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NOTE

WHY SO GLUM?
TOWARD A FAIR BALANCE OF COMPETITIVE INTERESTS IN DIRECT-TO-CONSUMER ADVERTISING AND THE WELL-BEING OF THE MENTALLY ILL CONSUMERS IT TARGETS

Erin Lenhardt†

I. INTRODUCTION

You are likely to have seen the ads on television. In one, a forlorn, misshapen oval shuffles across a white field only to encounter a group of contented ovals of which he is too anxious to become a part. When our friend the oval encounters a prescription pharmaceutical; however, its shuffle becomes a bounce, and its frown converts into a grin. Such direct-to-consumer advertising (DTCA) is a product of the last decade,¹ when the Food and Drug Administration (FDA) relinquished a measure of its control over pharmaceutical companies’ advertising strategies.² DTCA “has been defined as ‘promotional efforts by a pharmaceutical company to present prescription drug or drug

† J.D. Candidate, Case Western Reserve University School of Law. I would like to thank Professors Sharona Hoffman and Melvyn Durchslag for their guidance in writing this note. Loving dedication of the note is made to C. Sims Lenhardt for his support throughout law school and during the writing process, to Robin E. Guthrie for her friendship, and to Dan and Connie Spahn for their steadfast encouragement of my legal education. The views set forth herein do not necessarily reflect those of the law firm with which the author is to be associated.

¹ Milton Liebman, FDA Takes the Mystery Out of TV Ads, MED. MARKETING & MEDIA, Sept. 1997, at 34-36 (discussing the beginning of DTCA and outlining requirements for pharmaceutical advertisements on television).

² Nicholas P. Terry, Cyber-Malpractice: Legal Exposure for Cybermedicine, 25 AM. J.I. & MED. 327, 342 (1999) (“The pharmaceutical industry has zealously adopted DTC advertising. The impetus came, of course, when the Food and Drug Administration ... relaxed many of its marketing controls.”) (citations omitted).
Pharmaceutical companies' increased spending on DTCA is evidence of their interest in the proliferation of their brand through exposure to a broad audience of end-users. Indeed, DTCA investing reached $1.3 billion in the United States in the year 2000. Additionally, 8.5 million Americans each year request prescriptions based on the content of DTCA campaigns and subsequently receive those prescriptions from their doctors.

On the other hand, the audience of consumers has important interests at stake. In one regard, consumers benefit from the information in the ads. Arguably, the product information empowers patients to participate more actively in their health care. However, the information in these ads is suspect. Pharmaceutical companies seek to cast their products in a positive light, and conventional marketing wisdom advises that they target the niche which is most vulnerable to their message. Moreover, the one-sided nature of advertising media like magazines, television broadcasts, and even web banners does not promote immediate discourse. Doctors and potential patients cannot rebut the assertions made in the ads, and sometimes do not realize the persuasive effect of the spin contained therein. In many ways, therefore, the audience of potential end-users is held captive to drug companies' rights to advertise. This note will focus on pharmaceutical companies' efforts to target individuals with illness and to carve out a new market among individuals who have been functioning without the

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4 See Marta Wosinska, Just What the Patient Ordered? Direct-to-Consumer Advertising and the Demand for Pharmaceutical Products, HARVARD BUSINESS SCHOOL MARKETING RESEARCH PAPERS, No. 02-04, Oct. 2002, at 1, at http://ssrn.com/abstract_id=347005 (“Only five years ago, ads for prescription drugs were rare, but now some prescription drugs have advertising budgets that top familiar brands such as Pepsi, Budweiser, Dell or Nike.”).
5 Barbara Mintzes, For and Against: Direct to Consumer Advertising is Medicalising Normal Human Experience, 324 BRIT. MED. J., 908, 909 n.2 (2002).
7 See generally PHILIP KOTLER, A FRAMEWORK FOR MARKETING MANAGEMENT 170-187 (2d ed. 2003).
8 Of course, physicians are claimed to act as the “learned intermediary” between the drug companies and consumers, but doctors do not filter the immediate effect of the advertisement upon consumers. See infra note 111, for more explanation of the “learned intermediary” doctrine.
aid of drugs but who may be persuaded into believing that they need pharmaceuticals to help them cope with mental inadequacies.

As a preliminary matter, it is important to understand how DTCA is currently regulated. The Food, Drug and Cosmetic Act (FDCA) is the authority under which the FDA regulates and enforces the sale of prescription drugs in the United States. All drug advertising, including DTCA of prescription drugs, is regulated by the FDA, through its administrative powers. However, unless a drug company requests early review of a draft advertisement, FDA review of pharmaceutical advertisements is only made post hoc, after the public has been exposed to the advertisements. Regulation of advertisements is generally post hoc as well. FDA enforcement includes sending cease and desist and warning letters to offending drug companies and requesting that such companies broadcast remedial advertisements to correct any misrepresentations. The FDA does not have the authority to fine drug companies.

False advertising, therefore, is regulated and punished by the FDA. However, many "truthful" ads, as defined by FDA regulations, continue to enjoy publication and stream into our living rooms to assert that we, or our friends and family, are walking around with latent

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11 See Hearing, supra note 9, at 36: FDA generally cannot require that prescription drug advertisements be reviewed and approved prior to their use. Prior FDA review of advertisements occurs only in very narrow circumstances, primarily for products receiving accelerated approvals. In other words, FDA’s review of promotional materials is intended to occur post hoc – once the materials have appeared in public.

12 Id. at 36, 42-46 (stating that companies are urged to correct any “misimpressions created by false, misleading, or unbalanced materials.”).

problems in desperate need of the aid of prescription drugs. Because DTCA, though legally truthful, may be based on biased and/or misrepresentative information, the interests of consumers, as well as those of drug companies, would be better served were the FDA to conduct an early evaluation of all final drafts of broadcast direct-to-consumer advertisements.

Pharmaceutical companies should make mandatory submissions to the FDA before any DTC advertisement is circulated. Borrowing from marketing research techniques, which are developed to assess the effect of advertising and positioning on the target audience, an early evaluation of DTC advertisements should include focus groups and survey evidence to consider how the ads may affect certain vulnerable or targeted audiences. Then, the advertisement should be evaluated under a balancing test which weighs the drug company’s right to commercial speech and trademark use versus the potential harm to targeted audiences. In order to enhance the potential educational benefit of DTCA, clinical reports and journal articles should more clearly disclose any conflicts of interest.

Part I of this note will present background on how DTCA is currently regulated. Part II will discuss the advantages of DTCA. The first section in Part II will explore legal and market advantages to drug companies. The advantages considered stem from free commercial speech and trademark protection through advertising. The second section in Part II will examine whether DTCA offers consumers any information and empowerment advantage. Part III will address the disadvantages of DTCA. The first section in Part III will examine the concerns that DTCA raises about financial conflicts of interest in research which taint the information that potential and actual patients receive through the advertisements. The second section in Part III will discuss the danger of “medicalization,” or assigning a disease state to non-medical mental complications. Finally, Part IV offers several solutions which will respect American values of freedom of speech and free market economics while protecting consumers’ interests in helpful information about health care.

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II. BACKGROUND

A. Regulation Overview: Prescriptions for Truth in Direct-to-Consumer Advertising

The parameters within which prescription drug companies may advertise are defined by a variety of statutes in addition to common law precedent construing Constitutional commercial speech. First, § 202.1 of Title 21 of the Code of Federal Regulations sets forth, in detail, the manner in which drug companies may advertise. Section 202.1 addresses fine points such as ingredient information placement, the manufacturer’s duty to refrain from hyperbolic trade names, the typeface size of the drug name in relation to that of the manufacturer’s name, and the requirement of a “brief summary” describing potential side effects, efficacy, and contraindications. While § 202.1 relates specifically to prescription drug advertising, other regulations require truth in advertising more generally.

The Lanham Act (the Act) more generally regulates false advertising. Section 43(a) of the Lanham Act regulates false advertising with regard to trademarks:

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15 Commercial speech is considered more extensively with regard to the advantages that drug companies enjoy from DTCA, infra Part II.


17 § 202.1(a)(1) (“The ingredient information required by section 502(n) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter . . . .”)

18 § 202.1(3) (“The advertisement shall not employ a fanciful proprietary name for the drug or any ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, the drug or ingredient is a common substance . . . .”).

19 § 202.1(b)(2):

The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(emphasis added).

20 § 202.1(e) (defining the “brief statement” and declaring when it must appear in an advertisement: “True statement of information in brief summary relating to side effects, contraindications, and effectiveness . . . [is required for advertisements] broadcast through media such as radio, television, or telephone communications systems . . . .”).

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.²²

The Lanham Act was originally enacted in 1946 pursuant to the United States' entry into numerous treaties to protect the country against unfair international trade customs²³ and amended in 1988 to regulate false advertising more specifically.²⁴ Though some courts have implied that the Lanham Act protects consumers in general,²⁵ the majority of courts have held that the Lanham Act is focused not on consumer protection, but on unfair competition.²⁶ As such, the long-standing and current reality is that the Act does not provide standing

²³ MATTHEW BENDER, 2-15 THE LAW OF ADVERTISING (MB) § 15.02 (2004): During the early part of the twentieth century, the United States entered into a number of treaties in order to protect itself and other countries from unfair international trade practices. Certain provisions of these treaties obligated the United States and the other signatories to enact domestic laws for implementation. As a result, the Lanham Act, a comprehensive law dealing primarily with trademark protection, was enacted by Congress in 1946.
²⁴ Id. ("Section 43(a) was amended in 1988 to specifically denote false advertising as a cause of action within its purview.").
²⁶ Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1383 (5th Cir. 1996) ("[M]ost courts that have addressed the issue agree that in light of the pro-competitive purpose language found in § 45, 'consumers fall outside the range of 'reasonable interests' contemplated as protected by the false advertising prong of Section 43(a) of the Lanham Act.'" (quoting Serbin v. Ziebart Int'l Corp., 11 F.3d 1163, 1177 (3d Cir. 1993))).
for individual consumer suits.\(^{27}\) Nor does a state have standing to bring a suit on behalf of consumers under the Lanham Act.\(^{28}\)

Under the theory that the Lanham Act covers unfair competition, courts have interpreted the Act to allow recovery to commercial entities that can prove they have been harmed by a competitor’s false or misleading advertising.\(^{29}\) For such plaintiffs, the Lanham Act permits two categories of recovery.\(^{30}\) Advertising may be (1) false on its face; or (2) literally true but likely to confuse and/or mislead in the context in which it is marketed or sold.\(^{31}\) If an advertisement is patently false,

\(^{27}\) See id.

