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# PRE-APPROVAL OF PRESCRIPTION DRUG ADVERTISEMENTS IN THE SHADOW OF CENTRAL HUDSON

Clifford M. Ginn

## I. INTRODUCTION

The growth in prescription drug advertising in recent years has raised questions as to whether such advertising tends to lead to more or less informed decisions by patients and health care professionals. Pharmaceutical companies claim that advertisements help doctors with limited time keep abreast of important developments that could benefit their patients and empower consumers to participate more knowledgeably in health care decisions, all of which tends to improve public health. Consumer advocates respond that advertisements often provide incomplete, misleading, or outright false information, and lead doctors and consumers to choose drugs that are less effective, more dangerous, and more expensive than other drugs or non-drug treatment alternatives.

The Food and Drug Agency (FDA) has primary responsibility for ensuring the accuracy of prescription drug advertisements, but to date it has failed adequately to protect the public from the dangers of such advertising, and has thus also prevented the emergence of its possible benefits. The FDA only regulates advertisements after they have run, often too late to correct the misinformation that unlawful advertisements promote. Furthermore, it appears that the FDA only takes action against a fraction of the unlawful advertisements that actually run. The enormous public confidence that the FDA enjoys exacerbates the ill effects of under-

regulation; the public assumes that because the FDA regulates these advertisements, they must all be accurate, or at least much more so than most advertising.

The current system has two primary flaws: a failure to regulate advertisements before they run, and a lack of sufficient resources to carry out the FDA's regulatory mandate. Pre-approval would prevent the promulgation of false or misleading information (and the costs of correcting it), promote accurate information, and create greater incentives for pharmaceutical companies to make their advertisements more honest from the beginning. However, pre-approval would be more resource-intensive than the current regime, and even under that regime the FDA does not have the resources to detect and take action (much less forceful, effective action) against all or even most unlawful advertisements. At the same time, the benefits of improved public health likely outweigh the costs of additional enforcement resources.

Even if pre-approval constitutes good policy, however, the FDA must regulate in a manner that does not violate commercial speech protections under the First Amendment of the United States Constitution. In recent decades, the Supreme Court has subjected regulation of truthful advertising to a form of intermediate scrutiny, and has been hostile to many forms of commercial speech regulation. The FDA in particular has run afoul of commercial speech requirements on a number of occasions.<sup>1</sup>

As this Article will show, the FDA can subject prescription drug advertisements to pre-approval without

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<sup>1</sup>*See, e.g.,* *Thompson v. Western States Medical Center*, 535 U.S. 357, 360 (2002) (striking down as violative of the First Amendment a Food and Drug Modernization Act of 1997 provision that exempted “compounded drugs” from the FDA’s standard drug approval process, so long as the producers of those drugs refrained from advertising or promoting them); *Pearson v. Shalala*, 164 F.3d 650, 658–60 (D.C. Cir. 1999) (holding that the FDA could only choose suppression of a dietary supplement “health claim” for which there was not “significant scientific agreement,” rather than inclusion of the claim on the product label along with an appropriate disclaimer, if it could establish that there was no less restrictive alternative to protect public health).

violating the First Amendment. In fact, such a regime would advance commercial speech doctrine's goal of ensuring consumer access to accurate information. Part II of this Article explains the concerns that prescription drug advertising raises. Part III summarizes the current regulatory regime, and Part IV summarizes relevant First Amendment doctrine. Part V discusses the outlines of a pre-approval regime and the policy issues surrounding it. Part VI explains why such a regime would be consistent with the First Amendment. Part VII concludes.

## II. The Costs and Benefits of Prescription Drug Advertising

A.

Until the 1980s, prescription drug advertising aimed almost exclusively at prescribers, although promotion methods have changed over time. Traditionally, pharmaceutical companies relied on advertising in medical journals, the efforts of a strong sales force, and provision of direct mail information to make physicians and other health care professionals aware of their products and to promote interest in prescribing them.<sup>2</sup> In recent decades, the industry has dramatically expanded its promotion arsenal, relying on such methods as newspaper articles, television talk show interviews, traveling road shows, medical journal supplements, and press conferences.<sup>3</sup> The FDA has expressed concern about this expansion into arenas where the promotional

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<sup>2</sup>See Wayne L. Pines, *A History and Perspective on Direct-To-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 491 (1999).

<sup>3</sup>Speech by Kenneth R. Feather, Acting Director, FDA Division of Drug Advertising and Labeling, before the Annual Meeting

aspect may be just as real, but less apparent.<sup>4</sup>

The scope of promotional efforts toward health care professionals is quite remarkable. Although DTC advertisement has grown dramatically, it still only makes up between 14 and 15 % of the pharmaceutical industry's promotional budget, and the remainder targets professionals.<sup>5</sup> A recent study by Rosenthal et al. discusses the breakdown of pharmaceutical industry spending on various kinds of promotion to professionals.<sup>6</sup> It reports that other literature found that sponsorship of meetings and events constituted 12 % to 15 % of marketing activities targeting health care professionals.<sup>7</sup> In 2000, the industry spent \$4.038 billion on office-based promotion, \$765 million on hospital-based promotion, \$484 million on journal advertising, and \$7.954 billion on free samples, for a total of \$13.241 billion.<sup>8</sup> Of these four types of promotion, journal advertising was the only one that did not exhibit significant growth over the period from 1996 to 2000.<sup>9</sup> The ratio between overall promotion and sales remained fairly constant between 1996 and 2000, with the relative proportion devoted to DTC advertising increasing and the relative proportion devoted to the four types of non-DTC promotion Rosenthal et al. discuss decreasing.<sup>10</sup>

The most substantial area of growth in promotion targeting health care professionals has been within the sales force. Between 1994 and 1998 the sales force of the top forty pharmaceutical companies grew from 35,000 full-time sales representatives and supervisors to over 56,000, with the latter figure representing one

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of the Pharmaceutical Manufacturers of America Marketing Section, Mar. 14, 1989 (on file with the author).

<sup>4</sup>See, e.g., *Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 102d Cong., 1st Sess. 3 (Sept. 12, 1991) (statement of David A. Kessler, M.D., Commissioner of Food and Drugs) (“Selected promotional practices have gotten out of hand. We are particularly concerned about the increased prevalence of new forms of promotion – such as promotional events labeled as scientific and technical seminars, special journal supplements and video news releases.”)

<sup>5</sup>See Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENGL. J. MED. 498, 498–99 (2002). Rosenthal et al. actually find that DTC advertising constitutes nearly 16 % of the total spending on the promotional budget items they consider, but as they note, they do not consider meetings and events, which other published data indicate make up 12 % to 15 % of the industry's non-DTC promotional budget. *Id.* at 499. Factoring this in brings the DTC figure to 14.2 % or 14.5 %, respectively.

<sup>6</sup>Rosenthal et al., *supra* note 5.

<sup>7</sup>*Id.* at 499.

<sup>8</sup>*Id.* at 499 tbl. 1.

<sup>9</sup>See *id.*

<sup>10</sup>See *id.*

salesperson and \$100,000 per eleven doctors in the country.<sup>11</sup> Those representatives made an estimated 23.7 million office and hospital calls per year, as of the year 2000.<sup>12</sup> Congress and the FDA have a long history of concern about the tactics of detailers, particularly their tendency to provide unbalanced presentations and to promote uses for a drug that have not gained FDA approval.<sup>13</sup>

However, the real story of the last two decades is the dramatic rise of DTC advertising. The first direct-to-consumer (DTC) print advertisement appeared in 1981.<sup>14</sup> After the FDA ended a brief voluntary moratorium to study the issues raised by DTC advertising,<sup>15</sup> such advertising grew at a remarkable rate. DTC spending grew from \$12 million in 1989 to \$2.38 billion in 2001.<sup>16</sup> Between 1996 and 2000, DTC advertising practically doubled as a percentage of the pharmaceutical industry's promotional budget.<sup>17</sup> In 2000, 64 % of the industry's DTC advertising budget went to television advertising.<sup>18</sup> Television advertisement grew by a factor of seven between 1996 and 2000, whereas DTC print advertisements "only" grew by 56 %.<sup>19</sup>

However, most of the current advertising is confined to a few therapeutic classes: those that treat conditions

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<sup>11</sup> Abigail Zuger, *Fever Pitch: Getting Doctors to Prescribe Is Big Business*, N.Y. TIMES, Jan. 11, 1999, at A1.

<sup>12</sup> 65 Fed. Reg. 81,082, 81,108 (Dec. 22, 2000).

<sup>13</sup> See, e.g., Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (strictly limiting the practice of leaving drug samples with prescribers); *Marketing and Promotional Practices of the Pharmaceutical Industry: Hearing Before the Senate Comm. on Labor and Human Resources*, 101st Cong., 2d Sess. 183 (1990) (question by Sen. Kennedy) ("How in the world is FDA going to really know whether . . . [detailers] are giving a balanced or a tipped presentation, which obviously as sales representatives, they've got a financial interest in whether these products are going to go?"); *Examination of the Pharmaceutical Industry, 1973-74: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93rd Cong., 1st & 2d Sess. 141 (Dec. 18, 1973-May 4, 1974) (statement of Senator Gaylord Nelson) ("daily, personal, face-to-face meetings with individual doctors . . . are the most powerful communication mechanism, and the drug industry devotes at least \$700 million (seven-tenths of total advertising and promotion expenditures) to this activity."); *id.* at 186, 765, 771, 791 (testimony of former sales representatives and other witnesses about the high pressure on detailers to sell, and the resulting under-emphasis on side effects and use of "gifts and gimmicks" to win over physicians and their staffs); *Competitive Problems in the Drug Industry: Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business*, 90th Cong., 2d Sess. 3506 (1968) (testimony of Dr. Robert McCleery, Acting Deputy Director of the FDA's Bureau of Medicine) (describing how one company told its sales force to de-emphasize serious side effects and other warnings for an anti-inflammatory drug and to encourage physicians to use it for unapproved uses). The FDA has engaged in such actions as contacting sales representatives for information, seeking access to internal detailer training manuals and other materials, and the launch of a toll-free hotline for reporting of promotional abuses. See F-D-C Rep. ("The Pink Sheet"), June 17, 1991, at 10; F-D-C Rep. ("The Pink Sheet"), May 27, 1991, at T & G 1.

<sup>14</sup> See Feather, *supra* note 3.

<sup>15</sup> The FDA called for a moratorium in 1983, see FDA Statement of Policy, Sept. 2, 1983, and ended it in 1985, see 50 Fed. Reg. 36,677 (Sept. 9, 1985).

<sup>16</sup> See 21 MED. AD. NEWS 44-45 tbl., 48 tbl. (June 2002).

<sup>17</sup> Rosenthal et al., *supra* note 5, at 499.

<sup>18</sup> See *id.*

<sup>19</sup> See Rosenthal et al., *supra* note 5, at 500 tbl. 1.

whose symptoms consumers can recognize easily (e.g. arthritis, seasonal allergies, and obesity); those that treat chronic, often undiagnosed diseases (e.g. high cholesterol, osteoporosis, and depression); and those that enhance quality of life (such as treatments for skin conditions or hair loss).<sup>20</sup> In 2000, 20 drugs accounted for 58.8 % of all industry DTC advertising.<sup>21</sup> This is in stark contrast to promotion targeting health care professionals, which is used for almost all brand-name drugs.<sup>22</sup>

The rise of DTC advertising has a great deal to do with a general trend toward increased patient participation in decisions affecting their health, accompanied by increased patient access to medical information.<sup>23</sup> This trend has several causes. First, in the 1960s, the FDA developed the concept of Patient Package Inserts, information included with prescription drugs that would provide patients with information about the use and risks of those drugs, and began requiring them for certain drugs.<sup>24</sup> The trend increased in the 1970s.<sup>25</sup> The obvious intent of the policy was to protect consumers, but it also had an empowering effect. Second, in the late 1970s and early 1980s, consumers began to gain easier access to information about diseases and prescription drugs.<sup>26</sup> Significantly, the Physicians' Desk Reference and the U.S. Pharmacopeia's book on prescription drugs became available to consumers at this time, and the news media began to cover more

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<sup>20</sup>Alan F. Holmer, *Direct-To-Consumer Advertising – Strengthening Our Health Care System*, 346 NEW ENGL. J. MED. 526, 527 (2002); see Rosenthal et al., *supra* note 5, at 501 tbl. 2 (listing the twenty most-advertised drugs, most of which fit into the categories Holmer suggests).

