997, at B6 (stating that commercials are long, wordy, and packed with scary-sounding medical warnings that could turn off consumers).

learn it may affect their blood pressure is better off with allergy symptoms than those of uncontrolled blood pressure. In this patient, being under-medicated is preferred. While this may not always be the case, it is illustrative of how a patient with all necessary information may be better equipped to ensure their own health status. The deterrent argument assumes that consumers are unable to accurately assess their own risk. It is unclear whether the average consumer can truly appreciate a risk that they do not fully understand.⁷¹ However, by not disclosing full information, the consumer is denied the opportunity to understand and the opportunity to make a rational decision regarding their own personal well being.

Consumers flooded with adverse reaction information may be initially deterred at the onset of such a proposed regulation. This effect would likely be only temporary. As consumers begin to learn that all drugs have adverse profiles and begin to learn how to assess and compare adverse drug information, the end result will be a patient who is more informed and active in their own health decisions.

E. The Strain on the Doctor-Patient Relationship

There is no doubt that the nature of the doctor-patient relationship has changed over the last few decades.⁷² The physician of the past was rarely questioned by the patient, even when the doctor had clearly erred. Today, with more consumers armed with available health information, doctors are frequently questioned and patients are taking a more active role in their treatment. While not true with all patients, many “active” patients are turning the tables and converting the doctor into a more “passive” health care provider. Upon arrival at an appointment with a physician, active patients have what they believe to be an extensive knowledge of their condition. In addition, active patients present the physician with an agenda of what type of health care they demand and how it will be delivered. The physician is left in a passive role answering questions and when applicable, dispelling false notions.

An active patient, and all patients, undoubtedly deserve access to health information. Arguably, consumer-directed advertising is a part of this valuable consumer information base. However, if this information is biased or in some way incomplete, the end result tends to put the patient in a worse position than with no information at all.⁷³ By allowing prescription drug advertisements which are unbalanced in relation to the good and bad aspects of a medication, the FDA is

⁷¹This is an important reason why consumer-directed advertisements should be in “patient language” rather than in scientific terminology.

⁷²“Ever-increasing complexity and costs have brought about vast changes in the delivery of medical services. Today, most would not recognize Norman Rockwell’s portrait of the family doctor.” *Dunn v. Praiss*, 656 A.2d 413, 415 (N.J. 1995); Emanuel and Dubler have expressed the fundamental elements of the ideal physician-patient relationship embodied in our intuitions and common to ethical analyses and legal standards as “the six C’s” choice, competence, communication, compassion, continuity, and (no) conflict of interest. Ezekiel J. Emanuel & Nancy Neveloff Dubler, *Preserving the Physician-Patient Relationship in the Era of Managed Care*, 273 JAMA 323, 324-25 (1995).

⁷³See STEPHEN FRIED, BITTER PILLS: INSIDE THE HAZARDOUS WORLD OF LEGAL DRUGS 299-301 (stating that with such consumer-directed advertising, the line between over-the-counter and prescribed drugs has dimmed and that patients begin to view all advertised drugs as innocuous).

fostering an atmosphere in which all patients may be getting an inadequate introduction to prescription drugs.

With the advent of managed care, many physicians have had to cut back their actual amount of time with each patient. This is an unfortunate effect of managed care, but nonetheless a reality. Nurses and other support staff have commonly relieved the doctor of some preliminary office visit functions and “prepare” the patient so the doctor can quickly examine the patient. When doctors must spend a portion of this short time responding to inquiries made regarding possible drug therapies that the active patient suggests, the overall health of the patient may be compromised.⁷⁴ The time spent regarding these therapies directly takes away from the doctor’s active role in treating the patient.⁷⁵

Arguably, it is part of the physician’s role to respond to questions as the patient’s health care provider. In excess, this passive role is likely new for most physicians. Consumer-directed advertising puts an additional burden on physicians. Most physicians will have to learn more about every drug to adequately assess its appropriateness for their patient. For example, if a physician has a “favorite” drug to prescribe for a particular condition (for any number of reasons—efficacy, cost, etc.) and a patient inquires about another specific drug that the doctor is less familiar with, the doctor must either look up the prescribing information about that drug or dissatisfy the patient by denying the medication request. The third possibility is for the physician to prescribe the drug without complete knowledge of its efficacy. The first possibility imposes additional responsibility and time constraints on the physician; the second, a dissatisfied patient; and the third, increased physician liability.

The manufacturers’ dependency on physicians to play an active role in fulfilling disclosure requirements and shifting liability is demonstrated by this point. Drug

⁷⁴ See Crigger, *supra* note 2, at 47 (stating that ethicists at the Medical College of Wisconsin Bioethics Division noted that the problem with the increase in patient information is “that conversations about advertised medications must take place during the ever-dwindling amount of time doctors can actually spend with individual patients”).