\(^{28}\) E.g. Florida ex rel. Broward County v. Eli Lilly & Co., 329 F. Supp. 364 (S.D. Fla. 1971) (holding that a state, on behalf of its consumer-citizens who were harmed by deceptive prescription drug practices, does not have standing under either the Lanham Act or the Federal Food, Drug and Cosmetic Act). See also MATTHEW BENDER, 2-15 THE LAW OF ADVERTISING (MB) § 15.02 (2004):

The state brought a class action on behalf of itself and consumers against the defendant drug company alleging, in a second amended complaint, in part, that the class had sustained damages as the result of false representations by defendant regarding the effectiveness of certain drugs, giving rise to a cause of action under Section 43(a). The court held that members of the general public, as consumers rather than competitors, have no right of action under the Lanham Act. In reaching this conclusion, the court relied on the purpose of the Act . . . as well as on certain writers in the field.


\(^{31}\) Id. at n.2 (citing examples of courts interpreting two theories of recovery):


Second Circuit: Johnson & Johnson v. GAC Int’l, Inc., 862 F.2d 975, 9 U.S.P.Q.2d 1316 (2d Cir. 1988); Johnson & Johnson Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp., 960 F.2d 294, 22 U.S.P.Q.2d 1362 (2d Cir. 1992) (claiming that “In order to recover damages or obtain equitable relief, a plaintiff must show that either: 1) the challenged advertisement is literally false, or 2) while the advertisement is literally true it is nevertheless likely to mislead or confuse customers.”) id.; S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232, 57 U.S.P.Q.2d 1912 (2d Cir. 2001) (ad which is literally false requires no proof of the ad’s meaning to the public).

Third Circuit: Castrol, Inc. v. Pennzoil Co., 987 F.2d 939, 25 U.S.P.Q.2d 1666, 1669 (3d Cir. 1993) (“Thus, there are two different theories of recovery for false advertising under Section 43(a) of the Lanham Act: ‘(1) an advertisement may be false on its face; or (2) the advertisement may be literally true, but given the merchandising context, it nevertheless is likely to mislead and confuse consumers.’”) id.; Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., 290 F.3d 578, 62 U.S.P.Q.2d 1757 (3d Cir. 2002) (“If a plaintiff proves that the chal-
courts will hold the ad in violation of the statute even absent evidence regarding how consumers are affected by the message in the ad.\(^3\) However, when an advertisement is only implicitly false—meaning that the advertisement is \textit{per se} true but nonetheless likely to mislead consumers—market research is conducted to ascertain whether consumers will, in fact, be misled by the advertisement in question.\(^3\) The market research used to investigate whether an ad is implicitly false includes consumer questionnaires, surveys and focus groups, which must be considered as evidence of how consumers perceive the message in the advertisement.\(^3\) Also, at any stage beyond preliminary

\(^{32}\) Id. at \S 27.55.

\(^{33}\) Id.; Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982) (holding that Coke is entitled to an injunction if Tropicana’s statement that it is the only orange juice not made with concentrate and water is found to be a misrepresentation); and Jacob Jacoby et al., \textit{Survey Evidence In Deceptive Advertising Cases Under The Lanham Act: An Historical Review of Comments From the Bench}, 84 TRADEMARK REP. 541, 542-47 (1994).

\(^{34}\) McCarthy, \textit{supra} note 30, at \S 27:55. A helpful explanation of how survey evidence is used to prove that the challenged ad is misleading is provided in Jacoby, \textit{supra} note 33, at 544, stating:

While consumers’ beliefs about what the ad is saying . . . and their beliefs about the product itself . . . may be correlated, the key to assessing likely deception concerns the former. Surveys seeking to measure likely consumer deception need to focus on what the consumer believes \textit{the ad said or implied} about the product . . . not necessarily on what the consumer believes about the product itself . . . Consumer surveys would also be relevant for assessing “materiality,” i.e., whether the incorrect understanding then made a difference in the consumers’ decision and purchasing behavior.
injunction, it is important that market research and survey evidence elicit how consumers have actually reacted to the advertisement versus how they may have reacted.\(^{35}\)

In addition to regulation of advertising under the Lanham Act, discussed above, § 5 of the Federal Trade Commission Act (FTCA), 15 U.S.C. § 45,\(^{36}\) regulates misleading and false advertising. Specifically, § 5, entitled “Unfair Methods of Competition,” announces that deceptive or unfair business practices are unlawful.\(^{37}\) Regulation under the FTCA has been controversial and has spurred debate on issues such as federalism, the threat of over-reaching regulation, and whether the FTC could restrict unfair advertising which is not deemed to be false or deceptive.\(^{38}\) But President Clinton reauthorized the FTC in 1994 for the first time since 1980.\(^{39}\) As such, the FTC may not determine that an act is unfair and thus unlawful\(^{40}\) “unless the act or practice causes or is likely to cause substantial injury to consumers that is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.”\(^{41}\) Each state has adopted its own version of the FTC regulations in section 5 to define deceptive, unfair and/or misleading business practices.

(emphasis added).

\(^{35}\) McCarthy, supra note 30, at § 27:55.

\(^{36}\) 15 U.S.C. § 45 provides, in pertinent part:

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C. § 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C. § 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(emphasis added).

\(^{37}\) Bruce I. McDaniel, Annotation, What Constitutes “False Advertising” of Drugs or Devices Within §§ 5 and 12 of the Federal Trade Commission Act (15 USCS. §§ 45, 52), 49 A.L.R. Fed. 16, 24 (1980) (discussing federal cases and FTC decisions concerning the illegality of unfair or deceptive advertising of drugs or devices).

\(^{38}\) DeVore, supra note 21, at 384.

\(^{39}\) Id.

\(^{40}\) Id.

These acts are sometimes called "Little FTC Acts." The acts differ from state to state, but "they have in common a core set of standards forbidding 'unfair' or 'deceptive' practices, as well as provisions for governmental and private enforcement of the acts."

Having broadly considered the way in which truth in advertising generally, and DTCA specifically, is regulated, the advantages of DTCA may be more readily ascertained. The following section begins with advantages from the point of view of pharmaceutical companies.

III. DTCA: THE ADVANTAGES

Among the advantages of DTCA are (1) freedom of commercial expression; (2) maximization of investments in product quality through trademark law; and (3) consumer empowerment through direct access to relevant healthcare information. In the sections which follow, these advantages are explored in greater depth.

1. Freedom of Expression

One arguable advantage of DTCA is that it encourages free expression. Under the First Amendment, pharmaceutical companies are enabled to communicate their marketing messages because these messages are protected as commercial speech. The right to commercial speech was first addressed and rejected by the Supreme Court in 1942 in Valentine v. Christensen.

The right to commercial speech was first addressed and rejected by the Supreme Court in 1942 in Valentine v. Christensen. Cur-
rently, however, commercial speech enjoys extensive protection, especially in light of recent Supreme Court cases. Contemporary commercial speech regulation began with *Virginia Pharmacy Board v. Virginia Citizens Consumer Council (Virginia Pharmacy).* In *Virginia Pharmacy*, the Supreme Court held that speech proposing a commercial transaction is protected under the First Amendment both as (1) a commercial right to advertise and (2) a public right to receive advertising. Following *Virginia Pharmacy*, the Supreme Court, in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n (Central Hudson)* determined that freedom of commercial speech enables consumers to determine their best interests based on information gleaned through open communication. Accordingly, the Supreme Court has rejected governmental suppression of commercial information as paternalistic. The Court has taken a firm stance in favor of commercial expression, even where the content proclaimed to be factual and informative is, in actuality, incomplete.

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48 Id. at 757 ("If there is a right to advertise, there is a reciprocal right to receive the advertising, and it may be asserted by these appellees.").


50 Id. at 561-562 ("The First Amendment, as applied to the States through the Fourteenth Amendment, protects commercial speech from unwarranted governmental regulation. Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information") (citation omitted). See also Linmark Assocs., Inc. v. Willingboro, 431 U.S. 85, 92 (1977) (stating that the "free flow of commercial information" is an important societal interest regardless of the commercial subject matter).

51 *Central Hudson*, 447 U.S. at 562 ("[P]eople will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication, rather than to close them," citing *Va. Pharmacy*, 425 U.S. at 770.).

52 *Central Hudson*, 447 U.S. at 562 ("Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all," citing *Bates v. State Bar of Arizona*, 433 U.S. 350, 374 (1977)).
Though it has been modified by more recent cases,53 the test adopted by the Supreme Court in *Central Hudson* is the standard to be applied to cases wherein commercial speech is contested. First, the test demands an inquiry into whether the expression is protected by the First Amendment. In order to survive the *Central Hudson* test: (1) the speech must concern lawful activity and must not be misleading; (2) the government interest in regulating commercial speech must be substantial; (3) regulation of the speech must directly advance the government interest asserted; and (4) regulation must be no more extensive than necessary to serve the interest asserted.54 The Supreme Court has used this test to reach a variety of outcomes, some protecting the freedom of commercial speech, and some favoring regulation of speech.55 Significantly, recent Supreme Court cases, such as *44 Liquormart, Inc. v. Rhode Island*66 and *Thompson v. Western States*

53 See, e.g., *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) (renumbering the governmental balancing test as part one and considering the inquiry into the legality and truth of the speech as a prerequisite to applying the test); and *Brody*, *supra* note 46, at 383 (citing *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (moving closer to strict scrutiny review of regulations limiting commercial speech by rejecting the paternalism underlying commercial speech limitations and placing the burden on the government to show why it did not adopt plaintiff’s given alternative to regulating commercial speech.).

54 Central Hudson, 447 U.S. at 563-66; Alex Kozinski & Stuart Banner, *Who’s Afraid of Commercial Speech?*, 76 Va. L. Rev. 627, 630 (1990); see also *DeVore*, *supra* note 21, at 349.