<sup>21</sup>Rosenthal et al., *supra* note 5, at 501 tbl. 2. In order from most-promoted to least, those drugs were Vioxx, Prilosec, Claritin, Paxil, Zocor, Viagra, Celebrex, Flonase, Allegra, Meridia, Flovent, Pravachol, Zyrtec, Singuair, Lipitor, Nasonex, Ortho Tri-Cyclen, Valtrex, Lamisil, and Prempro. *Id.*

<sup>22</sup>*Id.* at 501.

<sup>23</sup>Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 424 (2002); Holmer, *supra* note 20, at 527.

<sup>24</sup>See Pines, *supra* note 2, at 489–90. For examples of PPI regulations, see 21 C.F.R. § 201.305 (2002) (isoproterenol inhalation products); *id.* § 310.501 (oral contraceptives); *id.* § 310.515 (estrogens). The FDA had planned a mandatory pilot program to test the viability of requiring PPIs for all prescription drugs, see 47 Fed. Reg. 7200 (Feb. 17, 1982), but it ultimately withdrew the final regulation and turned away from the development of a PPI regime, see *id.* at 39,147, 39,147 (Sept. 7, 1982).

<sup>25</sup>Pines, *supra* note 2, at 490.

<sup>26</sup>*Id.* at 490–91.

health stories.<sup>27</sup> Third, the many innovations in drug technology tended to generate increased consumer interest in prescription drugs.<sup>28</sup> Finally, the significant advances in medical technology at the time changed the nature of the doctor-patient relationship.<sup>29</sup>

The emergence of First Amendment protection for commercial speech in a line of Supreme Court cases beginning in 1976<sup>30</sup> may also have made it easier for drug companies to begin DTC advertising. It is possible that drug companies refrained from DTC advertising in part out of fear of regulatory reprisal, but the new commercial speech doctrine placed limits on the federal government's power to regulate advertising, and thus reduced the regulatory risks for companies taking the bold step of advertising to consumers. Indeed, Justice Rehnquist's dissent in *Virginia Pharmacy Board v. Virginia Citizens Consumer Council*<sup>31</sup> predicted that the Court's new commercial speech doctrine would lead to "active promotion of prescription drugs, liquor, cigarettes and other products the use of which it has previously been thought desirable to discourage."<sup>32</sup>

Whatever the causes of the rise of DTC advertising may be, it has now become commonplace, and even consumer advocates acknowledge that an outright ban on it would violate the First Amendment.<sup>33</sup> Questions remain, however, as to how prescription drug advertising impacts health care professionals, patients, and the relationship between them, and as to how the FDA should regulate such advertising.

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<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 491.

<sup>29</sup> *Id.*

<sup>30</sup> See *Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

<sup>31</sup> 425 U.S. 748 (1976).

<sup>32</sup> *Id.* at 781 (Rehnquist, J., dissenting). Justice Rehnquist demonstrated remarkable prescience in suggesting several ads that a hypothetical pharmacist might now run: "Pain getting you down? Insist that your physician prescribe Demerol. You pay a little more than for aspirin, but you get a lot more relief.' 'Can't shake the flu? Get a prescription for tetracycline from your doctor today.' 'Don't spend another sleepless night. Ask your doctor to prescribe Seconal without delay.'" *Id.* at 788.

<sup>33</sup> See Sidney M. Wolfe, *Direct-To-Consumer Advertising – Education or Emotion Promotion?*, 346 NEW ENGL. J. MED. 524, 526 (2002).



B.

There is considerable dispute as to the effects of prescription drug advertising.

While there are many unique features to the prescription drug context, it makes sense to begin by examining the primary theories of human behavior that underlie more general debates about the effects of advertising. Two of the most prominent frameworks for analyzing advertising and other economic phenomena are rational choice theory and behavioral economic theory. Rational choice economic theory presumes that every human being is a rational maximizer of his own utility.<sup>34</sup> Although utility theory can serve as a simplifying assumption in order to make potentially useful predictions about economic phenomena, economists, political scientists, sociologists, and most especially legal scholars often go further and treat it as “normatively binding and descriptively valid.”<sup>35</sup> Rational choice theorists usually equate utility and wealth, in part for purposes of simplifying models, and in part to prevent the theory from collapsing into tautology (i.e. “individuals do what they want”).<sup>36</sup> By contrast, behavioral economic theory maintains that rational choice theory does not accurately reflect human behavior; psychological and sociological research demonstrate that cognitive

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<sup>34</sup>More specifically, rational choice theory relies on four axioms: Ordering, Continuity, Independence, and Invariance. See Colin Camerer, Individual Decision Making, in *The Handbook of Experimental Economics* 587, 618 (John H. Kagel & Alvin E. Roth eds., 1995) (describing the first three axioms); Daniel Kahneman & Amos Tversky, *Choices, Values, and Frames*, 39 AM. PSYCHOLOGIST 341, 343 (1984) (arguing that rational choice theory tacitly relies on the invariance axiom as well). There have been different formulations of these axioms and dispute as to their content. See R. DUNCAN LUCE & HOWARD RAIFFA, *GAMES AND DECISIONS: INTRODUCTION AND CRITICAL SURVEY* 25–31 (1957).

The ordering axiom holds that as between any two objects, an individual will prefer one to the other, or be indifferent to both: in other words, individuals can always compare different items. Continuity holds that at some level of probability, in a choice between the certainty of gaining one item and the possibility of gaining another, more desired item, an individual will be willing to gamble. Independence holds that when two objects are substituted into identical lotteries, an individual’s preference between them does not change. Under invariance, “different representations of the same choice problem should yield the same preference.” Amos Tversky & Daniel Kahneman, *Rational Choice and the Framing of Decisions*, in *RATIONAL CHOICE: THE CONTRAST BETWEEN ECONOMICS AND PSYCHOLOGY* 67, 69 (Robin M. Hogarth & Melvin W. Reder eds., 1987).

<sup>35</sup>William M. Goldstein & Robin M. Hogarth, *Judgment and Decision Research: Some Historical Context*, in *RESEARCH ON JUDGMENT AND DECISION MAKING* 4, 11 (William M. Goldstein & Robin M. Hogarth eds., 1997).

<sup>36</sup>See Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: The Problem of Market Manipulation*, 74 N.Y.U. L. REV. 630, 641 n.31 (1999).

biases and failures,<sup>37</sup> even among highly educated individuals.<sup>38</sup> Importantly for the advertising context, some scholars have demonstrated that economic actors can and do exploit these systemic biases to profit at consumers' expense.<sup>39</sup>

A thorough rehashing of the debate between these two approaches would take this discussion too far off topic, so it is enough to say that this Article generally adopts the behavioral approach. A survey of the literature reveals that rational choice theory cannot explain economic reality as described in empirical studies as well as the behavioral approach can.<sup>40</sup> This disparity becomes broader the less one deals with purely intercorporate transactions, and the more one moves into consumer transactions, particularly those where a consumer could not acquire "perfect information" without gaining scientific expertise far beyond the ken of what most individuals possess. Furthermore, as will become apparent, there is substantial empirical data specifically in the field of prescription drug advertising that suggests the behavioral model is the better one.<sup>41</sup>

In any case, even rational choice economics acknowledges the possibility of market failures, and that such failures justify government intervention. While rational choice models often begin by assuming "perfect information," a rational choice economist would have to admit that consumers (and probably even doctors) lack perfect information. The search costs for acquiring such information are high for doctors and insurmountable for consumers. Also, there are obvious externalities in this context. In many if not most cases,

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<sup>37</sup>A series of law review articles in the late 1990s established the foundations of behavioral law and economics. See Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420 (1999); Hanson & Kysar, *supra* note 36, at 630; Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471 (1998); Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. CHI. L. REV. 1175 (1997). Daniel Kahneman and Vernon L. Smith, two of the economists on whose work these authors built, have since won the Nobel Prize in Economics. Nobel e-Museum, <http://www.nobel.se/economics/laureates/2002> (last visited Feb. 8, 2003).

For a review of the behavioral law and economics literature, see Donald C. Langevoort, *Behavioral Theories of Judgment and Decision Making in Legal Scholarship: A Literature Review*, 51 VAND. L. REV. 1499 (1998).

<sup>38</sup>See, e.g., Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, in JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 3, 7-8 (Daniel Kahneman, Paul Slovic, & Amos Tversky eds., 1982) (discussing evidence that many experienced research psychologists erroneously believe in "the law of small numbers").

<sup>39</sup>See generally Hanson & Kysar, *supra* note 37.

<sup>40</sup>See *supra* note 37.

<sup>41</sup>See generally Part II.C & D.

neither doctors nor patients face substantial consequences for choosing a more expensive drug over a less expensive one.<sup>42</sup> Rather the cost is socialized through the insurance markets. Although carelessness in choosing drugs raises health care costs for everyone, it would be difficult for an individual to determine by how much, and to do a proper cost-benefit analysis. Were the individual able to do such an analysis, he would still likely find that the search costs of becoming fully informed (or finding a better doctor) would be higher than the addition to his health insurance premiums. Finally, health care is not a particularly competitive market.<sup>43</sup> Prescription drug patents create monopolies (at least temporarily), a handful of companies controls a large share of the market (and sometimes only one or two companies occupy the market for treatments of a particular condition).<sup>44</sup> The barriers to entry are substantial (the expense of bringing even one prescription drug to market is quite high). Most rational choice economists would grant that market failures justify government intervention of some kind.

C.

There are two reasons to examine the impact of advertising and other forms of promotion on doctors. First of all, it is worth determining whether promotion changes prescribing behavior, and in what ways, in order to evaluate the public health consequences of non-DTC promotion. Second, such a determination sheds light on the extent to which doctors, as learned intermediaries, can correct for any undesirable distorting effect that DTC advertising may have in creating excessive consumer demand for particular prescription drugs.

This latter discussion is particularly relevant, given that advocates of DTC advertising usually assert that

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<sup>42</sup> See Michael S. Wilkes & Miriam Shuchman, *Pitching Doctors*, N.Y. TIMES, Nov. 5, 1989, § 6 (Magazine), at 88, 89.

<sup>43</sup> See Susan Heilbroner Fisher, Note, *The Economic Wisdom of Regulating Pharmaceutical Industry "Freebies,"* 1991 DUKE L.J. 206, 207–08, 207 n.7.

<sup>44</sup> See *id.*

doctors can protect patients against any ill effects of such advertising, leaving only the benefits thereof. Thus, if doctors are generally unable effectively to sort through the mass of information about treatment options to a particular prescription drug, and patient demand for drugs also influences prescribing behavior, DTC advertising may be distorting health care markets in undesirable ways.

There is little question that promotion affects prescribing behavior, although many debate how much it does and whether it does so in a desirable way. Pharmaceutical manufacturers obviously think that promotion influences doctors – one could hardly imagine them spending such extraordinary amounts on marketing otherwise if they thought otherwise. However, industry apologists suggests that the effect of promotion is an educative one (bringing the existence and characteristics of new drugs to doctors’ attention) rather than a distorting one (giving doctors an inflated view of new drugs’ merit).