⁷⁵ In a recent survey of almost 5,000 physicians questioned about consumer-directed advertising of prescription drugs, the following results were noted: (1) more than 60% of physicians said that they would like to see consumer-directed advertising stopped or decreased; (2) nearly 40% said they felt that the consumer audience in general lacks adequate knowledge about pharmaceuticals to understand the advertisements; (3) almost one-third said that consumer-directed advertisements are misleading because they fail to provide adequate adverse information such as side effects; (4) approximately 20% feel that consumer-directed advertisements bring disharmony to the doctor-patient relationship and that they spend excessive time justifying their prescribing decision and why a requested drug is inappropriate for the patient; and, (5) more than 40% reported an increase in the number of brand name requests since consumer-directed advertising began. Marjorie Kauffman Sherr & Donna Cutrone Hoffman, *Physicians—Gatekeepers to DTC Success*, PHARMACEUTICAL EXECUTIVE, Oct. 1997, at 56. *But cf.* Stuart Elliott, *Take Two Direct Sales Pitches for Prescription Drugs and Call Your Pollster in the Morning*, N.Y. TIMES, Jul. 29, 1998, at D2 (reviewing consumer opinion of consumer-directed drugs and stating that consumer opinion toward such advertising is generally favorable. However, the same survey also revealed that consumers find the advertisements lacking in clarity and usefulness, and are concerned that these advertisements diminish prescription drugs by likening them to heavily advertised packaged goods).

manufacturers have defended consumer-directed advertising as providing important information that empowers patients and enhances choice. Patients are also protected from imprudently using medications by the fact that physicians control access through prescriptions.⁷⁶

VI. RECOMMENDATIONS FOR FDA REGULATION IMPROVEMENT

A patient undergoing surgery is entitled to full access to a range of information before electing to undergo the procedure under traditional principles of informed consent. Courts have defended an individual's right to determine the appropriateness of medical treatment,⁷⁷ and the selection of drug therapy should not be construed differently. Although this is not an issue of informed consent, it may be helpful to think of it in a similar framework. The patient must be able to accurately assess risk and benefit information in order to decide if a particular drug therapy is appropriate for themselves.

Risk versus benefit analysis seems to be present in many aspects of everyday life. For example, one may unconsciously weigh the risks of jaywalking against the benefit of inconvenience and time saved by not having to walk to the intersection to cross the street. In this example, it is highly likely that a reasonable person can assess the various risks present (i.e. getting hit by a car, getting arrested for jaywalking, etc.). In the case of prescription drugs, however, consumers are much more likely to have difficulty assessing the technical scientific risk information associated with a drug and weighing it against the drug's claimed benefits. In other words, consumers need more assistance and protection in making reasonable health care decisions, particularly in the area of prescription drugs. Presumably, even the most well-educated Americans, outside of medical fields, can not fully understand this type of scientific data. With current social problems such as the high rate of illiteracy, consumer protection is especially important in this area, and the FDA should maximize its authority to regulate the prescription drug market.

A. *Standard Percentile*

Currently, there is no requirement for the scope or quantity of adverse reaction information included in consumer-directed advertisements. The standard practice seems to be to list the top three; however, this may be grossly inadequate in the case of drugs with more "dangerous" adverse reaction profiles.

It is conceded that a complete list of adverse reactions for a drug is impracticable for a number of reasons. First, reactions occurring in infinitesimally small percentages of the population would unlikely deter or usefully educate even the most worrisome consumer. Also, from a practical viewpoint, if the FDA is to allow the practice of consumer-directed advertisements to continue (especially in the broadcast medium), the advertisements will need to allot time to establish the benefits of the stated drug in accordance with the "fair balance" requirements stated above.

⁷⁶ See Crigger, *supra* note 2, at 47.

⁷⁷ See *Estate of Behringer v. Medical Ctr.*, 592 A.2d 1251, 1278 (N.J. Super. Ct. Law Div. 1991) ("The purpose of this legal requirement is to protect each person's right to self-determination in matters of medical treatment. . . . Medical information or a risk of a medical procedure is material when a reasonable patient would be likely to attach significance to it in deciding whether or not to submit to the treatment.").

The FDA should consider requiring manufacturers to list all adverse events occurring in a standard percentile and above in the clinical test population. This figure would have to be researched and determined by the FDA in accordance with available adverse drug statistics. This uniform number would allow a patient to become comfortable with assessing adverse information and to accurately make comparison judgments between related medications. Patients will then be able to make a calculated risk decision regarding a major part of their health care. It is conceded that this risk decision would also involve other considerations such as (1) the nature of the particular risk involved and the placebo-associated risk percentage; (2) the perceived benefit of the drug therapy;⁷⁸ and (3) the cost of each of the risks and benefits. Also to a lesser extent, the professional advice of the prescriber, or from friends or family experiencing similar problems, may affect one's judgment.

B. Patient-Friendly Language

It is imperative that the disclosure of adverse events be in languages⁷⁹ that the ordinary consumer can understand.⁸⁰ As stated above, it is doubtful that increased disclosure will benefit the public health if not conveyed in a way that makes the additional information understandable. This presents no additional burden on the manufacturer, but rather just a simple translation of a scientific drug side effect to a lay person definition.