55 Compare *San Francisco Arts & Athletics, Inc. v. United States Olympic Comm.*, 483 U.S. 522, 539 (1987) (supporting a federal trademark statute’s restrictions on use of the word “Olympic” in commerce as “not broader than Congress reasonably could have determined to be necessary”); and *Went for It, Inc.*, 515 U.S., at 618 (upholding a Florida ethical rule forbidding plaintiffs’ attorneys from soliciting business through direct mailings to accident victims and their families in the first 30 days after the tragedy) with those favoring free speech over regulation, *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 412 (holding that Cincinnati’s city-wide ban on news-racks distributing advertising pamphlets was an infringement of commercial speech); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1995) (affirming the Tenth Circuit’s holding that a regulation which prohibited beer labels from indicating the alcohol content advanced no government interest in “a direct and material way” and, as such, violated the First Amendment protection of commercial speech); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (finding Rhode Island prohibitions against advertising the price of alcoholic beverages unconstitutional); and *Thompson*, 535 U.S. at 357 (permitting pharmacists to advertise specific compounded drugs and strengthening commercial speech rights by emphasizing that regulating speech must be a last resort and must not serve paternalistic ends). *See also DeVore*, *supra* note 21, at 349 (canvassing the history of commercial speech in the Supreme Court).

56 See 44 Liquormart, *supra*, 517 U.S. at 503:

Precisely because bans against truthful, nonmisleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest solely on the offensive assumption that the public will re-
Medical Center (Western States) have substantially expanded the right to commercial speech. Western States is especially relevant not only because it was recently decided, but also because the case considered regulation of drug advertising.

In Western States, decided in 2002, the Court considered the constitutionality of portions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The challenged portions of the FDAMA concerned regulations on drug compounding. Drug compounding is the alteration or weakening of prescription drugs on a doctor’s instruction. The FDAMA restrictions at issue prohibited pharmacists from advertising certain compounded drugs. Affirming the Ninth Circuit, the Court invalidated the speech restrictions in the FDAMA and rejected paternalistic regulations of commercial speech as per se invalid. The court focused on the fourth prong of the Central Hudson test and found that the fourth prong was not satisfied because means unrelated to speech restrictions could address the State interest in keeping people from convincing doctors to prescribe unnecessary drugs. Significantly, however, the first prong of the Central Hudson test was not at issue, as the government did not argue that the advertisements at issue were misleading. This leaves open a possibility for protecting consumers’ rights to truth in advertising through common law where statues, such as the Lanham Act, do not provide consumers with standing.

Another recent Supreme Court opinion is particularly relevant to this paper. In Lorillard v. Reilly, the court held that Massachusetts unfair or deceptive trade regulations on tobacco sales to minors withstood a Central Hudson analysis. Specifically, the Massachusetts regulations prohibited unattended self-service displays of tobacco products in order to prevent minors from accessing tobacco products without interacting directly with a salesperson. The majority reasoned that the State had a substantial interest in curtailing tobacco

spond “irrationally” to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.

Id. at 360.
Brody, supra note 53, at 382.
Thompson, 535 U.S. at 360.
Id. at 377.
Id. at 376.
Id. at 368.
Id. at 570.
Id. at 569.
sales to minors and that the State's means were narrowly-tailored where the regulations related to product placement and not necessarily expression. Further, the Court emphasized that the State legislature left open alternative means for vendors to communicate information about products and for consumers to glean product information.\(^{67}\)

*Lorillard* may be construed as allowing an exception, for minors, to the rule that paternalistic regulations are *per se* invalid under the First Amendment.\(^{68}\) But it is also clear that the court held open the possibility that regulations, notwithstanding their arguable paternalistic nature, will pass First Amendment muster as long as the State interest is substantial, another legal interest is advanced (i.e. preventing underage purchase of tobacco), and other avenues of commercial communication are left open for the advancement of commercial communication and consumer information.\(^{69}\) What is clear, however, is that the Court specifically chose not to do away with the *Central Hudson* test as the benchmark for First Amendment decision-making.\(^{70}\)

In sum, drug companies, like most for-profit enterprises, have an interest in freedom of speech in advertising. The law protects commercial speech under the First Amendment as long as it survives the *Central Hudson* test, which attempts to regulate false information and balance freedom of commercial expression with government interests.\(^{71}\) Remember, however, that under the *Central Hudson* test and statutes discussed in Part I, speech which is false, misleading or illegal may be regulated by the government. However, recent expansion of pharmaceutical companies' rights to communicate through DTCA,\(^ {72}\) and even more recent Supreme Court decisions narrowing government control under the *Central Hudson* test,\(^ {73}\) are encouraging an expanding right to commercial expression. One specific commercial interest in expression is the control and maintenance of branding through trademarks.

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\(^{67}\) *Id.* at 568-71.

\(^{68}\) *See id.* at 580-81 (Thomas, J., concurring in part and concurring in judgment).

\(^{69}\) *Id.* at 570-71.

\(^{70}\) *Id.* at 554-55.

\(^{71}\) *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 563 (1980) ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.").

\(^{72}\) *See McLellan, supra* note 6, at 1951 ("Since [1997 when regulations on DTCA were relaxed], DTC advertising, much of it on television, has risen by nearly 150%.").

\(^{73}\) *See supra* notes 54, 57-63 and accompanying text.
2. DTCA Facilitates Public and Private Benefits Afforded by Trademark Law

Significantly, and as discussed below, trademark policy is rooted in considerations of both consumer and commercial interests. Incongruently, despite this emphasis on consumer interests, as discussed above, the Lanham Act, which governs trademark law at the statutory level, does not provide a private cause of action for consumers. The following section will explore how companies' protection of branding through trademark and consumers' interests in commercial information are furthered through direct to consumer advertising.

From a business perspective, drug companies may attain a return on their research and development investments by establishing a trusted brand name which consumers request from their physicians. Drug companies expend considerable capital and effort in order to create and promote a brand whose strength conveys a positive message to a broad base of consumers. In fact, a pharmaceutical consulting firm, IMS Health, reported that the pharmaceutical industry spent more than $19 billion in 2001 on advertising, including DTCA. This figure only includes spending in the United States. Therefore, drug companies often request that the FDA remark on "draft" advertisements in order to avoid wasting resources on advertisements that will be discontinued by the government. Accordingly, a rule requiring review would not only be the logical next step but also should be initiated in order to protect both consumer interests and the financial interests of corporations.

The typical consumer advantages conceived by trademark law are specious with regard to drug advertising. For example, one benefit of DTCA may be that consumers gain a short-cut to remembering which drug company provided them with a quality cure for their ailment. While this is considered a benefit to consumers of most products, because their search costs are decreased when making a repeat purchase or when purchasing from a company with whom they have associated a measure of quality, this benefit is not so strong with DTCA of pharmaceuticals. With prescription drugs, the doctor, not the consumer/patient, ultimately makes the determination of treatment, and

74 See Wosińska, supra note 4, at 1 (discussing the large amount of capital spent on DTCA).
75 Antonuccio, supra note 13, at 1029 (discussing drug companies' exceptional marketing spending).
76 Accordingly, a rule requiring review would not only be the logical next step but also should be initiated from the point of view of protecting specific consumer interests as well as the financial interests of corporations. See Wosińska, supra note 4, at 8 n.11.
patients cannot purchase prescription medications on their own, without first visiting a doctor.\textsuperscript{77}

The American market economy encourages advertising because, for example, the economics-driven legal regime of trademark law provides greatest protection for those companies who have established strong brand names.\textsuperscript{78} Further, a trade name's strength is partially defined by how readily and widely recognized it is in the public mind.\textsuperscript{79} Indeed, the spectrum which determines the strength of a word used as a trademark considers whether a word has developed "secondary meaning."\textsuperscript{80} A trademark acquires secondary meaning when the public associates the product bearing the trademark with a specific, even if anonymous, source.\textsuperscript{81} Advertising and sale in commerce are necessary for a trademark to achieve secondary meaning.\textsuperscript{82} For an example of how secondary meaning works, take Chevron gasoline. The word “Chevron” means v-shaped in English. However, after use of the term in advertising and in the marketplace, consumers identify Chevron with a specific source of gasoline. Through this association, the owners of the Chevron trademark can direct consumers to their resources and services. Also, consumers can depend on a particular quality of service when patronizing a Chevron station. Once secondary meaning is achieved in the marketplace, a trademark receives a wider girth of protection against any potential or actual infringers.\textsuperscript{83} Specifically, a company is unlikely to successfully claim that it unintentionally infringed a well-known mark, and an infringer can bring

\textsuperscript{77} On the other hand, it seems the very reason that drug companies spend enormous capital on DTCA is in order to encourage patients to lead their physicians to a branded prescription.

\textsuperscript{78} James Burrough, Ltd. v. Sign of the Beefeater, Inc., 540 F.2d 266, 276 (7th Cir. 1976):

A mark that is strong because of its fame or its uniqueness, is more likely to be remembered and more likely to be associated in the public mind with a greater breadth of products or services, than is a mark that is weak because relatively unknown or very like similar marks or very like the name of the product.

\textsuperscript{79} \textit{Id.}

\textsuperscript{80} \textit{See} Abercrombie & Fitch Co. v. Hunting World, Inc. 537 F.2d 4, 9 (2d Cir. 1976) (defining the spectrum of mark strength).

\textsuperscript{81} \textit{KINNEY & LANGE, P.A., INTELLECTUAL PROPERTY LAW FOR BUSINESS LAWYERS} § 10.4.1 (1996) ("A trademark ... acquires secondary meaning when consumers associate the product with a single, perhaps anonymous, source.").

\textsuperscript{82} \textit{Id.} ("The two primary ways of showing secondary meaning are by demonstrating extensive advertising, which presumably results in extensive recognition, or by conducting a survey.").

\textsuperscript{83} \textit{See generally} MATTHEW BENDER, TRADEMARK PROTECTION AND PRACTICE (MB) § 2.09 (2003) (discussing trademark strength and secondary meaning).
fewer defenses against a mark with secondary meaning. In order to maximize protection from infringement under the Lanham Act, a mark must be registered and "used" in commerce. A mark can even gain "incontestability" through use.

From a marketing perspective, one private interest protected by trademark law is "brand equity" achieved through broad recognition of a trademark or trade name. Brand equity is the positive differential effect that knowing the brand name has on customer response to the product or service. High brand equity allows a company to enjoy reduced marketing costs because of high brand awareness and loyalty, gives a company more leverage in bargaining with distributors and retailers, permits the [company] to charge more because the brand has higher perceived quality, and offers some defense against price competition.