One reason drug advertising has the effect it does is that physicians in fact use such advertising as one of their primary sources of medical information.<sup>45</sup> This reliance has long raised concern amongst physicians, consumer advocates, and others.<sup>46</sup> Numerous studies with varying methodologies have found a strong correlation between a physician’s relative reliance on prescription drug promotion information and poor prescribing practices.<sup>47</sup>

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<sup>45</sup>See BEN GAFFIN & ASSOCIATES, INC., ATTITUDES OF U.S. PHYSICIANS TOWARD THE AMERICAN PHARMACEUTICAL INDUSTRY, cited in S. REP. NO. 448, 87th Cong., 1st Sess. 154–64 (1961); Marjorie A. Bowman, *The Impact of Drug Company Funding on the Content of Continuing Medical Education*, 6 MOBIUS 66 (1986); Marjorie A. Bowman & David L. Pearle, *Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education*, 8 J. CONTINUING EDUC. HEALTH PROF. 13 (1988); Nicole Lurie et al., *Pharmaceutical Sales Representatives in Academic Medical Centers: Interaction with Faculty and House Staff*, 5 J. GEN. INTERNAL MED. 240 (1990); W. Paul McKinney et al., *Attitudes of Internal Medicine Faculty and Residents Toward Professional Interaction with Pharmaceutical Sales Representatives*, 264 JAMA 1693 (1990); James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There’s No Such Thing as a Free Lunch*, 102 CHEST 270 (1992).

<sup>46</sup>See, e.g., Charles D. May, *Selling Drugs by “Educating” Physicians*, 36 J. MED. EDUC. 1, 8–9 (1961) (“The traditional independence of physicians and the welfare of the public are being threatened by the new vogue among drug manufacturers to promote their products by assuming an aggressive role in the “education” of doctors).

<sup>47</sup>See generally, e.g., Joel Lexchin & Barbara Mintzes, Comments to the Food and Drug Administration on Direct-to-Consumer Advertising of Prescription Drugs, Sept. 2002, [www.fda.gov/ohrms/dockets/dailys](http://www.fda.gov/ohrms/dockets/dailys) (last visited Feb. 8, 2003) (summarizing the literature); Jerry Avorn et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 AM. J. MED. 4 (1982); Bowman & Pearle, *supra* note 45; Joel Lexchin, *The Medical Profession and the Pharmaceutical Industry: An Unhealthy Alliance*, 18 INT’L J. HEALTH SERVICES 603 (1988); Orlowski & Wateska, *supra* note 45; David Siegel & Julio Lopez, *Trends in Antihypertensive Drug Use in the United States: Do the JNC V Recommendations*

Some recent examples demonstrate how advertising can lead physicians to falter, sometimes egregiously, in their role as gatekeepers. The painkiller bromfenac (Duract) and the heart drug mibefradil (Posicor) were recently withdrawn from the market due to serious safety problems.<sup>48</sup> These safety problems were known before the drug was approved, and many alternatives to each drug existed that were safer than, less expensive than, and at least as effective as they were.<sup>49</sup> However, the drugs were heavily promoted to physicians, who then wrote 200,000 prescriptions for mibefradil and 2.5 million for bromfenac.<sup>50</sup> The FDA actually cited Hoffman-La Roche, Inc., mibefradil's manufacturer, for a medical journal advertisement that falsely claimed that mibefradil had an "unparalleled safety profile."<sup>51</sup> It is difficult to explain physicians' faulty prescribing behavior here except as a result of manufacturer promotion and of over-reliance by physicians on advertisements as a source of drug information.

Another incident involved a study by Pollare et al. relating to the effects of hydrochlorothiazide on serum cholesterol levels and glucose metabolism.<sup>52</sup> The results of the study appeared in a front-page story in the *New York Times* ("New Study Says Diuretics Raise Heart Attack Risks"), as well as in 200 other newspaper articles, and enjoyed nationwide television coverage.<sup>53</sup> In concert with a public relations firm, a major pharmaceutical company organized a press conference and sent audio and video spots to radio and television stations nationwide.<sup>54</sup> Dr. Marvin Moser and his co-authors estimate that thousands of patients called their

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*Affect Prescribing?*, 278 JAMA 1745 (1997). The Avorn et al. study used an ingenious design: it asked doctors about their beliefs about a drug, in addition to asking where they got information. Avorn et al., *supra*. Thus, some doctors alleged that they relied primarily on academic sources of information, but then stated beliefs that almost certainly did not come from reading the medical literature (e.g. the erroneous belief that cerebral vasodilators effectively treat senile dementia). *Id.*

<sup>48</sup>DEP'T HEALTH & HUMAN SERVICES, FOOD & DRUG ADMINISTRATION, FDA Talk Paper: Wyeth-Ayerst Laboratories Announces the Withdrawal of Duract from the Market, June 22, 1998; DEP'T HEALTH & HUMAN SERVICES, FOOD & DRUG ADMINISTRATION, FDA Talk Paper: Roche Laboratories Announces Withdrawal of Posicor from the Market, June 8, 1998.

<sup>49</sup>Larry D. Sasich (Public Citizen Health Research Group), Comments on Proposed Food and Drug Administration Survey Entitled "FDA: Attitudinal and Behavioral Effects of Direct-to-Consumer Advertising of Prescription Drugs" (Sept. 29, 1998) (Docket No. 98N-0748) (HRG Publication # 1460), at <http://www.citizen.org/publications/release.cfm?> (last visited Feb. 8, 2003).

<sup>50</sup>*Id.*

<sup>51</sup>Letter to Rudolph W. Lucek, Group Director, Drug Regulatory Affairs, Hoffman-La Roche, Inc., from Janet Norden, MSA, RN, Regulatory Review Officer, FDA, Division of Drug Marketing, Advertising, and Communications (Sept. 5, 1997).

<sup>52</sup>Thomas Pollare et al., *A Comparison of the Effects of Hydrochlorothiazide and Captopril on Glucose and Lipid Metabolism in Patients with Hypertension*, 321 N. ENGL. J. MED. 868 (1989).

<sup>53</sup>Marvin Moser et al., *Who Really Determines Your Patients' Prescriptions?*, 265 JAMA 498, 498 (1991).

<sup>54</sup>*Id.*

doctors after hearing about the Pollare et al. study, and state that based on personal observations, many physicians have changed their treatment practices in response to both this media coverage and extensive promotion targeting professionals, which included a national cable television program.<sup>55</sup> Dr. Moser and his colleagues explain that the data in the Pollare et al. study were not new, that the conclusions drawn therefrom (in particular that use of diuretics increased the risk of heart attacks) were “pure speculation,” and that “none of the newer agents appear to combine all the favorable characteristics of thiazide diuretics (including their relatively low cost).”<sup>56</sup> Although the *New York Times* later ran a follow-up article and a letter to the editor that placed the study’s findings in perspective, these neither ran on the front page nor garnered much attention.<sup>57</sup> In fact, new prescriptions for all oral diuretic agents declined by 13 % in four months, going from 2,155,000 in September 1989 (the date of the Pollare et al. study’s release) to 1,874,000 in January 1990.<sup>58</sup> This dramatic change in prescribing behavior seems primarily attributable to the publicity, and demonstrates two things. First of all, the many doctors who stopped prescribing oral diuretic agents must not have been familiar with the existing data that Pollare et al. more or less just replicated. If the study was enough to make them stop prescribing oral diuretic agents, and they were familiar with existing data, then they never would have prescribed oral diuretic agents. Second, the doctors who changed their prescribing behavior were evidently unable or unwilling to weigh the new study against existing literature in order properly to weigh the benefits and risks of oral diuretic agents. Moser et al. demonstrate that such consideration would have led them to continue prescribing oral diuretic agents.

Nabumetone (Relafen), a nonsteroidal anti-inflammatory drug (NSAID) approved by FDA for treatment of rheumatoid arthritis and osteoarthritis in 1992, provides a similar example. The manufacturer claimed that nabumetone was as effective as other NSAIDs and caused relatively few ulcers.<sup>59</sup> The FDA-approved package

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<sup>55</sup>*Id.* at 499.

<sup>56</sup>*Id.* at 499–500.

<sup>57</sup>*Id.* at 499.

<sup>58</sup>*Id.*

<sup>59</sup>*Nabumetone – A New NSAID*, 34 THE MEDICAL LETTER ON DRUGS AND THERAPEUTICS 37 (1992).

insert stated that nabumetone was “comparable to naproxen [Naprosyn].”<sup>60</sup> The worst side effect from NSAIDs is hemorrhage or perforation of the gastrointestinal tract, and as became clear by 1994, ibuprofen (Motrin and many generics) created the least risk of this effect, naproxen created an intermediate risk, and the relative risk for nabumetone remained unknown.<sup>61</sup> Despite the lack of any effectiveness advantage over competitors, the uncertainty as to toxicity risk, and the fact that its wholesale cost was over seven times as much as naproxen and over 6.5 times as much as ibuprofen, nabumetone sold exceptionally well.<sup>62</sup> SmithKline Beecham sales of the drug grew substantially during the second quarter of 1994, increasing by 52 %, thanks to a DTC advertising campaign.<sup>63</sup> Nabumetone was the 48th most-prescribed drug in 1994, and moved up to 44th in 1995,<sup>64</sup> when SmithKline Beecham spent \$11 million on DTC advertising for the drug.<sup>65</sup> There is no apparent reason why SmithKline Beecham should have been able to sell any nabumetone at all: it was at best equivalent to dramatically cheaper alternatives, and possibly more dangerous. Again, doctors failed in their gatekeeping role.

Given how heavily doctors apparently rely on pharmaceutical advertising and promotion, the unbalanced and often misleading nature of medical journal advertisements potentially leads doctors astray on many occasions. One study has suggested that as many as 92 % of all medical journal advertisements may violate FDA guidelines.<sup>66</sup> 28 % of the ads surveyed were considered unsuitable for publication, 34 % needed major revisions, and only 82 % of the references cited in the advertisements could actually be verified.<sup>67</sup> Ads lacked information on safety (56 %), efficacy (72 %), appropriate populations (53 %), side effects and

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<sup>60</sup>*Nabumetone (Relafen) Product Information*, in PHYSICIANS’ DESK REFERENCE (1996).

<sup>61</sup>See D.N. Bateman, *NSAIDs: Time To Re-evaluate Gut Toxicity*, 343 LANCET 1051 (1994).

<sup>62</sup>See Larry D. Sasich & Sidney M. Wolfe (Public Citizen Health Research Group), Health Research Group Comments on Direct-to-Consumer Prescription Drug Promotion, submitted to the Food and Drug Administration (Aug. 12, 1996) (Docket No. 95N-0227) (HRG Publication #1400).

<sup>63</sup>*Id.*

<sup>64</sup>*The Top 200 Drugs 1995*, AM. DRUGGIST, Feb. 1996, at 18.

<sup>65</sup>Sasich & Wolfe, *supra* note 62.

<sup>66</sup>Michael S. Wilkes et al., *Pharmaceutical Advertisements in Leading Medical Journals: Experts’ Assessments*, 116 ANNALS INTERNAL MED. 912, 916 (1992). Many have cited the Wilkes et al. study with approval. See, e.g., David A. Kessler, *Addressing the Problem of Misleading Advertising*, 116 ANNALS INTERNAL MED. 950 (1992) (“As the study by Wilkes and coworkers indicates, the problem of misleading drug advertisements is real.”).

<sup>67</sup>See Wilkes et al., *supra* note 66.

contraindications (50 %), and references (63 %).<sup>68</sup> Advertisements also contained misleading references (10 %), textual statements (24 %), and graphs and tables (10 %).<sup>69</sup> Even though some of the criticism of the study is well-placed (though much of it is not),<sup>70</sup> it is hard to avoid concluding that some substantial percentage of medical journal prescription drug advertisements either fail to provide a balanced presentation or in fact mislead readers. There is certainly no reason to believe that presentations by detailers would prove any more accurate than journal advertisements.<sup>71</sup>

Other studies reached similar results. Herxheimer et al. reported that half of the 6700 advertisements

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<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> There are three primary critiques in the legal literature. See Howard Beales, III & William C. MacLeod, *Assessments of Pharmaceutical Advertisements: A Critical Analysis of the Criticism*, 50 FOOD & DRUG L.J. 415 (1995); Jacob Jacoby, *Misleading Research on the Subject of Misleading Advertising: The Wilkes et al. Investigation of Pharmaceutical Advertising in Leading Medical Journals*, 49 FOOD & DRUG L.J. 21 (1994); Paul H. Rubin, *Are Pharmaceutical Ads Deceptive?*, 49 FOOD & DRUG L.J. 7 (1994).