C. An Illustration

To illustrate the practical effects of this proposed standard percentile in patient friendly language, the adverse reactions from several recent broadcast advertisements will be compared with the adverse reactions occurring in one percent and greater of the clinical test population in the table below.⁸¹

⁷⁸ For example, a consumer may risk seemingly benign side effects such as headache or nausea in order to prevent a heart attack, but may not be willing to endure those same side effects in order to relieve a runny nose.

⁷⁹ See *Pushing Ethical Pharmaceuticals Direct to the Public*, *supra* note 40, at 921 (stating that drug information is currently not written for the general reader with terms like HMG-CoA, AST, ALT, and 3-alpha-hydroxy metabolites appearing in such advertisements).

⁸⁰ The FDA has recognized that consumers don't have the technical background to understand the professional labeling that accompanies a drug product and recommends the use of "FDA-approved" labeling. "FDA-approved" labeling is labeling intended to be understood by the patient to help them use their medication more effectively and safely. However, the quantity or scope of information that would meet this recommendation is not explained by the FDA. Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314, 24,315 (1996).

⁸¹ Advertised information for Valtrex from: Valtrex commercial (Discovery Channel broadcast, Nov. 13, 1998). (Valtrex commercial is promoting Valtrex for treatment of genital herpes with 500mg twice-daily dosage only. Only that adverse reaction information is required in accordance with FDA regulations, so only that information will be included here); advertised information for Nasonex from: Nasonex commercial (Discovery Channel broadcast, Nov. 13, 1998); adverse drug reaction information from: Valtrex product information (Glaxo Wellcome) & Nasonex product information (Schering Corporation).

	Valtrex	Nasonex
Description	-(valacyclovir hydrochloride, Glaxo Wellcome, Inc.)-indicated for the treatment of genital herpes.	-(mometasone furoate monohydrate, Schering Corporation)-indicated for treatment of nasal symptoms of allergic reactions.
Advertised Adverse Drug Reactions	-nausea -headache	-headache -viral infection -sore throat -nose bleed -coughing
Adverse Drug Reactions (Occurring in 1% or Greater of Clinical Test Population) & [Placebo]	-nausea (6%)[8%] -headache (17%)[14%] -vomiting (1%)<1%] -dizziness (2%)[3%] -abdominal pain (3%)[3%] -dysmenorrhea (painful menstruation) (1%)<1%] -arthralgia (joint pain) (1%)<1%] -depression (0%)<1%]	-headache (26%)[22%] -viral infection (14%)[11%] -sore throat (12%)[10%] -nose bleed (11%)[6%] -coughing (7%)[6%] -upper respiratory infect. (6%)[2%] -dysmenorrhea(painful menstruation) (5%)[3%] -musculoskeletal pain (5%)[3%] -sinusitis (sinus inflammation) (5%)[3%] -(Occurring in pts. between 5% and 2% and more frequently than placebo: arthralgia(joint pain), asthma, bronchitis(chest inflammation), chest pain, conjunctivitis(eye inflammation), diarrhea, dyspepsia(indigestion), earache, flu-like symptoms, myalgia(muscle pain), nausea, rhinitis(nasal inflammation)

The inclusion of placebo-related risk information is an important element in consumer-directed information. This allows the patient to assess their risk of a particular adverse reaction in the absence of the medication. At first, it may seem that the relative risk of many of the above listed adverse reactions are not significantly higher than the placebo percentage. However, the test population (including the placebo group) of the clinical trial consists of individuals with the particular condition that is attempting to be cured. For example, the risk of nose bleed from using Nasonex nose spray is eleven percent compared with a six percent risk in the placebo group. This may not seem like a significant increase, but patients using the spray are experiencing the side effect at a rate that is nearly double their usual risk.

With the inclusion of the above product information in addition to what is currently being disclosed, consumers will have a more complete framework within which to make rational health care decisions. It benefits the public health to have a

federally regulated standard for all broadcast advertisements rather than to allow manufacturers with a largely financial interest to determine the amount of adverse drug information included.

VII. CONCLUSION

The prescription drug industry and the nature of advertising have changed dramatically in the sixty years that have passed since the FDA developed regulations that controlled advertising in the industry. The current FDA regulations regarding prescription drug advertising need to be supplemented or amended to include for more stringent requirements when prescription drugs are advertised directly to consumers.

A standard percentile, over which all adverse reactions must be reported by all manufacturers, is needed to ensure safety and uniformity within the prescription drug industry.

Information provided to consumers about prescription drugs must be complete and unbiased. Additionally, the language used in such advertisements must be in terms that ordinary consumers can understand to allow them to make rational health care decisions for themselves consistent with traditional principles of informed consent.

This increased regulation on the information provided by pharmaceutical companies directly to the public will have the effect of decreasing unwanted drug side effects because the patient will know in advance their statistical risk of such an adverse event. The consumer may then decide, together with doctor recommendations, whether a particular drug therapy is appropriate for themselves and be prepared to accept adverse reactions should they occur.