Among the other benefits of a strong trademark are (1) source-identification, whereby a consumer identifies a particular brand with a manufacturer; (2) protection of goodwill, which can be defined as creating and protecting consumers' positive mental association with a good; and (3) the ability to protect a trademark which has become famous from dilution. Dilution is the erosion of a trademark's

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84 A policy rationale for a wider girth of protection for trade names which have achieved secondary meaning or are fanciful, non-standard English words is, in part, because it is undesirable that a merchant should have a monopoly on the common descriptive use of a word. For example, "Apple" is protected when it arbitrarily applies to computers but would go unprotected if applied to an orchard.

Defenses such as claiming that a trademark has become generic or claiming good faith limited geographic rights to a trademark are factually weaker when the senior user of a trademark mark has achieved secondary meaning.

[T]he right of the registrant to use such registered mark in commerce for the goods or services on or in connection with which such registered mark has been in continuous use for five consecutive years subsequent to the date of such registration and is still in use in commerce, shall be incontestable . . . .

86 Park 'N Fly, Inc. v. Dollar Park & Fly, Inc., 469 U.S. 189, 192 (1985) ("Incontestable status provides, subject to the provisions of § 15 and 33(b) of the Lanham Act, 'conclusive evidence of the registrant's exclusive right to use the registered mark . . . .').

87 Kotler, supra note 7, at 218.

88 See generally JANE C. Ginsburg et al., TRADEMARK AND UNFAIR COMPETITION LAW 44-47 (3d ed. 2001) (discussing the general properties of trademark excerpted from William Borchard, A TRADEMARK IS NOT A PATENT OR A COPYRIGHT (2000)).
uniqueness. And because trademarks generally increase in strength with public association between the mark and the good to which it refers, drug companies have an interest in making their trademark known to a broad audience. Through DTCA, drug companies can gain increased trademark strength because patients, as well as doctors, come to know which drug companies produce which pharmaceuticals. Capitalizing on this, DTCA on television and in print includes the manufacturer's brand name as well as the name of the branded drug.

There is also a consumer, or public, interest protected by trademark law. A cause of action for trademark infringement protects business investments through assurance that no second-comer can trade off the goodwill established by a company's labor and expenditure. Accordingly, one policy rationale behind protecting trademarks is that consumers benefit from trademarks due to decreased search costs. For example, a consumer who comes to expect and

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89 Allegedly unconcerned with consumer confusion and concerned entirely with the value of the trademark owner's property, dilution is perhaps the most property-oriented of a trademark holder's intellectual property rights. Dilution stands on uncertain ground, however, since the Supreme Court narrowed the scope of a dilution claim. Moseley v. V Secret Catalogue, Inc., 537 U.S. 418, 432-35 (2003) ("[T]he mere fact that consumers mentally associate a junior user's mark with a famous mark is not sufficient to establish actionable dilution). See also Frank I. Schechter, The Rational Basis of Trademark Protection, 40 HARV. L. REV. 813, 825-31 (1927) (describing dilution as a novel rationale for protecting trademarks as property).

90 Goodwill can be defined as a reputation for consistent quality.


(1) Any person who shall, without the consent of the registrant—
(a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or
(b) reproduce, counterfeit, copy, or colorably imitate a registered mark and apply such reproduction, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive,
shall be liable in a civil action by the registrant for the remedies hereinafter provided.

92 See Smith v. Chanel, Inc., 402 F.2d 562, 566 (9th Cir. 1968): Preservation of the trademark as a means of identifying the trademark owner's products, implemented both by the Lanham Act and the common law, serves an important public purpose. It makes effective competition possible in a complex, impersonal marketplace by providing a means through which the consumer can identify products which please him and
appreciate a certain quality from Crest toothpaste can efficiently make buying decisions with regard to oral hygiene products. In this way, a trademark acts as a shorthand guarantee of quality. Trademark infringement suits, then, protect not only a business interest in communicating that quality to the consumer, but also the consumer interest in spending less time searching for a quality product or service. In addition to benefits associated with trademark law, consumers may directly benefit from the informational content of DTCA. The following section explores whether information in DTCA does, in fact, provide a benefit to consumers.

3. The Advantages of DTCA to Consumers: Education and Autonomy

One rationale for DTCA is that consumers benefit from the information in DTC advertisements. Arguably, the product information empowers patients to participate more actively in their healthcare, which leads to greater autonomy.

In order for the information in the DTCA to benefit consumers, consumers must have a need for the information. In *American Attitudes Toward and Willingness to Use Psychiatric Medications*, Doctor Thomas Croghan et al. argue that those in need of treatment for mental illness are under-served. According to the authors, in any given year, up to 44 million Americans suffer from a diagnosable mental illness. The authors’ study, however, reveals that skepticism shades Americans’ attitudes about medical treatment for psychological disorders. Indeed, while respondents to the study claimed that they believed psychiatric medications to be effective, their responses revealed that they were unlikely to take such medications. The authors de-
terminated no complete explanation for this gap between attitude and behavior. However, several theories were suggested. One theory is that the stigma surrounding mental illness deters disclosure. Accordingly, the authors argue that, despite the research and analysis of other experts, DTCA does not necessarily lead to unnecessary use of prescription drugs. On the contrary, advertising may help to remove the stigma associated with mental impairment. As a result, people may become more willing to consider helpful treatment.

The FDA conducted a survey in 2002 wherein it polled about 500 physicians to determine the effect of DTCA on the physician-patient relationship. The results became available in the fall of 2003. According to the survey, “[s]ome physicians thought the ads made their patients more aware of possible treatments.” Also, “[m]any physicians reported that they thought DTC ads made their patients more involved in their health care.” These results support the argument that DTCA induces consumers to become more autonomous and informed about how, or if, to treat their ailments. Further, many studies suggest that patients are more open to new treatments when they are informed about their disease and that advertising’s suggestion that depression is a widespread condition will de-stigmatize mental illness over time. In theory, this would lead to greater communication about and necessary treatment of mental illness.

However, physicians have reported the detriments of patients’ perceived empowerment through incomplete information from DTCA. One doctor compared his physician’s office to a fast food drive-through window whereby patients expect their orders to be exactly and expeditiously filled. Others describe the patient/physician

the discrepancy between the level of need for mental health services and the actual use of medical treatments.

98 Id.
99 Id. (“[T]he gap may be explained in part by the stigma associated with mental illness that evokes fear and embarrassment about disclosure, deterring persons from seeking treatment.”).
100 The authors cite to Thomas W. Croghan, The Controversy of Increased Spending for Antidepressants, 20 HEALTH AFF. 129, 130 (2001).
101 Croghan, supra note 94, at 173.
102 Hearing, supra note 9, at 47.
103 Id. at 48.
104 Id.
105 Mark A. Graber & Michelle Weckmann, Pharmaceutical Company Internet Sites As Sources of Information About Antidepressant Medications, 16 CNS DRUGS 419, 422 (2002).
106 Id.
relationship since DTCA as a negotiation, rather than a counseling and treatment session, where patients are open to help from their doctor. In the next section, this note will explore in more depth some disadvantages of DTCA, specifically with respect to consumers with mental illness.

IV. DISADVANTAGES OF DTCA

This section will examine case studies which illuminate some disadvantages of DTCA vis-à-vis those who may suffer from a mental illness. These disadvantages include (1) financial conflicts of interest which taint the information consumers, potential and actual patients, receive via DTCA; and (2) the medicalization of mental and/or emotional frailty.

1. Financial Conflicts of Interest and Their Effect on Educating the Consumer

Though one benefit of DTCA is its informative value, it is important to understand that DTC ads do not provide information as a public service. Even with a physician acting as the gatekeeper to prescription drugs, consumers' interest in truth in DTCA deserves vigilant protection. As discussed above, a pro-DTCA approach may describe the advertisements as informative because they enable consumers to counter-balance market inefficiencies such as "imperfect consumer information." To illustrate, when a traditional firm advertises, the informative content of the advertisement will, theoretically, help consumers make efficient choices about how to allocate their scarce resources of time and money. The goal of informative advertising is to acquaint consumers with new products or to educate consumers about the new attributes of existing products. However,

108 Id. at 287-88.
109 Friedman v. Rogers, 440 U.S. 1, 12-13 (1979) ("[A]ssociations of trade names with price and quality information can be manipulated by the users of trade names [and] there is a significant possibility that trade names will be used to mislead the public.").
110 See Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966): "[T]he purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.
111 Wosińska, supra note 4, at 4 (stating the benefits of "informative" advertising).
112 Id.
113 Kotler, supra note 7 at 312.
drug companies, like all firms that advertise, ultimately seek financial gain, so with the information comes an attempt to persuade. Persuasive advertising targets consumer desires and vulnerabilities and ultimately seeks to create changed or new consumer needs. This section is concerned with how DTCA affects the particular vulnerabilities of consumers who may suffer from mental illness.