Two related complaints were that the study purported to have experts determine which ads were misleading, yet the communicative impact of an ad could only reliably be determined via an economic study of the target audience, and that the study failed to simulate real-world conditions. See Jacoby, *supra*, at 22–23. Real-life conditions would be impossible to simulate, however, and the use of actual doctors would have limited utility. If doctors were brought in to read ads, they would do so more closely than usual, even if they were not told the purpose of the study. They would have to write up their subjective understanding of the advertisement’s message, and then experts would have to compare that with the scientific literature. That might constitute a more perfect study, but it seems that a medical expert can make a reasonable evaluation as to whether an ad would likely mislead a colleague.

Similarly it was noted that the experts lacked the legal knowledge to reliably determine whether the ads violated FDA standards. Rubin, *supra*, at 10–11. They were given no definition of the term “educational value,” nor did they have the expertise to determine whether the ad would tend to lead a doctor to misprescribe treatments. *Id.* at 11–13. The study was faulted both for using experts, who were not representative readers, and for assigning only two or three readers per ad. Jacoby, *supra*, at 25–26. These critics do not explain how their concerns could be addressed without having at least four experts, four federal regulators, four doctors, and four experts look at every ad, a study design that would increase expenses by a multiple of at least five.

Possible distortions in the Wilkes et al. study’s results came from a yea-saying bias (subjects are more apt to say yes to a question), scaling bias (no mixing up of associations between numbers and levels of agreement with statements), forced-choice format (no option for “no opinion” – respondents had to agree or disagree), lack of controls, lack of double blind admission, relinquishment of interviewer control, and alleged ambiguity in the wording of questions. *Id.* at 27–28. It was also suggested that the standard for measuring the quality of the ads, juxtaposing them with “all obtainable references,” created too high a standard. *Id.* at 30. These are all valid criticisms, but far from fatal.

Data analysis and reporting were also criticized. See Jacoby, *supra*, at 33–34. It was also pointed out that the study’s results failed to account for “noise” differences in perception would lead some portion of even an ideal sample of advertisements to be misperceived. *Id.* at 30. However, a reader of the study can correct for those problems, and will see that the study’s essential finding of low advertisement quality remains safely intact.

The study was criticized for asking experts to focus on the ad as a whole, Jacoby, *supra*, at 32, but the whole impression seems to be a more valid and important question than whether an individual claim is factually accurate. After all, it is the physician’s overall impression that will influence whether she will prescribe a particular drug. Finally, one article emphasizes the accuracy of most of the ads’ statements in isolation. See Beales & McLeod, *supra*, at 416. The FDA and a good many reasonable people besides believe that an ad with incomplete information can mislead and, more importantly, can encourage a physician to prescribe in a way that a fully informed physician would not.

<sup>71</sup> See *supra* note 13.



surveyed in leading journals in eighteen countries lacked important warnings and precautions.<sup>72</sup> When Wade et al. asked pharmaceutical companies to provide their best evidence to support marketing claims, they found that out of 67 references cited, only 31 contained original data and only thirteen were controlled trials.<sup>73</sup> Stryer and Bero determined that advertisements contained more promotional material than educational material, and rarely contained information about important therapeutic breakthroughs.<sup>74</sup> Although doctors can look to the medical literature in order to evaluate these advertisements' claims, they face two hurdles. The first is that doctors lack sufficient time to do the painstaking review necessary to determine the best course of treatment. The second is that even the apparently objective sources of scientific information are increasingly influenced by the pharmaceutical industry. There is considerable evidence that companies place pressure on journals to publish favorable studies, reject unfavorable studies, and edit out dissenting views by researchers involved in favorable studies.<sup>75</sup> Scientific information appearing

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<sup>72</sup>See Andrew Herxheimer et al., *Advertisements for Medicines in Leading Medical Journals in 18 Countries*, 23 INT'L J. HEALTH SERVICES 161 (1993).

<sup>73</sup>Victoria Wade et al., *Drug Companies' Evidence To Justify Advertising*, 2 LANCET 1261 (1989).

<sup>74</sup>Daniel Stryer & Lisa A. Bero, *Characteristics of Materials Distributed by Drug Companies: An Evaluation of Appropriateness*, 11 J. GEN. INTERNAL MED. 575 (1996).

<sup>75</sup>See Richard A. Deyo et al., *The Messenger Under Attack – Intimidation of Researchers by Special-Interest Groups*, 336 NEW ENGL. J. MED. 1176, 1179 (1997) (urging that journals may “need to set up defenses against potential threats of withholding advertising”); *id.* at 1177 (“While the manuscript describing the study [which found that calcium channel blockers caused heart attacks] was under editorial review, pharmaceutical manufacturers tried to discover the identity of the journal to which it had been submitted, and it appeared to the investigators that opponents were trying to interfere with the publication of the study”); Robert H. Fletcher & Suzanne W. Fletcher, *Pharmaceutical Advertisements in Medical Journals*, 116 ANNALS INTERNAL MED. 951, 952 (1992); Int'l Comm. of Med. Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, 277 JAMA 927, 934 (1997) (“[A]dvertising must not be allowed to influence editorial decisions.”); Drummond Rennie, Editorial, *Editors and Advertisements: What Responsibility Do Editors Have for the Advertisements in Their Journals?*, 265 JAMA 2394, 2395–96 (1991) (same); see also David Orentlicher & Michael K. Hehir, II, *Advertising Policies of Medical Journals: Conflicts of Interest for Journal Editors and Professional Societies*, 27 J.L. MED. & ETHICS 113, 113–16, 118 (1999); Arthur S. Relman, Editorial, *New “Information for Authors” – and Readers*, 323 NEW ENGL. J. MED. 56, 56 (1990) (explaining journal policy against publishing review articles or editorials about a product if any author has a financial relationship with an interested manufacturer); Lawrence K. Altman, *The Doctor's World: Hidden Discord Over Right Therapy*, N.Y. TIMES, Dec. 24, 1991, at C3 (describing a journal's initial refusals to publish dissenting views of one researcher in a study suggesting that an antibiotic effectively treats ear infections, and noting that “scientific journals profit handsomely from drug company advertisements, and the influence of industry on such publications has rarely been studied”); Vanessa O'Connell, *Medical Journals Chase Drug-Ad Dollars*, WALL ST. J., May 22, 2001, at B8.

in symposia<sup>76</sup> and in journal supplements<sup>77</sup> is generally suspect, or at least of lower quality than studies published in medical journals. There appears to be a publication bias as well: funding for studies often ceases if a company considers the results unfavorable, so it is more difficult for unfavorable studies to reach completion and make it into print.<sup>78</sup> Finally, an increasing number of articles published in leading journals (as many as 11 %) are in fact ghost written.<sup>79</sup>

Even if it were easier for physicians to negotiate this morass of scientific and quasi-scientific information, they would still face substantial pressures from patients who had seen DTC advertising, and it does seem

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<sup>76</sup>See Lisa A. Bero et al., *The Publication of Sponsored Symposiums in Medical Journals*, 327 NEW ENGL. J. MED. 1135, 1137 (1992) (“Financial pressures on journals appear to contribute to the increasing publication of symposiums.”). Bero et al. warned that “[s]ymposiums may be given more credence than they deserve, because they often resemble regular journal issues and may be presented as educational materials. . . .The acceptance of symposium publications could distort the medical literature and ultimately alter physicians’ prescribing practices and patient care.” Id. at 1138. See also Mildred K. Cho & Lisa A. Bero, *The Quality of Drug Studies Published in Symposium Proceedings*, 124 ANNALS INTERNAL MED. 485, 488 (1996).

<sup>77</sup>See Paula A. Rochon et al., *Evaluating the Quality of Articles Published in Journal Supplements Compared with the Quality of Those Published in the Parent Journal*, 272 JAMA 108, 111–12 (1994) (finding that the lack of regular peer review led to supplements containing studies of inferior quality).

<sup>78</sup>See David Blumenthal et al., *Withholding Research Results in Academic Life Sciences: Evidence from a National Survey of Faculty*, 277 JAMA 1224, 1226 (1997) (describing how some researchers delay publication of their studies “to slow dissemination of undesired results”); Editorial, *The Tightening Grip of Big Pharma*, 357 LANCET 1141, 1141 (2001) (condemning the “[e]ffort by drug companies to suppress, spin, and obfuscate findings that do not suit their commercial purposes”); Drummond Rennie, Editorial, *Thyroid Storm*, 277 JAMA 1238 (1997) (describing how industry increasingly sponsors research and seeks to control its publication); Lawrence K. Altman, *Drug Firm, Relenting, Allows Unflattering Study to Appear*, N.Y. TIMES, Apr. 16, 1997, at A1 (describing how the manufacturer of the brand-name version of a thyroid drug seriously delayed publication of a study it had sponsored that determined its drug was no better than cheaper generic versions); David Brown, *Scientists Report Bid to Block Publication of an AIDS Study*, WASH. POST, Nov. 1, 2000, at A10 (describing a biotechnology company’s interference with the publication of an unfavorable study, sponsored by the company, of its experimental AIDS vaccine); Sheryl Gay Stolberg, *Gifts to Science Researchers Have Strings Attached, Study Finds*, N.Y. TIMES, Apr. 1, 1998, at A13 (describing a survey published in JAMA which found that “more than half of the university scientists who received gifts from drug or biotechnology companies admitted that the donors expected to exert influence over their work, including review of academic papers before publication”).

Some journals have recognized the problem. See Frank Davidoff et al., *Sponsorship, Authorship, and Accountability*, 286 JAMA 1232, 1233 (2001) (“We will not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication.”).

Pharmaceutical companies are not the only ones who try to exert influence over studies they sponsor. The NIH tried to condition research grants to develop an artificial heart on control over publication, but a court held that the contract provision violated the First Amendment. See Bd. of Trustees of Leland Stanford, Jr. Univ. v. Sullivan, 773 F. Supp. 472 (D.D.C. 1991).

<sup>79</sup>See Thomas Bodenheimer, *Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENGL. J. MED. 1539, 1541–43 (2000); Annette Flanagan et al., *Prevalence of Articles with Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals*, 280 JAMA 222, 223–24 (1998) (finding that eleven percent of sampled articles had ghost authors); Doug Levy, *Ghostwriters a Hidden Resource for Drug Makers*, USA TODAY, Sept. 25, 1996, at 1A; Troyen A. Brennan, Letter, *Buying Editorials*, 331 NEW ENGL. J. MED. 673 (1994) (describing one company’s offer of an honorarium to a researcher if he would sign his name to an editorial endorsing one of the company’s drugs).

that at least sometimes doctors given in to unwise patient requests. For example, in the hydrochlorothiazide episode, it is unclear to what extent doctors were responding to the media hype and to what extent to patient demands (encouraged by that hype), but in either case doctors who changed their prescribing behavior failed to act as effective gatekeepers. Available evidence suggests that this episode and the others described above were far from anomalous. It is well-documented that prescribing practices vary in ways not explainable by differing patient needs.<sup>80</sup> One study identified physicians who prescribed three drugs “at a rate far greater than that warranted by scientific evidence of their effectiveness.”<sup>81</sup> Patient demand was the most common reason the physicians gave for prescribing the drugs.<sup>82</sup> Another study showed that a patient’s expectation is a main factor in determining whether a doctor will prescribe an antibiotic.<sup>83</sup> Two studies have reaffirmed that patients who expect a prescription are “many times more likely to receive one.”<sup>84</sup> An FDA-commissioned study found that 13 % of the participants said they would be upset with their physicians if they denied a request for a prescription of an advertised drug.<sup>85</sup> Given the relative ease of switching doctors, one can imagine the impact the threat of losing 13 % of one’s practice would have. In one demonstration that DTC advertising correlates with inappropriate prescribing practices, a study found that 23.5 % of Americans over 65, a population that DTC advertising targets heavily, receive at least one of twenty inappropriate drugs.<sup>86</sup> All of this suggests that physicians do not serve as a sufficient check on the dangers of DTC prescription drug promotion. Unfortunately, managed care organizations do not appear to be reducing faulty prescribing practices.<sup>87</sup> In summary, the evidence suggests that promotion to medical professionals leads

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<sup>80</sup>See Marjorie C. Weiss et al., *Pressures on the General Practitioner and Decisions To Prescribe*, 13 J. FAMILY PRACT. 432 (1996); Elina Hemminki, *Review of Literature on the Factors Affecting Drug Prescribing*, 9 SOC. SCI. MED. 111 (1975).

<sup>81</sup>Rebecca K. Schwartz et al., *Physician Motivations for Nonscientific Drug Prescribing*, 28 SOC. SCI. MED. 577 (1989).

<sup>82</sup>*Id.*

<sup>83</sup>Robert M. Hamm et al., *Antibiotics and Respiratory Infections: Are Patients More Satisfied When Expectations Are Met?*, 43 J. FAMILY PRACT. 64 (1996).

<sup>84</sup>Trisha Greenhalgh, *Pressure To Prescribe*, 315 BMJ 1482 (1997).

<sup>85</sup>Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 FOOD DRUG COSM. L.J. 497, 502 (1984).

<sup>86</sup>Sharon M. Wilcox et al., *Inappropriate Drug Prescribing for the Community-Dwelling Elderly*, 272 JAMA 292 (1994).

<sup>87</sup>William J. Hueston et al., *Evaluation and Treatment of Respiratory Infections: Does Managed Care Make a Difference?*, 44 J. FAMILY PRACT. 572 (1997).

to inappropriate prescribing practices, and that physicians are unable or unwilling to counteract the ill effects of DTC advertising. This does not mean that current prescribing practices are worse than they would be in the absence of advertising to professionals and consumers. It does, however, suggest that stronger regulation is necessary to ensure that such advertising is more accurate and informative. This is particularly so because consumers themselves are even less able to sort through distortions in prescription drug advertising than doctors are.

D.

Representatives of the pharmaceutical industry argue that DTC advertising has many health and educational benefits. A 1998 survey found that over 53 million consumers had discussions with their doctors about a drug they saw advertised, while another 49 million sought information from another source.<sup>88</sup> Viewing of DTC ads led a projected 21.2 million consumers to discuss a medical condition or illness with their doctors for the first time, and as many as 12.1 million to receive a prescription.<sup>89</sup> The study also suggested that DTC advertising may help improve patient compliance with their drug regimes.<sup>90</sup> The mere prompting of patient-physician dialogue may in fact have significant health benefits, as common diseases like diabetes,<sup>91</sup> high cholesterol,<sup>92</sup> depression,<sup>93</sup> and high blood pressure<sup>94</sup> often go undiagnosed or untreated. An ad for a nicotine patch that aired during the 1992 Super Bowl led to a dramatic increase in demand for the patch,

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<sup>88</sup> See Alan F. Holmer, *Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians*, 281 JAMA 380, 380 (1999) (citing the study in PREVENTION MAGAZINE, NATIONAL SURVEY OF CONSUMER REACTIONS TO DIRECT-TO-CONSUMER ADVERTISING (1998)).

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> American Diabetes Association, *Clinical Practice Recommendations 1997*, 20 DIABETES CARE (suppl. 1) S1 (1997).

<sup>92</sup> *Pill Pushers*, ECONOMIST, Aug. 8, 1997, at 58.

<sup>93</sup> See Robert M.A. Hirschfeld et al., *The National Depressive and Manic-Depressive Association Consensus Statement on the Undertreatment of Depression*, 377 JAMA 333 (1997).

<sup>94</sup> NATIONAL CENTER FOR HEALTH STATISTICS, NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (1994).

and may have helped many individuals stop smoking.<sup>95</sup> Patient visits to doctors for osteoporosis increased by roughly 74 % as a result of DTC advertisements for a new treatment.<sup>96</sup> Increased use of prescription drugs, and particularly of cholesterol-lowering,<sup>97</sup> anticoagulant,<sup>98</sup> and beta-blocker<sup>99</sup> drugs, may produce substantial public health gains, so DTC advocates urge that the increasing sales resulting from DTC advertising in fact correlate with improvements in public health.<sup>100</sup>

Some also argue that advertising has positive economic effects. In particular, some have suggested that advertising will tend to reduce prices through shifts to lower-priced brands or drugs, reduction in manufacturers' prices (due to competition), reduced retail prices, and substitution of lower-cost advertising techniques.<sup>101</sup> However, even if DTC advertising improves public health and makes health care markets efficiency beyond what would exist without such advertising (both much-disputed propositions),<sup>102</sup> that does not mean that government and stakeholders cannot reduce its risks and costs as well. If DTC advertising gives consumers false optimism about dangerous drugs, then there is no question that FDA regulation to ensure promotional accuracy will not only reduce risks and costs, but will likely extend the benefits to which the pharmaceutical industry points.

The available evidence shows that DTC advertising tends to be no less unbalanced and misleading than medical journal advertising. *Consumer Reports* reviewed 28 DTC ads and found that one-third were not

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<sup>95</sup>Holmer, *supra* note 88, at 381.

<sup>96</sup>IMS Health, National Disease and Therapeutic Index (1996).

<sup>97</sup>John R. Downs, *Primary Prevention of Acute Coronary Events with Lovastatin in Men and Women with Average Cholesterol Levels*, 279 JAMA 1615 (1998).

<sup>98</sup>AGENCY FOR HEALTH CARE RESEARCH, THE SECONDARY AND TERTIARY PREVENTION OF STROKE PATIENT OUTCOMES RESEARCH TEAM 9TH PROGRESS REPORT (1995).

<sup>99</sup>Stephen S. Gottlieb et al., *Effect of Beta-Blockade on Mortality Among High-Risk and Low-Risk Patients After Myocardial Infarction*, 339 N. ENGL. J. MED. 489 (1998).

<sup>100</sup>See Holmer, *supra* note 88, at 381.

<sup>101</sup>See, e.g., Alison Masson & Paul H. Rubin, *Matching Prescription Drugs and Consumers: The Benefits of Direct Advertising*, 313 N. ENGL. J. MED. 513, 514–15 (1986).

<sup>102</sup>See, e.g., Eric P. Cohen, *Direct-to-the-Public Advertisement of Prescription Drugs*, 318 N. ENGL. J. MED. 373, 375 (1988) (arguing that promotion may ultimately increase costs, rather than increase competition, that firms will tend to focus more on successful marketing and less on innovation, and that increased (and excessive) purchases of prescription drugs will lead to unnecessarily high insurance premiums and taxes).

factually accurate, and many of the accurate ads left out important information or put it in fine print.<sup>103</sup> Half did not convey important information on side effects in the main promotional text, and only 40 % honestly discussed efficacy and fairly described risks and benefits in the main promotional text.<sup>104</sup> 39 % of the ads were considered “more harmful than helpful” by at least one reviewer.<sup>105</sup> The FDA-mandated “brief summaries” in 61 % of the ads were in medical jargon and small print, and in a separate study, a research psychologist and reading-comprehension expert rated these summaries as ranging from “extremely difficult” to “ultra difficult” to read.<sup>106</sup> Most drug ads also fail to point out lifestyle and behavior changes that can be at least as effective as medication.<sup>107</sup>

Other studies have reached similar results. Bell et al. evaluated 320 advertisements in 18 popular magazines and found that most of them “provided only a minimal amount of information.”<sup>108</sup> In particular, few ads discussed the relevant condition’s precursors or prevalence, misconceptions about the condition, the drug’s mechanism of action, success rate, or treatment duration, or behavioral changes or alternative treatments that could achieve the same ends as the drug.<sup>109</sup>

A few examples demonstrate more specifically how DTC advertisements seek to inflate consumer perceptions of prescription drug products. An advertisement for the dangerous diabetes drug troglitazone (Rezulin), published in the December 1998 *El Tiempo Latino*, a publication distributed with newspapers in cities with large Hispanic populations, presented the drug’s benefits and promotional information in Spanish and its risks and warnings in English.<sup>110</sup> Advertisements for allergy products Seldane, Hismanal, Claritin, and Flonase

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<sup>103</sup> *Drug Advertising: Is This Good Medicine?*, CONS. REP., June 1996, at 62.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 62–63.

<sup>107</sup> *Id.*

<sup>108</sup> Robert A. Bell et al., *The Educational Value of Consumer-Targeted Prescription Drug Print Advertising*, 49 J. FAMILY PRACT. 1092 (2000).

<sup>109</sup> *Id.*

<sup>110</sup> Larry D. Sasich & Sidney M. Wolfe, Letter to Minnie Baylor-Henry, Director, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration (Jan. 6, 1999), at <http://www.citizen.org/publications/release.cfm?> (last visited Feb. 8, 2003).

imply that they are 100 % effective (they are not).<sup>111</sup> Ads for Rogaine fail to mention that it does not really work for men over 40.<sup>112</sup> The ad for MetroGel mentions the pimples, broken blood vessels, and nose growth that occur in those suffering from rosacea, but relegates to fine print the admission that the drug only treats the pimples.<sup>113</sup> The FDA had to pull ads for the arthritis drug Celebrex that portrayed arthritis sufferers rowing boats and using scooters.<sup>114</sup>

There is considerable evidence that these advertisements do in fact mislead consumers. An FDA-commissioned study found that the format of advertisement substantially impacts consumers' perception of the relative risks and benefits of drugs.<sup>115</sup> In general, disclosure of a higher number of the risks and of specific rather than general risks, whether in television or print format, led to a more balanced evaluation of the benefit-risk ratio, although full disclosure tended to increase the amount of knowledge consumers carried away, whereas in print ads it decreased the total amount of knowledge.<sup>116</sup> It is worth noting that the ads produced for this study were designed to present drugs as "important medicines," whereas many ads treat prescription drugs somewhat more like ordinary consumer products, and that subjects in a study will likely study ads more carefully than they would in real life.<sup>117</sup> Thus, if anything, the potential for consumers to develop distorted understandings of the benefits of prescription drugs is higher even than the study suggests.

Even if the profit motive did not prevent manufacturers from producing balanced accurate, and informative advertisements,<sup>118</sup> consumers' lack of expertise would still make it difficult for them to make good decisions based on the information.<sup>119</sup> Given that consumers must often have exaggerated impressions of prescription

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<sup>111</sup>*Drug Advertising: Is This Good Medicine?*, *supra* note 103.

<sup>112</sup>*Id.*

<sup>113</sup>*Id.*

<sup>114</sup>Chris Adams, *FDA Scrambles to Police Drug Ads' Truthfulness*, WALL ST. J., Jan. 2, 2001, at A24.

<sup>115</sup>Morris & Millstein, *supra* note 85, at 502–03.

<sup>116</sup>*Id.* at 500–01.

<sup>117</sup>*See id.* at 502–03.

<sup>118</sup>*See* American Academy of Pediatrics, Committee on Drugs, *Prescription Drug Advertising Direct to the Consumer*, 88 PEDIATRICS 174 (1991) (arguing that the profit motive does prevent honest advertising); Lynnette R. Bradley & Julie Magno Zito, *Direct-to-Consumer Prescription Drug Advertising*, 35 MED. CARE 86, 88 (1997) (noting that consumers lack "necessary clinical and pharmacologic expertise to accurately evaluate and comprehend prescription drug advertising" and that DTC may lead to excessive drug consumption); Cohen, *supra* note 102, at 373–34.

<sup>119</sup>*See generally* Cohen, *supra* note 102,

drugs' benefits, the drive that DTC advertising has created for consumers to demand those drugs may at best be misallocating scarce health care resources and may at worst be creating a serious threat to public health and safety.