Attention to magazines, billboards, television, and radio will reveal that those who may suffer from mental illness are targeted heavily by pharmaceutical companies. Further, research on DTCA spending exposes drug companies' focus on marketing psychotropic drugs. Indeed, a study supported by the Henry J. Kaiser Family Foundation chose antidepressants as one of five therapeutic classes to track in order to study DTCA across the pharmaceutical industry because they are among the most heavily advertised and best-selling pharmaceuticals. It seems the marketing efforts are succeeding, since sales of antidepressants are exceptionally high. A December 2003 article in the American Psychologist points out that antidepressants are now the "top selling drug category." And, of all the marketing strategies used to sell their pharmaceuticals, DTCA is

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114 Id.
115 Wosińska, supra note 4, at 4-5 ("[Persuasive advertising] alters consumers' tastes and creates spurious product differentiation and brand loyalty.").
117 Meredith B. Rosenthal et al., Promotion of Prescription Drugs to Consumers, 346 NEW. ENG. J. MED. 498, 499 (2002) (These drugs were studied specifically "because they rank among the top 20 therapeutic classes in terms of sales and contain at least one product for which there is substantial spending on [DTCA].").
118 Antonuccio, supra note 13, at 1029.
119 Id. at 1029-30:

Consumer Reports has documented drug industry marketing strategies ("Miracle Drugs," 1992; "Pushing Drugs," 1992) that include but are not limited to the following: (a) giving free samples and information to doctors, (b) advertising in medical journals, (c) using "ask your doctor" media ads aimed directly at the consumer . . . (d) sponsoring promotional dinner meetings with substantial gifts or even cash provided to attendees, (e) paying consultants to speak at scientific meetings in which it is possible to circumvent FDA guidelines that require disclosure of side effects, (f) funding only those research projects that have a high likelihood of producing favorable results for a particular drug company's product . . . (g) terminating negative studies before they are ready for publication, (h) involving large numbers of physicians in studies not intended to yield publishable information but simply designed to yield maximum product exposure, (i) including "look-alike" publication supplements (i.e., non-peer-reviewed articles underwritten by a drug company that appear in a special issue of a peer-review journal) in
thought to have the "most profound effect."\textsuperscript{120} To summarize, those with mental illness are now heavily targeted by DTCA and antidepressants are marketed aggressively so that they remain among the top-selling prescription drugs.\textsuperscript{121}

The recent FDA study highlights some of the detrimental ways in which DTCA efforts are affecting prescribing habits of physicians.\textsuperscript{122} On a positive note, forty percent of physicians reported their belief that patients are able to comprehend the possible negative side-effects and risks associated with a drug from the DTCA alone.\textsuperscript{123} However, many physicians reported that they feel "pressure to prescribe something when patients mention DTCA ads."\textsuperscript{124} Eight percent of physicians admitted that in past interactions with patients who requested a specific drug by brand name they felt "very pressured" to prescribe the exact drug requested.\textsuperscript{125} Twenty percent felt "somewhat pressured" in the same circumstances.\textsuperscript{126} Many doctors felt that they needed to provide patients with information in addition to that which patients parroted from the direct-to-consumer ads.\textsuperscript{127} About seventy-five percent of physicians reported that their understanding of DTC ads is that they cause patients to overestimate the efficacy of the drugs advertised.\textsuperscript{128} One could argue that, given these statistics, there may be a Lorillard-type\textsuperscript{129} exception to the \textit{per se} invalidity of paternalistic regulation of speech where mentally impaired patients bombarded with DTCA are unable to decipher truth in the ads. A stronger argument, however, and one that avoids this sort of paternalism-within-paternalism, is that

\begin{itemize}
  \item professional journals, (j) offering to pay journalists to cover their products,
  \item (k) offering pre-packaged information for journalists in the form of video news releases that give the appearance of having been independently developed . . . and (l) helping to fund patient advocacy and other public interest groups so the consumer group appears to be publicly carrying the banner of a particular drug.
\end{itemize}

\textsuperscript{120} Id. at 1030.
\textsuperscript{121} Id. at 1029-30.
\textsuperscript{122} Although the study is interpreted by the FDA to reveal the positive effects that DTCA has had on the physician/patient relationship, the results reproduced herein depict some of the negative effects of DTCA on that relationship. It is important to emphasize that the results are based on physicians' perceptions. Reporting on those perceptions is constrained by what physicians are willing to admit.
\textsuperscript{123} Hearing, supra note 9, at 48.
\textsuperscript{124} Id.
\textsuperscript{125} Id.
\textsuperscript{126} Id.
\textsuperscript{127} Id.
\textsuperscript{128} Id.
\textsuperscript{129} See discussion of \textit{Lorillard v. Reilly} in Part II, subpart 1 of this note.
misleading information in DTCA fails the first prong of the *Central Hudson* test.

A previous study supported by the Henry J. Kaiser Family Foundation noted that research justifies DTCA critics’ fears about wasteful and improper prescribing.\(^{130}\) In fact, patients’ demands for specific drugs have been reported as the most serious hindrance to appropriate prescribing.\(^{131}\) Where a doctor has understandable financial concerns about acquiring and maintaining patient relationships, s/he may not be the buffer once hoped for between biased information in DTCA and the self-prescription of drugs.\(^{132}\)

Though DTCA does contain some information for consumers, this information is slanted. The pharmaceutical industry wields significant financial influence over the studies and clinical information that patients ultimately receive,\(^{133}\) so the scope and depth of pure information available to consumers is limited by corporate interests.\(^{134}\) For example, Upjohn, which produces the drug Xanax, supported a much-anticipated study on treatment of panic disorder and agoraphobia.\(^{135}\) However, when it appeared that the study’s results would show that Xanax actually interfered with treatment, Upjohn not only suddenly

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\(^{130}\) Rosenthal, *supra* note 118, at 498.

\(^{131}\) *Id.* at 503 ("[C]oncern may be justified by previous findings that demand by patients is the most common reason offered by physicians for inappropriate prescribing.").

\(^{132}\) Making physicians directly accountable to patients, the learned intermediary doctrine shields drug companies from liability to patients where drug companies have provided physicians with adequate warning of adverse effects. Armed with information from pharmaceutical companies, the physician acts as the learned intermediary between drug companies and consumer-patients. *See generally* Mitchell S. Berger, Note, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion*, 55 FOOD & DRUG L.J. 525, 528 (2000) (referring to the chief rationale for the learned intermediary doctrine: "that the doctor rather than the patient ‘makes the decision to use a particular prescription drug’") (citation omitted).

\(^{133}\) Antonuccio, *supra* note 13, at 1030:

> It is difficult to think of any arena involving information about medications that does not have significant industry financial or marketing influences. Industry financial ties extend to federal regulatory agencies, professional organizations, continuing medical education, researchers, media experts, and consumer advocacy organizations. Such widespread corporate interests may contribute to self-selecting academic oligarchies, narrowing the range of acceptable clinical and scientific information or inquiry.

*See, e.g.*, Giovanni A. Fava, *All Our Dreams Are Sold*, 67 PSYCHOTHERAPY & PSYCHOSOMATICS, 191, 192 (1998) (discussing the prevalence and effects of conflict of interest, specifically in clinical and scientific trials which are published in medical journals).

\(^{134}\) Antonuccio, *supra* note 13, at 1030.

\(^{135}\) *Id.* at 1030.
ended support for the study but also invited other professionals who had previously supported the study to critique it.\textsuperscript{136}

Another example of how conflicts of interest between physicians’ education and drug company sponsorships influences the content which is ultimately included in DTC advertisements is evident in psychiatrist David Healy’s rescinded offer to head the depression research unit at the University of Toronto.\textsuperscript{137} In the early months of the 2000, Healy accepted an offer to head the Mood and Anxiety Disorders Program within the Centre for Addiction and Mental Health (CAMH) at the University of Toronto.\textsuperscript{138} In meetings with other department heads as part of Healy’s recruiting process, Healy was clear about his research and publications on controversial effects of Selective Serotonin Reuptake Inhibitors (SSRIs).\textsuperscript{139} However, when Healy gave a speech outlining his book which was to be published by Harvard University Press on the topic of psychopharmacology, he publicly spoke of the link between SSRIs and suicidal behavior.\textsuperscript{140} After the lecture, Healy was reprimanded by David Goldbloom, Physician in Chief of the CAMH.\textsuperscript{141} Goldbloom emphasized that Healy should not have suggested that Eli Lilly knew of the link between Prozac and suicide.\textsuperscript{142} Healy claims that he did not make such a suggestion in his lecture.\textsuperscript{143} By the following week, when Healy gave an almost identical lecture at Cornell Medical School, CAMH had already rescinded his offer as department head.\textsuperscript{144} It later became clear that CAMH cancelled the job offer because the center was funded, in large part, by Lilly, SmithKline Beecham (now GlaxoSmithKline) and other pharmaceutical companies.\textsuperscript{145} Indeed, when Healy sued the university in the first ever breach of academic freedom suit, the university clarified that Healy’s misfortune was linked to “representations to the university by academics with close contacts to industry.”\textsuperscript{146}

The pharmaceutical industry also has more direct financial interests in psychotropic drug research. In January 2003, the \textit{Journal of the American Medical Association (JAMA)} published a meta-analysis

\begin{itemize}
  \item \textsuperscript{136} \textit{Id.} at 1031.
  \item \textsuperscript{137} \textit{Id.}
  \item \textsuperscript{139} \textit{Id.}
  \item \textsuperscript{140} \textit{Id.} at 253-54; see also Antonuccio, \textit{supra} note 13, at 1031.
  \item \textsuperscript{141} Healy, \textit{supra}, note 139, at 253-54.
  \item \textsuperscript{142} \textit{Id.} at 254.
  \item \textsuperscript{143} \textit{Id.}
  \item \textsuperscript{144} \textit{Id.}
  \item \textsuperscript{145} \textit{Id.} at 255.
  \item \textsuperscript{146} Antonuccio, \textit{supra} note 13, at 1031.
\end{itemize}
of thirty-seven existing studies on the effects of conflict of interest in biomedical research.\textsuperscript{147} The results of the study suggest that biomedical research is heavily influenced by both financial and non-financial ties to industry.\textsuperscript{149} In fact, the study found that nearly one quarter of biomedical researchers have ties to the pharmaceutical industry.\textsuperscript{150} These ties include financial sponsorship of research, industry gifts related to research such as discretionary funds and biomaterials, and “dual affiliations” with companies and research universities. Lead research authors (34\%) and investigators (7.6\%) even had personal financial ties such as paid consulting and/or speaking engagements, equity in pharmaceutical companies, company-owned patents, and advisory board positions.\textsuperscript{151} Importantly, this study and others have determined that industry sponsorship leads to pro-industry conclusions regarding experimental drugs.\textsuperscript{152} Moreover, though peer-reviewed journals have been found to manage conflicts of interest through disclosure policies, even amid journals with explicit disclosure guidelines, few articles actually included disclosures of conflicts of interest.\textsuperscript{153} In sum, DTC advertising claims must be founded in research and testing in order to be deemed truthful,\textsuperscript{154} but where biased studies inform any post hoc review of the ads, consumer interests are not adequately addressed. Further, the fact that DTCA disseminates information based on biased and/or misleading studies weakens the commercial speech argument that consumers have an important

\textsuperscript{147} The researchers defined conflicts of interest as “a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).” Justin E. Bekelman et al., \textit{Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systemic Review}, 289 JAMA 454, 454 (2003).

\textsuperscript{148} Id.

\textsuperscript{149} Id. at 463.

\textsuperscript{150} Id. at 454.

\textsuperscript{151} Id. at 456.