The rise of DTC advertising appears to be leading to several harms, including unnecessary increases in spending on prescription drugs, improper use thereof, and harm that results even from proper use.<sup>120</sup> Distortions of patients' preferences place pressures on their physicians to prescribe heavily advertised medicines, and even the doctors who are willing to resist those pressures and guide patients to more appropriate treatments may themselves be duped by prescription drug promotion. The medical literature itself is increasingly becoming a minefield of covert marketing, and time-pressed physicians have great difficulty separating the wheat from the chaff.

Although it would be nice if the pharmaceutical industry and the medical profession worked more to self-regulate and to raise ethical standards, the absence of any meaningful prospect for such reforms suggests that the FDA will have to do a much better job of ensuring that information reaching doctors and patients is in fact reliable.

### III. FDA REGULATION OF PRESCRIPTION DRUG PROMOTION

With the Kefauver-Harris Drug Amendments of 1962,<sup>121</sup> Congress transferred authority to regulate prescription drug advertising targeting health professionals from the Federal Trade Commission (FTC) to the

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<sup>120</sup>Matthew F. Hollon, *Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand*, 281 JAMA 382 (1999).

<sup>121</sup>Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).



FDA.<sup>122</sup> Neither the Amendments nor the legislative history make clear whether the FDA would have jurisdiction over DTC advertising as well, because the pharmaceutical industry basically did not engage in it at the time, but the FDA has since assumed such jurisdiction without objection.<sup>123</sup> The Food, Drug, and Cosmetic Act (FDCA)<sup>124</sup> now requires that any advertisement include the drug’s generic name and formula, and a “brief summary,” which must include information about the drug’s effectiveness and risks.<sup>125</sup> The FDA has adopted regulations to implement these requirements. It has defined “advertisement” (which is not defined in the FDCA) to include manufacturer-sponsored drug promotion information other than “labeling.”<sup>126</sup> Examples of “advertising” include “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.”<sup>127</sup> FDA regulations have also created two major requirements as to advertisement content. The first is that the “brief summary” must state the drug’s indications for use, side effects, contraindications, warnings, and precautions.<sup>128</sup> Second, under the “fair balance doctrine,” the entire advertisement must provide a balanced presentation of all clinically relevant information (i.e. the benefits should not be unduly emphasized and the risks must be presented clearly and prominently).<sup>129</sup> In the DTC context, risk information must appear in the main text of the advertisement, in non-technical language.<sup>130</sup> No advertisement can be false or misleading, and the information presented must be consistent with the

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<sup>122</sup>See 21 U.S.C. § 352(n)(3) (2000) (“no advertisement of a prescription drug . . . shall, with respect to the matters specified in this paragraph . . . , be subject to the provisions of section 12 through 17 of the Federal Trade Commission Act.”).

<sup>123</sup>See Memorandum of Understanding, 36 Fed. Reg. 18,538 (Sept. 9, 1971) (agreement between the FDA and the FTC that the FDA will have primary authority over prescription drug advertising); Palumbo & Mullins, *supra* note 23, at 427.

<sup>124</sup>Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301 et seq.).

<sup>125</sup>21 U.S.C. § 352(n) (2002).

<sup>126</sup>See 21 U.S.C. § 321(k) (defining “labeling” as “any written, printed, or graphic matter upon or accompanying the drug”); 21 C.F.R. § 202.1(l)(1) (2002) (defining “advertising”); *id.* § 202.1(l)(2) (including under the term “labeling” items such as “[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the “Physicians [sic] Desk Reference”) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor”).

<sup>127</sup>21 C.F.R. § 202.1(l)(1).

<sup>128</sup>See *id.* § 202.1(e) (2002).

<sup>129</sup>See *id.* § 202.1(e)(5)–(7).

<sup>130</sup>60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

approved labeling.<sup>131</sup>

The FDA treats DTC advertising and advertising targeted toward professionals similarly, and it recognizes three categories of advertising:

- (1) “Product-claim,” containing safety and efficacy claims about a particular drug(s);
- (2) “help-seeking,” containing information about a disease or condition and a recommendation for the consumer to consult a health care provider, when appropriate, while excluding discussions of specific treatments or drugs; and
- (3) “reminder,” containing the name of the drug and other limited information, but excluding all representations or suggestions about the drug(s).<sup>132</sup>

The “brief summary” and “fair balance” requirements only apply to “product claim” ads.<sup>133</sup>

The Division of Drug Marketing, Advertising, and Communications (DDMAC), within the FDA’s Center for Drug Evaluation and Research (CDER), has begun to recognize the need to regulate DTC ads differently from those targeting professionals.<sup>134</sup> Because consumers have less expertise than doctors and perceive and process claims and information differently, the FDA interprets fair balance to require clear, non-technical language and adequate information about context and risks in DTC advertising.<sup>135</sup>

The DDMAC requires manufacturers to submit advertisements to it at the time when they first run, and requests that manufacturers submit ads for evaluation prior to release.<sup>136</sup> A manufacturer that does get pre-approval gains a safe harbor; although the FDA can later change its mind, it will give the manufacturer reasonable notice and opportunity to withdraw the advertisement before taking any regulatory action.<sup>137</sup>

Pre-clearance is only required if a drug received approval on an expedited basis.<sup>138</sup>

The DDMAC monitors advertisements to find and correct violations, and also relies on complaints by private citizens, professionals, and companies.<sup>139</sup> Violators receive either a Notice of Violation (NOV) Letter (if the

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<sup>131</sup> See 21 C.F.R. § 202.1(e)(5)–(7).

<sup>133</sup> 21 C.F.R. § 202.1(e)(2)(i).

<sup>134</sup> See Palumbo & Mullins, *supra* note 23, at 429.

<sup>135</sup> *Id.*

<sup>136</sup> 21 C.F.R. § 314.81(b)(3)(i) (2002).

<sup>137</sup> *Id.* § 202.1(j)(4) (2002).

<sup>138</sup> *Id.* § 314.550 (2002).

<sup>139</sup> See Palumbo & Mullins, *supra* note 23, at 429.

violation is minor) or a warning letter (threatening to bring legal action if the violation is not corrected); such letters are posted on the CDER's website.<sup>140</sup> NOV letters request discontinuation of the violative behavior, generally to commence within two weeks.<sup>141</sup>

DDMAC took 140 enforcement actions in 1997, 157 in 1998, 108 in 1999, 69 in 2000, 72 in 2001, 28 in 2002, and only 4 for the first two months of 2003.<sup>142</sup> Given that television advertisements, which tend to be more manipulative than print advertisements, have become more prominent recently, that overall DTC advertising has increased dramatically, and that there is no evidence of a sea change in advertisement quality, this dwindling enforcement activity demonstrates a substantial abdication of the FDA's enforcement responsibilities.

The FDA issued a final "Guidance for Industry, Consumer-Directed Broadcast Advertisements" in 1999, to deal with the special concerns of broadcast advertising.<sup>143</sup> Although the guidance lacks legal force, the FDA has represented that compliance with it will serve as a safe harbor against legal action.<sup>144</sup> It allowed advertisers to substitute "adequate provision" of approved product labeling for the brief summary.<sup>145</sup> Each advertisement must include a "major statement," which discloses major risks.<sup>146</sup> "Adequate provision" requires that the advertisement include: a toll-free number, through which consumers can order the drug's labeling or have it read over the phone; a website address that provides the package labeling text; reference to another method of obtaining package labeling, sufficient for a person with limited Internet access or

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<sup>140</sup> See *id.*; <http://www.fda.gov/cder/warn/index.htm> (last visited Feb. 8, 2003).

<sup>141</sup> See Palumbo & Mullins, *supra* note 23, at 429.

<sup>142</sup> See <http://www.fda.gov/cder/warn/index.htm> (last visited Feb. 8, 2003).

<sup>143</sup> FDA, Guidance for Industry, Consumer-Directed Broadcast Advertisements, Aug. 1999, available at <http://www.fda.gov/cder.guidance/1804fml.htm> (last visited Feb. 8, 2003) [hereinafter FDA, Broadcast Advertisements Guidance]. Hearings on DTC advertising were held in 1995. Dept. of Health and Human Services, Food and Drug Administration, FDA Public Hearing on Direct-to-Consumer Promotion, Silver Spring, MD (Oct. 18-19, 1995) [hereinafter 1995 FDA Hearings].

<sup>144</sup> See Palumbo & Mullins, *supra* note 23, at 430.

<sup>145</sup> See 21 C.F.R. § 202.1(e)(1) (2002); FDA, Broadcast Advertisements Guidance, *supra* note 143.

<sup>146</sup> See FDA, Broadcast Advertisements Guidance, *supra* note 143; 1995 FDA Hearings, *supra* note 143.

who is uncomfortable directly requesting the information; and a statement that pharmacists or health care providers may provide more information.<sup>147</sup>

The FDA's regulatory approach continues to evolve. However, as the FDA seeks to develop flexible responses to new regulatory challenges, it must contend with constitutional limitations on its regulatory powers.

#### IV. FIRST AMENDMENT CONSTRAINTS ON FDA REGULATION OF ADVERTISING

In recent decades, the Supreme Court has given increasing First Amendment protection to commercial speech. The distinction between commercial and non-commercial speech arose in *Valentine v. Christensen*,<sup>148</sup> with the former falling outside the First Amendment.<sup>149</sup> 35 years later, in 1976, *Virginia Pharmacy Board* commenced the commercial speech revolution.<sup>150</sup>

There are three tests for identifying “commercial speech.”<sup>151</sup> The Court has “usually defined [it] as speech that does no more than propose a commercial transaction.”<sup>152</sup> When advertisements discuss social issues, the Court looks to whether a combination of three elements – advertising format, reference to a specific product, and economic motivation for speech – exists.<sup>153</sup> Commercial speech is also “expression related solely to the economic interests of the speaker and its audience.”<sup>154</sup>

*Central Hudson Gas v. Public Service Commission*<sup>155</sup> laid out the current test for whether a regulation of

<sup>147</sup>See FDA, Broadcast Advertisements Guidance, *supra* note 143.

<sup>148</sup>316 U.S. 52 (1942).

<sup>149</sup>See *id.* at 54 (“[T]he Constitution imposes no such restraint on government as respects purely commercial advertising.”).

<sup>150</sup>The revolution arguably began a year earlier, in *Bigelow v. Virginia*, 421 U.S. 809, 829 (1975), which held that Virginia could not criminalize abortion advertisements, but that case also involved the constitutional right to abortion.

<sup>151</sup>See generally *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422–23 (1993).

<sup>152</sup>*United States v. United Foods*, 533 U.S. 405, 409 (2001). See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001); *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

<sup>153</sup>*Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66–67 (1983).

<sup>154</sup>*Central Hudson Gas & Electric Co. v. Public Service Commission*, 447 U.S. 557, 561 (1980).

<sup>155</sup>447 U.S. 557 (1980).

commercial speech passes constitutional muster. To qualify for protection the speech “at least must concern lawful activity and not be misleading.”<sup>156</sup> If the speech meets that standard, the regulation must “directly advance” a “substantial” governmental interest, and “not [be] more extensive than is necessary to serve that interest.”<sup>157</sup> “No more extensive than is necessary” is different from and less exacting than “least restrictive alternative.”<sup>158</sup>

Commercial speech doctrine is grounded in four primary interests: “the consumer’s interest in the free flow of information” (which “may be . . . keener . . . than his interest in the day’s most urgent political debate”); society’s “strong interest in the free flow of commercial information;” the “public interest” in having the “private economic decisions” that allocate resources “be intelligent and well informed;” and “the formation of intelligent opinions as to how [the economic system] ought to be regulated or altered.”<sup>159</sup> The doctrine thus looks unfavorably upon asserted governmental interests that “rest[] in large measure on the advantages of [keeping citizens] in ignorance,” and on regulations that take a “highly paternalistic approach.”<sup>160</sup> By contrast, the doctrine does permit reasonable time, place, and manner restrictions, and the government may seek to ensure “that the stream of commercial information flows cleanly as well as freely.”<sup>161</sup> It is also worth noting that unlike most free speech doctrine, the primary emphasis is on the listener’s autonomy, not the speaker’s.<sup>162</sup>

Because commercial speech is more “objective” and “hardy” than other forms of speech, not only do regulations restricting it receive less scrutiny than restrictions on, say, political speech, but commercial speech also lacks other kinds of First Amendment Protection.<sup>163</sup> For example, commercial speech’s special characteris-

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<sup>156</sup>*Id.* at 566.