\textsuperscript{152} Id. \textit{See also} Erik Von Elm, \textit{Betting Only on Winning Horses or Something More Sinister: Why Are the Conclusions of Industry Sponsored Studies So Likely to Be Pro-Industry?}, 32 Int’l J. Epidemiology 481, 482 (2003). For further confirmation that trials sponsored by firms in the pharmaceutical industry tend to draw conclusions which are in favor of the drug companies and their products, see Bodil Als-Nielsen et al., \textit{Association of Funding and Conclusions in Randomized Drug Trials: A Reflection of Treatment Effect or Adverse Events?}, 290 JAMA 921, 921 (2003) (In fifty-one percent of trials which were funded by for-profit organizations, the drug being studied was determined to be the “treatment of choice.” Compare with only sixteen percent of trials which were funded by non-profit organizations).

\textsuperscript{153} Bekelman, \textit{supra} note 148, at 459.

information interest – namely the ability to participate rationally in their care – in the dissemination of DTC advertisements.

Finally, drug companies make shrewd use of the information highway to advertise directly to consumers. The information contained on official\textsuperscript{155} sites, such as Pfizer’s Zoloft site, has an overt advertising bend: “Feeling sad? Anxious? Tired? Restless? You may be suffering from depression or anxiety.”\textsuperscript{156} Other sites ostensibly contain unbiased information but are funded by pharmaceutical companies. For example, the website Literature Review Service on Depression is funded by Solvay Pharmaceuticals, which produces fluvoxamine, an antidepressant.\textsuperscript{157} Also, the Web MD Health and Depression Resource Center is sponsored in part by Eli Lilly, which produces the well-known Prozac.\textsuperscript{158}

An article entitled Pharmaceutical Company Internet Sites As Sources of Information About Antidepressant Medications presented the results of a study on the value of information on the official websites of several major pharmaceutical companies.\textsuperscript{159} Websites promoting Effexor, Remeron, Luvox, Wellbutrin, Celexa, Serzone, Zoloft, Prozac and Paxil were searched and evaluated.\textsuperscript{160} The authors found that only one site mentions the trade name of other drugs, no website mentions the cost of the drugs, only one site presents statistical information on the drug’s efficacy, and only one of the sites lists the percent of the population who may suffer adverse effects from the drugs.\textsuperscript{161} Though the selective nature of the consumer-oriented information on the sites could be put into context by some of the information presented for physicians, studies show that only a minority of Americans read at a level that would allow comprehension of this information.\textsuperscript{162}

Indeed, some have suggested that drug company websites should not be viewed as primarily informative but as direct to consumer ad-

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{155} Official websites, as opposed to unofficial websites, are those authored and maintained by the company that manufactures the product(s) featured on the website.
\item \textsuperscript{156} Zoloft.com available at \url{http://www.zoloft.com} (last visited Oct. 22, 2004).
\item \textsuperscript{157} Antonuccio, supra note 13, at 1035.
\item \textsuperscript{158} Id.
\item \textsuperscript{159} Graber, supra note 106.
\item \textsuperscript{160} Id. at 421.
\item \textsuperscript{161} Id.
\item \textsuperscript{162} Id. (citing, e.g., Ann Foltz & Joan Sullivan, Reading Level, Learning Presentation Preference, and Desire for Information among Cancer Patients, 11 J. CANCER EDUC. 32 (1996); Terry C. Davis et al., Reading Ability of Parents Compared with Reading Level of Pediatric Patient Education Materials, 93 PEDIATRICS 460 (1994); and Feleta L. Wilson, Measuring Patients’ Ability to Read and Comprehend: A First Step in Patient Education, NURSING CONNECTIONS, Winter 1995, at 17).
\end{itemize}
\end{footnotesize}
Advertising. As such, the sites can contribute to the harms associated with DTCA. Ultimately, a study of the informative quality of pharmaceutical company internet sites reveals that the biased information contained therein will complicate consumers' ability to make intelligent choices regarding the use of prescription drugs.

2. Advertising Alchemy: The Power to Turn Non-Medical Problems into Medical Ones

Medicalization has been defined as a "process by which non-medical problems become defined and treated as medical problems, usually in terms of illnesses and disorders." Some have gone so far as to term this practice "disease mongering," or searching for treatable illness in consumers in order to create and expand markets for pharmaceutical companies. One tactic that advertising, in general, uses to expand the boundaries of product worth is manipulation of psychological biases. While a more complete examination of advertising's

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163 Graber, supra note 106, at 422.
164 Id.
165 Direct-to-consumer advertising can pose a problem for health professionals and lead to suboptimal prescribing. Physicians report that 88% of patients request a drug by brand name. Fifty percent of these patients would be disappointed if a physician did not give a requested prescription, and up to 25% would look for another physician. (citations omitted).
166 Id. at 422.
167 Conrad, supra note 14, at 26 (defining and exploring the issue of medicalization).

Behavioral research has discovered that human beings' capacity to reason, even when employing what appears to be only 'reason,' is subject to predictable biases . . . it is sufficient to summarize a few of these biases that are particularly relevant to advertising:

1. Confirmatory Bias. The tendency to misread evidence as confirming or supporting a hypothesis previously established. This is more familiarly known as the 'do not confuse me with the facts' bias. ('The French have a high fat diet and lower rates of coronary heart disease, so I do not need to worry about fat."
2. Motivated Reasoning. The tendency to review evidence in such a way as to arrive at a desired conclusion. This is more familiarly known as "rationalization." For example, one employing this line of reasoning might say, 'I am so busy I need to fly first class.'
manipulation of consumers' psychological biases is beyond the scope of this paper, some examples specific to DTCA of pharmaceuticals are instructive.

Advertising relies on human psychology to build brand recognition and loyalty. Courts explicitly allow some forms of branding propaganda. In fact, some courts consider mere puffing in ads to be "truthful" under the Lanham Act because the viewing audience is not expected to believe the hyperbolic content of the ad to be true. Also, statements about improved quality of life which are overblown and ignore common side effects such as sleeplessness and dependency are very harmful but pass legal muster. Further, though much of

3. **Optimistic Bias.** The tendency to underestimate probability that an undesirable occurrence (divorce, illness, death) will happen to the individual. This is the "it could not happen to me" bias. (The tobacco industry relies heavily on this bias.)

4. **Cognitive Dissonance.** The tendency to disregard evidence of unpleasant realities. This is more commonly referred to as 'denial.' (Also very important to tobacco industry.)

5. **The Illusion of Control.** The tendency to treat chance events as if either they involved skill or there was a causal relationship between the event and some action by the person. Also known as the 'God complex.' ("The phone always rings when I get in the shower!")

6. **Hindsight Bias.** The tendency to evaluate probabilities of an occurrence higher in the face of a known occurrence of the event than in the absence of such knowledge. This is commonly known as "Monday morning quarterbacking" and '20/20 hindsight.'

7. **Availability and Representativeness Biases.** The tendency both to calculate probabilities on the basis of the most available, and often the most vivid, facts and to attribute greater weight to known occurrences than is appropriate. Advertising may rely heaviest of all on this feature, as it is the basis for 'brand identification.'

8. **Anchoring and Adjustment Effect.** The tendency to anchor an estimate on a readily available figure despite knowledge of its irrelevance to the calculation. (Otherwise known to car salespersons as the 'sticker price effect'.)

(citations omitted).

169 See id. at 409-10 (describing how advertisers rely on human psychology have consumers develop a relationship to the advertised product).


171 See generally Piety, supra note 168, at 417 (stating that advertising deceives through an unrealistically easy depiction of life); see also Medicating Young Minds, TIME, Nov. 2003 at 48, 50. "Lexapro is the perfect answer for anxiety all right, provided you're willing to overlook the fact that it does its work by artificially manipulating the very chemicals responsible for feeling and thought . . . [and has] such side effects as weight loss and sleeplessness."
the information contained in DTC ads may be “truthful,” according to the FDA,\textsuperscript{172} Consumer Reports has found that many ads understate the side-effects and risks associated with drugs while exaggerating their effectiveness, make false claims that the advertised drug is better than competing drugs, and advocate unapproved uses for available drugs or endorse drugs which are still being tested for safety and efficacy.\textsuperscript{173} The following is a series of examples of how pharmaceutical marketing manipulates public understanding of what mental illness is in order to gain market share.

A. September Eleventh

Perhaps one of the most pronounced examples of DTCA’s manipulation of the psyche in order to sell psychotropics is the ad that GlaxoSmithKline ran in the New York Times Magazine following the events of September 11, 2001.\textsuperscript{174} The ad for Paxil appeared in October of 2001. In the background, a faceless crowd appeared to walk with the purpose of everyday New York urgency, while the foreground focused upon the visage and insecure bearing of one pensive (overwrought?) woman in the crowd. The ad read “Millions suffer from chronic anxiety. Millions could be helped by Paxil.”\textsuperscript{175}

Making a convincing argument that such DTCA medicalizes society by turning natural human experience into a condition treatable by prescription drugs, Barbara Mintzes, graduate researcher at the Centre for Health Services and Policy Research at the University of British Columbia, wisely queries: although many New Yorkers

[no doubt . . . felt anxious in the aftermath of the attack on the World Trade Center, experiencing symptoms highlighted in the advertisement, such as worry, anxiety, or irritability [, at] what point does an understandable response to distressing life events become an indication for drug treatment — and market opportunity?\textsuperscript{176}]

\textsuperscript{172} Any advertisement which continues to run, for example, in magazines or on television or radio is considered truthful on its face, as the FDA is charged with ridding existing DTCA of any false content. The FDA oversees DTCA through its Division of Drug Marketing, Advertising and Communications (DDMAC). The DDMAC monitors the information given to consumers through a comprehensive oversight program. See Hearing, supra note 9 at 33.


\textsuperscript{174} Mintzes, supra note 5, at 908.

\textsuperscript{175} \textit{Id.}

\textsuperscript{176} \textit{Id.}
Additionally, GlaxoSmithKline is not the only drug company to have launched important marketing efforts surrounding the attacks on the World Trade Center. During the one month directly following the tragedy, Pfizer spent twenty-five percent more on its Zoloft marketing campaigns than it had spent on promoting the product from January to June, on average.\textsuperscript{177} Zoloft is indicated for, among other things, Generalized Anxiety Disorder and Post-Traumatic Stress Disorder.\textsuperscript{178}

Apparently, drug companies are finding that there is an exceptional market opportunity for increased sales among healthy individuals who may be vulnerable to the suggestion that their coping mechanisms should be sharpened by prescription drugs. In the aggregate, pharmaceutical companies routinely focus forty percent of marketing spending on a set of ten drugs at a time.\textsuperscript{179} The ten drugs on which companies focus are typically the newest, most costly drugs which will serve large population groups for long periods of time.\textsuperscript{180} Moreover, companies are reported to choose advertising campaigns based on the percentage of patients who are likely to be persuaded to use the drug and the number of doctors who are likely to prescribe the drug.\textsuperscript{181} In recent years, anxiety medications have been the subject of this enhanced marketing effort.\textsuperscript{182}

B. Scared of Socializing

Another example of medicalizing a potentially commonplace social or personal difficulty is the case of social phobia. In 1997, Roche sought a new indication for Aurorix (moclobemide), its antidepressant.\textsuperscript{183} Accordingly, the company marketed Aurorix as a medical therapy for social phobia.\textsuperscript{184} Roche worked with a patient group, the Obsessive Compulsive and Anxiety Disorders Foundation of Victoria, to help promote its drug.\textsuperscript{185} Also as part of its promotion, Roche or-

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\textsuperscript{177} Brendan I. Koerner, \textit{Disorders Made to Order}, MOTHER JONES, July-Aug. 2002, at 58, 63.
\textsuperscript{178} See, \textit{e.g.}, Zoloft.com at \url{http://www.zoloft.com} (last visited Oct. 22, 2004).
\textsuperscript{179} Mintzes, \textit{supra} note 5, at 908.
\textsuperscript{180} \textit{Id.} ("Consistently, around 40% of spending on [DTCA] is on only 10 drugs, mainly new, expensive drugs for long term use by large population groups. In 2000, they were drugs for allergy, ulcer/reflux, anxiety, obesity, arthritis, impotence, and high cholesterol levels.").
\textsuperscript{181} \textit{Id.} ("[M]anufacturers assess whether a product-specific campaign is worth pursuing based on numbers of potential patients, the "persuadable" percentage, the proportion of doctors who will prescribe, and the value per patient (return per script multiplied by the duration of use.").
\textsuperscript{182} \textit{Id.}
\textsuperscript{183} Moynihan, \textit{supra} note 168, at 888.
\textsuperscript{184} \textit{Id.}
\textsuperscript{185} \textit{Id.}
\end{flushleft}
dered a press release to announce that over one million Australians were suffering from undiagnosed social phobia.\textsuperscript{186} Government figures available at the same time estimated that the total number of persons with social phobia was close to 370,000.\textsuperscript{187}

A spokesperson for Roche admitted that the company put "a lot of money into promoting social phobia . . ."\textsuperscript{188} The emphasis added to this quote underscores that not only the drug but also the disorder was specifically promoted to the public, including health professionals, the media, and prospective patients. It seems the marketing plan succeeded with regard to the media. Indeed, one newspaper article published in 1998, entitled \textit{Too Shy for Words} claimed that two million Australians were suffering from social phobia.\textsuperscript{189}

While this is an example from Australia, the adulation that this strategy received is of international importance. Indeed, a practical guidebook entitled \textit{Pharmaceutical Marketing} applauded the marketing model of social phobia. The guide reads

You may even \textit{need} to reinforce the actual existence of a disease and/or the value of treating it. A classic example of this was the \textit{need} to create recognition in Europe of social phobia as a distinct clinical entity and the potential of antidepressant agents such as moclobemide to treat it . . . [s]ocial phobia was recognised in the US and so transatlantic opinion leaders were mobilised to participate in advisory activities, meetings, publications etc. to help influence the overall belief in Europe.\textsuperscript{190}

(The "needs" highlighted in this excerpt illustrate the primary focus of most pharmaceutical companies: to market and sell a product. Such manipulation of consumer demand for prescription drugs carries far weightier consequences than conventional marketing of traditional consumer goods which, at most, causes consumers to make unnecessary purchases. Indeed, there is a legitimate fear that we will become a pill-popping generation, crippled by unnecessary drug addiction, severe side effects, expensive health care costs, and decreased autonomy.\textsuperscript{191}

\textsuperscript{186} Id.
\textsuperscript{187} Id.
\textsuperscript{188} According to the foundation’s chief at the time, “Roche [was] putting a lot of money into promoting social phobia . . . Roche funded [a] conference [on social phobia] to help get social phobia known among . . . health professionals . . . It was a vehicle to raise awareness with the media too.” Id.
\textsuperscript{189} Id. (“All the media stories seemed to be part of a wider push to change the common perception of shyness, from a personal difficulty to a psychiatric disorder.”).
\textsuperscript{190} Id. (emphasis added).
\textsuperscript{191} See generally Piety, supra note 168, at 436-39 (describing advertising’s
C. A SAD Case?

Scholars of legal protection of commercial speech in advertising have argued that advertising mistakenly assumes that the audience is made up of "rational actors." However, when drug companies specifically target those with mental illness, they are, doubtless, savvy enough to consider how these illnesses affect rationality. Take, for example, recent accusations that a leading drug company created the mental condition which has become known as "Social Anxiety Disorder" (SAD) in an attempt to boost sales. GlaxoSmithKline (GSK) has been accused of working with a public relations company to promote SAD in order to boost sales of Paxil over those of Eli Lilly's Prozac and Pfizer's Zoloft. In fact, as indicated by a marketing information sheet, media features of social anxiety increased from only fifty stories in 1997 and 1998 combined to more than one billion accounts in 1999 alone. Nearly ninety-six percent of those accounts conveyed the pressing message: "Paxil is the first and only FDA-approved medication for the treatment of social anxiety disorder." Popular culture icons from Rolling Stone magazine to "Ally McBeal" to Ricky Williams (of NFL fame) aided the advertising effort to convince the public that their fears were real, had a name, and could be cured by a drug made by GSK.

Attempting to rebut the concern that drug companies' ads may reach too broad an audience and persuade those without ailments that they need an SRRI like Paxil, Murray Stein, a professor of psychiatry at the University of California in San Diego, queried, "[w]ould somebody who is not having problems take a medicine that is costly and has side effects"? Again, however, the recent FDA study suggests that doctors feel pressure to prescribe medications suggested by their

failure to fully inform consumers of the addictive potential associated with drugs for psychological conditions); see, e.g., Medicating Young Minds, supra note 172, at 50.

192 See Piety, supra note 169, at 405-07.
193 See Rosenthal, supra note 118, at 503 ("For example, companies may launch advertising campaigns for products when they are approved for a new indication, in an attempt to differentiate them from other products in their class (e.g., Paxil for social anxiety disorder in 1999)"").
196 Id.
197 Id. at A6.
198 Id.
patients and that patients demand such medications. As such, empirical evidence belies Stein’s assertion.

Further, when ads like that for Zoloft (the oval ad discussed at the beginning of this paper) appeal to any person who has felt sad, a logical consequence may be that too many people become dependant on SSRIs to maintain mental well-being. Accordingly, Rex Cowdry, Medical Director for the National Alliance for the Mentally Ill, stated that “[s]ome marketing seems to imply that huge proportions of the population need pharmaceutical intervention for relatively common problems, and in the long run . . . that may undermine the credibility of the concept of serious mental illness.”

Though GSK’s product director has extolled his company’s success at uncovering a new market niche with the discovery of SAD, American Psychiatric Association experts have expressed concern that drug advertisements do not communicate the difference “between social anxiety and shyness.”

On a positive note, a number of physicians claim marketing efforts like that of GSK have afforded impaired individuals a name and cure for their ailment. Furthermore, ads that appeal to a broad audience and which celebrities endorse may help reduce the stigma associated with mental illness. In addition, physicians’ accounts reveal that many patients suffered from symptoms which were not associated with any pre-existing disease state. According to advocates of GSK’s work, “[t]hose truly suffering from the condition are profoundly debilitated, refusing promotions or taking jobs as night guards because they can’t stand to be around people.”

Furthermore, some patient advocacy groups trust drug companies’ intentions. Patient advocacy groups such as the American Psychiatric Association, the Anxiety Disorders Association of America, and a group called Freedom From Fear, even aided GSK in the movement. These nonprofit groups claim their involvement was fueled largely by the need for funding to broadcast a “potent public health


201 Id. In fact, the sad little oval at the beginning of this essay is a good example of this blurred line. The example comes from an ad for Zoloft, which is indicated for SAD but depicts a character that may arguably resemble anyone feeling rather down or bashful on a given day.

202 Id.

203 Id.

204 Id.
WHY SO GLUM?

message." However, we know that many consumer advocacy groups are sponsored by drug companies.206

D. Generation Rx207

A recent staggering increase in the number of children who are taking prescription drugs for mental and mood disorders is concomitant with the proliferation of DTCA since 1997.208 According to one study, between the years 1997 and 2000, there was an 18.8 percent increase in pediatric use of SSRIs to treat Major Depressive Disorder (MDD) and other psychiatric illnesses.209 Indeed, prescribing drugs to

205 Id.

206 E.g., Antonuccio, supra note 13, at 1035 ("Grass root organizations are ostensibly set up to advocate for patients with a particular medical condition . . . However, even casual scrutiny shows that many of these [grass root organizations] are typically heavily underwritten by the pharmaceutical industry and are designed, at least in part, to promote drug treatments.").

This article also provides interesting examples of advocacy organizations that are underwritten by pharmaceutical companies. For example, the National Alliance for the Mentally Ill (NAMI) received some $11.7 million support from drug companies between 1996 and mid-1999. Eli Lilly, manufacturer of Prozac, was the primary donor, contributing around $2.87 million. Lilly also lent NAMI an executive from the drug company who then worked from NAMI headquarters. An additional example is the advocacy organization named Children and Adults With Attention Deficit/Hyperactivity Disorder (CHADD). In the year 2002, pharmaceutical companies contributed over $500,000 to CHADD. Novartis, the company which manufactures Ritalin, arguably the most famous treatment for attention deficit disorder, was among the donating pharmaceutical companies. Id.