<sup>157</sup>*Id.*

<sup>158</sup>*See* Bd. of Trustees, State Univ. of New York v. Fox, 492 U.S. 469, 477 (1989).

<sup>159</sup>Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council, 425 U.S. 748, 763–65 (1976).

<sup>160</sup>*Id.* at 769–70.

<sup>161</sup>*Id.* at 772.

<sup>162</sup>*See id.* at 763–65

<sup>163</sup>*Id.* at 771 n.24.

tics “may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker.”<sup>164</sup> “They may also make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.”<sup>165</sup> They also make commercial speech less eligible (if at all) for the traditional prohibitions against prior restraints<sup>166</sup> and overbroad statutes.<sup>167</sup>

Two principles are particularly relevant to the drug promotion context: First, a vendor may not transform commercial speech into more protected speech by unnecessarily mixing the two. As Justice Scalia said in his opinion for the Court in *Board of Trustees, State University of New York v. Fox*,<sup>168</sup> “No law of man or of nature makes it impossible to sell housewares without teaching home economics.”<sup>169</sup> Second, there is no “vice” exception to commercial speech doctrine, so there is little doubt that commercial speech extends to similarly dangerous or (in some ways) undesirable prescription drugs.<sup>170</sup>

## V. Design and Justifications for a Pre-approval Regime

The current regime under which the FDA regulates prescription drug advertising is inadequate for several reasons.

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<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> See *Bates v. State Bar of Georgia*, 433 U.S. 350, 380–81 (1977) (“[T]he justification for the application of overbreadth analysis applies weakly, if at all, in the ordinary commercial context”).

<sup>168</sup> 492 U.S. 469 (1989).

<sup>169</sup> *Id.* at 474.

<sup>170</sup> See generally *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995). The “vice” exception did have a brief heyday. See *United States v. Edge Broadcasting Co.*, 509 U.S. 418 (1993) (lotteries); *Posadas de Puerto Rico Assoc. v. Tourism Company of Puerto Rico*, 478 U.S. 328 (1986) (gambling).

First, even if the FDA were willing and able to take regulatory action against every unlawful prescription drug advertisement, it would be nearly impossible to correct the damage caused by an advertisement's original publication or broadcast, particularly in the DTC context. If the advertisement merely ceases to run, there will still be patients and physicians with inaccurate perceptions of the drug. Even if the FDA requires the company to publish or broadcast a retraction of claims that it made, there is no guarantee that the individuals misled by the original advertisement will see the retraction. There is no guarantee that individuals misled by a print advertisement read the publication regularly. It seems unlikely that even a doctor who did read the relevant publication regularly would exhaustively read through every advertisement. Certainly consumers do not read through every advertisement in newspapers or magazines. With broadcast media, there is even less likelihood that a person who sees or hears a misleading advertisement will be watching or listening when the retraction comes on. Given the poor information quality of most prescription drug advertisements, and the likelihood that a great many of them violate FDA regulations, this inability to correct for the ill effects of misinformation is a serious problem. Obviously the longer the FDA takes to discover violations, the more damage those violations do.

Of course, the FDA does not in fact have the resources to catch all or even most of the unlawful advertisements, nor can it catch the ones it does find quickly. In recent years the DDMAC has not taken action against more than 157 advertisements in a year, yet this is only a fraction of the advertisements produced in a year, and a projection from any of the studies examining such advertisements for honesty, fairness, and accuracy would suggest that there are substantially more than 157 violations in a year. Even those violations that are discovered last a long time before being "corrected." A manufacturer does not need to give the FDA a copy of an advertisement until the ad begins to run. Even if the FDA began review the instant it received the advertisement (an unlikely state of affairs), such review obviously takes at least some time, and companies who receive regulatory letters are generally given 10 days to notify FDA how they plan to comply.

Therefore, in the best of cases, unlawful ads would likely run for at least three weeks before being removed. In reality, review likely neither begins immediately nor moves quickly, given the small number of FDA staff assigned to the task (apparently about 24 as of 2002).<sup>171</sup>

Even if the FDA did have the resources to perform its regulatory role, it has apparently become increasingly lax in its enforcement of advertising regulations. The number of enforcement letters sent out per year has decreased from 157 in 1998 (already inadequate) to 28 in 2002. Wilkes et al. found more violations than that just within a sample of 109 advertisements, a tiny fraction of the number that come out every year.<sup>172</sup> The FDA's abdication of its responsibilities in this department appears to be nothing short of astonishing. This failure adequately to regulate the content of prescription drug advertising is all the more troubling, given the high confidence the public has in the agency and the likely assumption that ads could not run without passing careful FDA scrutiny.

Thus, the FDA could not under the best of circumstances prevent substantial harm to the public interest from unlawful advertising, and its lack of resources and will to carry out its enforcement mandate make the situation far worse.

Requiring pre-approval for all prescription drug advertising could solve many of the problems under the current regime. Perhaps most importantly, it would prevent unlawful ads from reaching physicians and patients in the first place, and thus also prevent the confusion that must inevitably result under the existing system. It would also eliminate the costs of running retractions (although drug companies obviously consider the benefits from unlawful advertisement worth the risk of such costs).

Pre-approval would also create optimal incentives for both the pharmaceutical industry and the FDA. The industry would have strong motivation to produce appropriately balanced and accurate advertisements, since the chance of successfully getting an unlawful advertisement into print or on the air would go from high to

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<sup>171</sup>See THOMAS ABRAMS, DDMAC ENFORCEMENT AND POLICY UPDATE (Oct. 22, 2002), <http://www.fda.gov/cder/ddmac/Presentations/tomfdli902/index.htm> (last visited Feb. 8, 2002).

<sup>172</sup>See Wilkes et al., *supra* note 66.



extremely low. The costs of submitting an unlawful ad to the FDA would be substantial: the company doing so would not only have to pay to produce a new ad, it would lose valuable promotion time in a regime where its patent only lasts for so long, and it would have to go through another pre-approval waiting period. The substantial reduction in likelihood of successfully getting an unlawful ad past the FDA would also eliminate the race to the bottom that currently exists. Manufacturers who might otherwise prefer to produce balanced ads must nevertheless push the envelope as far as they can (or burst it) in order to compete with their competitors claims. A pre-approval regime would level the playing field and end this market failure. At the same time, the FDA would also have optimal incentives. The agency would be more obviously responsible for any public health crises or other ill effects arising from misleading advertisements. Of course, the FDA is accountable under the current regime, but with pre-approval it would be guaranteed that the FDA *affirmatively authorized* the running of the ad, a significant difference from a mere failure to take action against an ad.

Although pre-approval would require more resources than the FDA currently has for regulating prescription drug advertisements, it seems likely that the costs of adding staff would be small compared to the potential public health costs resulting from the failures of the current regime. It may also be that under pre-approval each ad would need less scrutiny than currently, because companies would generally produce more informative and balanced advertisements.

To the extent that prescription drug advertising is a desirable thing, there is no reason to believe that pre-approval will diminish such advertising or injure public health. No one disputes that advertising leads to substantially higher prescription drug revenues. If, as the pharmaceutical industry maintains, advertisements are currently lawful and informative, then under a pre-approval regime the ads will still be that way (and still create the same substantial marketing returns), and it is difficult to believe that the added delay costs of pre-approval would be enough to erase the enormous marketing benefits of advertising. If, as is actually the

case, prescription drug advertisements often fail to comply with FDA regulations, then pre-approval could only improve the information that consumers and physicians receive. If that led to a decrease in prescription drug sales, than that would just mean that there had been an excess of inappropriate prescriptions under the old system. In this latter instance, the old system would have involved a misallocation of societal resources as between development of truly innovative and useful drugs and marketing of less exceptional drugs.

Of course, the FDA would have to design its pre-approval system to minimize delay of advertisements in reaching the public. One way to do this would be to begin reviewing advertisements for a drug before it has been approved for use. There is no reason to believe that it would be difficult for companies to determine before a drug is approved what its primary risks are. Most of the content of the ad can be developed without knowing the specific results of the last round of clinical trials, and it would be easy enough to develop formats that could accommodate any gaps in information. For example a company preparing a print advertisement could show the FDA where it intends to place information about a drug's efficacy, so that the FDA could approve the rest of the ad provisionally, and then simply look at how the company presents the last piece of information when it becomes available. Similarly, the company could film the content of a broadcast advertisement and leave a gap in the voice-over for missing information.

There would be instances where a company was unsure whether a drug it had developed would gain FDA approval, and would therefore be unwilling to develop advertisements until it had gained approval. However, in such cases the uncertainty would likely result either from questions about efficacy or concerns about dangerous side effects. In either case, slowing the diffusion of the drug into the economy would often be more beneficial than harmful.

An optimal program would have the following features: It would permit review of advertisements before approval of a drug, and hopefully limit delays in approval for an advertisement to less than one month after a drug's approval for use. To the extent a drug company could not reasonably be expected to develop

advertisements before a drug's approval for use, there should be some provision for expedited review. The FDA should also develop some model advertisement formats that generally tend to meet fair balance and brief summary requirements. As firms began to follow the formats, the speed of review would increase, and a certain amount of standardization might make it easier for consumers and doctors to evaluate and compare advertised prescription drugs.

Whether the FDA shifts to pre-approval or not, it should require that prescription drug advertisements contain more information about efficacy, cost, and alternative forms of treatment. If a prescription drug truly is a superior product, it costs its manufacturer little to provide accurate information in these areas. If the drug is an inferior product, then it will either be easier for patients and doctors to determine as much, or the company will devote fewer or no resources to promoting it. Either course will lead to less prescribing of an inappropriate drug. Broadcast advertisements present special problems, and congressional action is likely necessary to strengthen requirements for such advertisements and to increase penalties for noncompliance.

## VI. PRE-APPROVAL DOES NOT VIOLATE THE FIRST AMENDMENT

Although the pharmaceutical industry (and perhaps some civil libertarians) might argue that pre-approval violates the First Amendment, that is not in fact the case.

It should be remembered at the outset that the only beneficiaries of commercial speech protection are honest advertisers; false and misleading advertisements get no protection. Also recall that the rights of the speaker are only recognized insofar as they advance the right of the hearer to a free flow of information.<sup>173</sup>

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<sup>173</sup>See generally *Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

The only difference between pre-approval and the current regime, which is obviously constitutional, is the prior restraint element. The case law is quite explicit that regulation of advertisements for truthfulness and disclosure of important information is not only permissible, but in fact a desirable way of furthering the purpose of commercial speech protection: to promote dissemination of accurate economic information. *Virginia Pharmacy Board* also specifically states that the presumption against prior restraints does not necessarily apply to commercial speech.<sup>174</sup>

There can be little doubt that regulation of prescription drug advertising serves substantial governmental interests. Pre-approval, like the current regime, seeks not to suppress truthful speech, but rather to ensure that advertising only provides truthful and balanced information. There is nothing “paternalistic” about ensuring “that the stream of commercial information flows cleanly as well as freely.”<sup>175</sup> This is to be distinguished from FDA advertising that actually suppresses speech.<sup>176</sup> Commercial speech’s “objectivity” and “hardiness” “may also make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.”<sup>177</sup> Truthful advertising, the only kind protected by commercial speech doctrine, would have no difficulty gaining pre-approval, so pre-approval has no more tendency to suppress protected speech than does the current regime.