One final illustration involves the National Mental Health Awareness Campaign (NMHAC). The organization was created in 2000 to do away with the stigma of "fear and shame that is strongly associated with mental disorders." Kerner, supra note 178, at 63. NMHAC especially targets teenagers and offers websites and toll-free numbers to direct parents and children to mental health care. This organization is tied to a pharmaceutical lobbying firm named FoxKiser, however. Until recently, the organization was headquartered in the Washington office of FoxKizer. Among FoxKizer's clients are AstraZeneca and Bristol-Meyers Squibb. Notably, a partner at FoxKiser named Michael Waitzkin has a position on NMHAC's board of directors. Id.

207 Medicating Young Minds, supra note 172, at 50.

208 Id.: Just a few years ago, psychologists couldn't say with certainty that kids were even capable of suffering from depression the same way adults do. Now, according to PhRMA, a pharmaceutical trade group, up to 10% of all American kids may suffer from some mental illness. Perhaps twice that many have exhibited some symptoms of depression. Up to a million others may suffer from the alternately depressive and manic mood swings of bipolar disorder . . . [Attention-deficit/hyperactivity disorder] rates are exploding, too.

209 MERRILL GOOZNER & JEFF DELVISCO, CENTER FOR SCI. IN THE PUB. INT., SSRI USE IN CHILDREN: AN INDUSTRY-BASED RECORD 2 (2004) (arguing that industr-
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try-sponsored research the benefits of pediatric SSRI use, while academic research presents many risks and harms associated with such use); see also Medicating Young Minds, supra note 172, at 51.

210 Medicating Young Minds, supra note 172, at 50.
211 GOOZNER & DELVISCO, supra note 210, at 2.
212 Medicating Young Minds, supra note 172, at 51 ("The practice [of prescribing drugs to children when they are not specifically approved for pediatric use] is common and perfectly legal but potentially risky. ‘We know that kids are not just little adults,’ says Dr. David Fassler, professor of psychiatry at the University of Vermont. ‘They metabolize medications differently.’").
213 GOOZNER & DELVISCO supra note 210, at 2.
214 Medicating Young Minds, supra note 172, at 50 ("[U]sage has outstripped our knowledge base . . . we’re experimenting on these kids without tracking the results.”).
215 Id.
216 See, e.g., Koerner, supra note 178.
217 Medicating Young Minds, supra note 172, at 51.
218 Id. at 58.

treat children’s mental faculties is being done with such frequency that some people have justifiably begun to ask, “Are we raising Generation Rx”?

Perhaps the most immediately dangerous facet of children’s increased use of prescription drugs to treat mental conditions is the use of prescription medications such as Paxil (paroxetine), Prozac (fluoxetine), and Zoloft (sertraline) without regulatory approval. In other words, these drugs have only been approved for adults but are given to children in decreased doses. In fact, only fluoxetine has been approved by the FDA for child and adolescent use. Notably, Dr. Glen Elliot, director of the Langley Porter Psychiatric Institute’s children’s center at the University of California, San Francisco, explained that pediatric use of SSRIs has surpassed knowledge about the drugs. More broadly, however, there lurks the societal issue that we are becoming a “quick-fix culture,” satisfied by short term, “feel-good” answers to complex problems without concern for the enduring consequences.

Dr. Ronald Brown, professor of pediatrics at the Medical University of South Carolina, credits early detection and diagnosis as the reason for increased pediatric use of SSRIs. However, the trend may actually have been initiated by pharmaceutical companies’ creation of new classes of drugs and/or creation of new indications for existing drugs. These drugs are introduced into the public with highly visible and extensive direct-to-consumer advertising campaigns. Furthermore, doctors report that visits are often too hurried, given that managed care programs will not pay for longer, “talk-therapy” sessions with patients. As such, one hypothesis in the attempt to determine why pediatric use of prescription drugs has been concomitant
with the growth of DTCA is as follows. First, children who suffer from mental illness, or their parents, view one of the copious advertisements of drugs claiming to heal mental disorders. Then, when children and their parents visit physicians to request help and mention the drugs they have seen in DTC ads, hurried harried physicians prescribe adult medication in decreased doses. The FDA’s recent survey evidence that patients are sometimes pressing physicians to meet their demands for advertised prescriptions helps ground this hypothesis.\(^{219}\) The next section explores what may be done to remedy this and the other potential harms associated with direct-to-consumer advertising.

**V. RECOMMENDATIONS**

Although specific groups of people, particularly the mentally ill, are targeted and may be peculiarly situated to absorb the ills of DTCA of pharmaceuticals, our capitalist economy advises continuing such advertising, and the advertising may be protected as commercial speech under the First Amendment. However, FDA examination of DTCA should be necessarily preemptive rather than post hoc. In evaluating the advertisements, the FDA should apply a test to the proposed advertisement that considers Constitutional free speech interests while making educated attempts to anticipate any harm that consumer samples have demonstrated.

This balancing test would be akin to a modified *Central Hudson* test. To reiterate the test, for the speech at issue to survive part one of the *Central Hudson* test, the speech must concern lawful activity and must not be misleading. Then, the government may regulate the commercial speech only if the government interest in doing so is substantial, regulation of the speech would directly advance the government interest asserted, and regulation is no more extensive than necessary to serve the interest asserted. When considering whether a given advertising campaign fails the first part of the *Central Hudson* test because it is likely to cause consumers substantial injury that is neither reasonably avoidable by consumers nor offset by benefits to consumers or competition,\(^{220}\) the FDA should make an initial review of which audiences are targeted. Practically speaking, the FDA could ascertain this information by reviewing pharmaceutical companies’ mandatory DTCA submissions. As demonstrated by this paper, one particular audience which is heavily targeted and may be harmed by

\(^{219}\text{Hearing, supra note 9, at 48.}\)

the ads’ message is the population of persons with actual or potential mental illness.\(^{221}\)

Then, the FDA should use techniques similar to those used in marketing research to consider whether the message conveyed to those audiences is unduly misleading or deceptive. One important characteristic of marketing research, which should be applied to evaluating DTCA, is the use of focus groups. A focus group is “a gathering of six to ten people who spend a few hours with a skilled moderator to discuss a product, service, organization, or other marketing entity.”\(^{222}\) To decrease expenses and improve speed and detail in response quality, some companies are employing online focus groups to evaluate their products and services.\(^{223}\) This may be an important way for the FDA to minimize the cost of focus group research.

Focus groups comprised of members of the targeted and vulnerable populations, together with social scientists, should evaluate proposed direct-to-consumer advertisements. The groups should be asked questions to elicit the truthfulness and completeness of the advertisement. Questions should be tailored to screen for material which would be illegal as false or misleading, according to the Lanham Act. Also, questions should be designed to determine whether group members would ask their doctors for the advertised medications. Screening in this way will help reveal any subtle messages in ads and will help the FDA anticipate viewers’ reactions and behavior in relation to the advertisements. Due to concerns over prior constraints under the First Amendment, the FDA, rather than refusing a misleading ad, should work with pharmaceutical companies to design an ad that more truthfully presents drug benefits and side effects to the targeted consumers.

Concededly, this solution poses problems of paternalism due to the assumption that consumers cannot readily decipher information in DTCA on their own. However, as the foregoing portions of this paper illustrate, advertising is a persuasive tool, which has been used by drug companies to convince the public of the existence of mental illness and its relevance to individuals. Further, misrepresentative information about pharmaceutical benefits is abundant in research efforts, which inform DTC advertisements. As such, individuals are not

\(^{221}\) As discussed, infra notes 117-22, antidepressants are now the “top selling drug category” and DTCA is thought to have had the most important effect on these sales.

\(^{222}\) Kotler, supra note 7 at 90-91.

\(^{223}\) Id. at 91 (“Many companies now conduct online focus groups to take advantage of lower cost and faster, more detailed feedback. General Motors is using the Web as a low-cost way to quickly gauge consumer reaction to vehicle features and designs.”).
met with information about which they can make independent determinations. Rather, they are often met with misrepresentative material on the important issue of their mental well-being. Early review of DTC ads may help to shed the misrepresentative material in the ads so that the public may make independent decisions about the information in DTC advertisements.

Also, admittedly, the sheer number of requests submitted for review, coupled with the attendant delay caused by extensive review may prove too high a cost for the FDA to accept such a proposition. However, analogizing to marketing research solutions more generally may be a feasible way for the FDA to address consumers' interests in DTC advertising.

Finally, with regard to information which informs the direct-to-consumer advertisements, the medical research community should be held to strict disclosure standards regarding conflict of interest. Though forced disclosure involves First Amendment concerns, norms within the arena of corporate law and securities regulations require disclosure of conflicts of interest, so that shareholders' financial interests are protected. Arguably, consumer interests in straightforward health information are more critical than consumer interests in honest financial information. Accordingly, ethics codes governing clinical reports and journal articles should require disclosure of drug company sponsorship at the beginning and/or end of any reports so sponsored. Just as the authors of medical research are accountable for their work due to the prominent display of their names (and, occasionally, their pictures) on the article itself, the monetary sponsors of the research accounts should bear responsibility for their contribution.

VI. CONCLUSION

Though there are important economic and self-expression interests involved in drug companies' right to advertise, the consumer interest against medicalizing common problems, and against relying on biased information when making healthcare decisions, outweighs these interests. More stringent supervision is needed.

Currently, there is a critical delay between the FDA’s discovery of deceptive advertising and any regulatory action on the part of the FDA. Consumers are already exposed to false or misleading informa-

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224 See, e.g. Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745, 788-89 (2002); and Smith v. Van Gorkom, 488 A.2d 858, 893 (Del. 1985) (holding company chairman and CEO liable for failing to disclose information to directors and then, accordingly, for failing to disclose to shareholders that they were not adequately informed by directors on the decision of whether the company should execute a leveraged buy-out).
tion because “the cycle of advertising has usually run its course before the FDA directive arrives.” Moreover, though drug companies will stop an offending ad from running after it has been regulated, there is evidence that drug companies repeat false claims in subsequent ads for identical drugs.

Consumers’ interests in truth in drug advertising must gain sharper focus. The problem with DTCA of psychiatric drugs is one that affects all consumers, as we have a keen concern in the appropriate medical approach to our mental health. Early FDA review of direct to consumer advertisements and educated screening of those advertisements, coupled with disclosure of conflicts of interest in drug research may begin to address consumer interests in DTC drug advertising. Solutions borrowed from business administration norms and corporate law, although not without complications, may help ensure that companies utilizing DTCA do not undermine consumers’ opportunity to make rational decisions about assessment and treatment of their mental health.

225 McLellan, supra note 6, at 1951.
226 Id.