One might argue that a pre-approval requirement could impede the flow of truthful commercial information by somehow chilling production of even truthful speech, but that result seems unlikely. As *Virginia Pharmacy Board* noted, “[s]ince advertising is the *Sine qua non* of commercial profits, there is little likelihood of its

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<sup>174</sup>*Id.* at 771 n.24.

<sup>175</sup>*Id.* at 772.

<sup>176</sup>It was suppression of speech that the Supreme Court invalidated in *Thompson v. Western States Medical Center*, 535 U.S. 357, 360 (2002)

<sup>177</sup>*Id.* at 771 n.24.

being chilled by proper regulation and forgone entirely.”<sup>178</sup> As was suggested above, truthful advertisers are already gaining substantial sales revenues from their advertising. Why would they suddenly stop advertising if they had to wait an extra two or three weeks to start running the advertisements? In fact, pre-approval would give truthful advertisers greater incentives to promote their products. Under the current system, unlawful advertisements are unlikely to be withdrawn, and even withdrawn ads will likely run for weeks before they stop, and the offending manufacturer will still reap gains from misinformation. Pre-approval would level the playing field – unlawful advertisers could no longer reach the print and broadcast media, so a product advertised truthfully would appear more attractive to consumers than it would have under the old system.

It is also clear that pre-approval would “directly advance” the government’s substantial interest in promoting a steady flow of truthful information about prescription drugs. What more effective way could there be to prevent consumer misinformation than to prevent deceptive ads from running at all? It is likely that a recognition that misinformation can harm consumers, even if it is later withdrawn, combined with an understanding that delay alone will not likely deter companies from advertising, explain the *Virginia Pharmacy Board* Court’s willingness to extend less protection against prior restraints to commercial speech than to other forms of speech. Pre-approval not only stems the tide of misinformation, but it may in fact encourage more truthful lawful advertisements. As suggested above, companies unwilling to create unlawful advertisements have more to gain from advertising in the newly leveled playing field than under the current regime. Moreover, advertisers may err on the side of more honesty and balance than is absolutely necessary to gain approval, because they do not wish to risk the costs of delay and of producing additional advertisements. While in other contexts this sort of pressure to speak in a particular way would run against the goals of the First Amendment, here it actually directly advances the First Amendment’s goal: the interest protected by

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<sup>178</sup> *Id.*

commercial speech doctrine is not the speaker's right of self-expression, but rather the right of hearers to acquire truthful economic information.

The most difficult question in the analysis is whether a pre-approval regime would be "more extensive than is necessary to serve [the government's] interest."<sup>179</sup> This inquiry does not require that pre-approval be the "least restrictive means," but rather that the regulation be "no more extensive than reasonably necessary to further substantial interests."<sup>180</sup> As has already been suggested, it is not at all clear that pre-approval would deter truthful commercial speech more than the current regime does; it may in fact have the opposite effect. If pre-approval is no less apt to produce a free flow of truthful information than is the current regime, there is certainly no constitutional difficulty.

In the unlikely event that pre-approval did in fact deter truthful speech, the analysis would become more complicated. A court considering the question would have to look not only to the options available to the FDA under its statutory authority, but also to other options that Congress could create. Otherwise, Congress could do an end run around the First Amendment by leaving the FDA with an unnecessarily speech-restrictive approach as the only means of effectively carrying out its mission. A court would have to weigh the information costs and benefits of numerous possible alternatives, many of which the government may never have tried. Given how much difficulty legislators and social scientists have resolving questions regarding the communicative effect of advertising and the likely response of businesses to particular regulations, it is unlikely that a court would fare better. The ultimate resolution may have more to do with a judge's "common sense" notions about human behavior than anything else, so the legal result may vary depending on the judge. Moreover, a court might reach different conclusions as to the constitutionality of pre-approval of DTC advertising as opposed to non-DTC advertising. In any case, the FDA or Congress would do well to assemble a record containing the best empirical information they can find about the likely

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<sup>179</sup>Central Hudson Gas v. Public Service Commission, 447 U.S. 557, 566 (1980).

<sup>180</sup>Bd. of Trustees, State Univ. of New York v. Fox, 492 U.S. 469, 477 (1989) (quoting *In re R.M.J.*, 455 U.S. 191, 203 (1982)) (internal quotation marks omitted).

effects of different regimes.

While it is impossible to be exhaustive in considering alternatives, and the way a court will rule is somewhat indeterminate, it is fruitful to consider the merits of specific alternatives. The first alternative would be the current regime. It is certainly within Congress's power to make the FDA's regulatory activity under this regime more like the "best-case scenario" outlined at the beginning of Part V, where the FDA has the resources to evaluate all prescription drug advertisements quickly, and has the political will to take regulatory action against all unlawful advertisements. The FDA could also force companies to withdraw unlawful advertisements more quickly. Thus, the FDA could plausibly make a determination within a few days after an advertisement begins to run, require that the advertisement be withdrawn "immediately," and require that the offending company run an advertisement specifically correcting any misstatements or supplying withheld information. In the case of medical journal advertisements, the FDA might also reasonably be able to require the journal to prominently run a correction to the information in the advertisement, given that such journals reasonably can be expected to exercise some editorial judgment in accepting ads for publication. Even under this dream scenario, however, there would be harms that pre-approval could have prevented. Even if misinformation is only broadcast for a week, there will still be many people who see or hear that information. There is no guarantee that a correction will reach those people. Some empirical evidence on how quickly commercial information diffuses would be helpful in evaluating the costs of allowing one week of misinformation. That would then have to be weighed against the costs that pre-approval would create in terms of deterrence of truthful advertising.

Another alternative would be the creation of a waiting period: if the FDA failed to object to a submitted advertisement within, say, two weeks of its submission, the manufacturer could run it. The FDA could retain the authority to take regulatory action at a later time, but this approach would limit the delay that truthful advertisements would experience before running. At first glance, this approach appears to have the

benefits of pre-approval, without the deterrent effect that an unduly long delay that might occur under a pre-approval regime. This would especially be the case if the FDA proved unable to evaluate advertisements expeditiously under a pre-approval regime. However, the waiting period approach would in fact have costs as compared to pre-approval. First of all, unlawful advertisements might in fact reach the public. The cases where the FDA would be unable to act in time before the ad's release would likely be ones in which the scientific information is complicated or indeterminate – precisely the cases in which it would be most difficult for doctors and patients to determine the truth on their own. Second, consumers would assume that all advertisements out there were truthful, thereby increasing the damage from the unlawful advertisements that get through. Admittedly, consumers may assume the accuracy of prescription drug ads even under the current regime, so this too would require some empirical research. Third, pre-approval would create more powerful incentives for the FDA to do its job. Under the waiting period approach, there would be no way to tell whether the FDA is scrutinizing advertisements closely or passively. The agency could always plead a lack of resources if any unlawful advertisements got through. On the other hand, under pre-approval, the FDA would have to make a definitive evaluation of the advertisement. If the FDA had to in fact sign off on the advertisement's content, it would necessarily take its job seriously.

Another alternative would be for Congress to create a federal cause of action for any health or economic injury resulting from an unlawful advertisement. Congress could create a presumption that any consumer injury resulted from the misinformation in the ad. Congress could even allow liability in cases where the consumer had not seen an advertisement, because the sources from whom the consumer or her doctor got information about the drug might have been impacted by promotion. Many states are currently considering the implications of DTC advertising for the learned intermediary doctrine, and there is no reason why Congress could not do the same.<sup>181</sup> However, this approach might prove both less effective in producing a

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<sup>181</sup>A discussion of the learned intermediary doctrine would be beyond the scope of this Article, and there is already a voluminous literature on the subject. See, e.g., Jeffrey J. Wiseman, *Another Factor in the "Decisional Calculus": The Learned Intermediary*



flow of truthful commercial information and more speech-restrictive than pre-approval. Liability would be less effective than pre-approval because the latter would catch all unlawful ads, whereas the former would require a consumer who has the time, resources, and knowledge of his rights necessary to go to court, and whose injury costs, adjusted for the risk that he might lose his lawsuit, were sufficient to justify going to court. The liability approach would thus be underinclusive, perhaps substantially so. More importantly, liability might have more of a chilling effect than pre-approval. Pre-approval would only deter truthful speakers who could not afford the cost of delay. Speakers who only gain a de minimis benefit from advertising would be unlikely to risk having a jury erroneously find their advertisement unlawful, and award a verdict accordingly. Many advertisers who could afford the delay under pre-approval would also be unwilling to take this risk. Finally, the government could respond to the threat of misinformation by compiling, publishing, and distributing information regarding the absolute and comparative merits of all the drugs on the market. Consumers and, more importantly, doctors would know that a definitive information source existed, and therefore any harm from unlawful advertisements that make it into the stream of commercial information under the current regime would be reduced. The first answer to the argument that the availability of this approach makes pre-approval unconstitutional is that it proves too much. Almost all regulation of advertising would be unconstitutional under that argument, since it is difficult to imagine a field where the government could not assemble comparative information and publish it. Yet *Virginia Pharmacy Board* specifically acknowledged that traditional regulation of advertisements' truthfulness and completeness remains constitutionally permissible. In part this is a recognition of the limits of governmental resources (the government could hardly publish such surveys for every product on the market), and the fact that government regulation by

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*Doctrine, The Physician-Patient Relationship, and Direct-to-Consumer Advertising*, 52 S.C. L. REV. 993 (2001); Yonni D. Fushman, *Case Comment: Perez v. Wyeth Labs, Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161 (2000); Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101 (2000); Mae Joanne Rosok, *Comment: Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE L. REV. 629 (2000).

and large targets misleading advertising, which does not in fact enjoy First Amendment protection. If the Constitution provides differential protection depending on commercial speech's truthfulness, then it must permit the government to separate the wheat from the chaff, or else the differential protection becomes a nullity.

Other alternatives certainly exist, but the evaluation of the representative approaches considered above suggests that as long as the FDA assembles enough of the existing evidence about how misleading ads affect doctors and patients, and particularly about doctors' shortcomings as gatekeepers, pre-approval should pass constitutional muster.

At the same time, if pre-approval does deter lawful advertising, it may be that requiring pre-approval of ads targeting professionals is more constitutionally suspect than requiring pre-approval of DTC advertising. Regulation of medical journal advertising is necessarily underinclusive, and a more inclusive approach would likely violate the First Amendment. Most of the promotion to professionals does not involve medical journal advertisements, but rather the activities of detailers and the industry sponsorship of "educational" events, studies, and literature. It is a complex question, beyond the scope of this Article, to what extent the Constitution permits the FDA to regulate these activities, but as a general matter the more speech partakes of exchange of scientific information, the less the FDA can regulate it. While regulation of print ads targeting professionals directly advances the government's substantial interest in preventing the most egregious forms of misinformation, because of physicians' technical knowledge, access to scientific information, and exposure to other more constitutionally protected forms of promotion, there may be a point beyond which the Court would require the government to rely more on such mechanisms as physician education, publication and distribution of reports comparing medicines, and so on. It is difficult to see why the line should be drawn

between pre-approval and the current regime, but wherever the Court draws a line, it may well be at a different place than for DTC advertising.

Before closing, brief mention should be made of the issues surrounding the Internet. While the Internet in some ways presents unique issues, it does seem that it can reasonably be fitted within the regulatory schemes already discussed. In particular, there are few relevant differences between Internet promotion and print advertisements, except perhaps in terms of separating “promotion” from “scientific exchange.”

## VII. CONCLUSION

Although prescription drug advertising may have substantial benefits, and the Constitution places limits on the extent to which the FDA can regulate it, the FDA needs to do more to battle such advertising’s tendency to promote inappropriate prescribing practices. Pre-approval would be one highly effective means of improving the quality of prescription drug information available to patients and doctors, and it would pass constitutional muster, at least if the FDA justified it with sufficient empirical information and limited delay in approving advertisements. Whatever regulatory approach the FDA ultimately adopts, it should require prescription drug advertisements to be more informative, and Congress should provide the FDA with sufficient resources to carry out its regulatory mandate.