

THE DIFFICULT CASE OF DIRECT-TO- CONSUMER DRUG ADVERTISING

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I. INTRODUCTION

This well-deserved and long overdue tribute to Steven Shiffrin, one of the leading First Amendment theorists of our time, provides a welcome opportunity to re-examine Professor Shiffrin's core teachings about the complexity of the First Amendment. The symposium organizers asked that I focus on the commercial speech doctrine. I happily undertook the assignment because my own thinking about commercial speech has been heavily informed by Professor Shiffrin's writings. For that reason, I have focused my attention on *The First Amendment and Economic Regulation: Away from a General Theory of the First Amendment*, Professor Shiffrin's early but highly influential critique of the commercial speech doctrine.¹

Away from a General Theory is as timely today as it was when it was published over two decades ago. In it, Professor Shiffrin sets forth a sweeping critique of conventional commercial speech theory

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1. 78 NW. U. L. REV. 1212 (1984). The article has been cited by courts and commentators hundreds of times, including the Supreme Court in *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 n.6 (1985).

that places him outside both of the two competing camps of First Amendment theorists. As Professor Shiffrin explains, neither camp fully grapples with the complexities embedded in government regulation of speech relating to commercial and economic activity.² Professor Shiffrin's critique gently but decisively exposes the flaws in each approach.³

Professor Shiffrin uses the article first to distance himself from theorists—I will call them “pro-protectionists”—who embrace the advent of the commercial speech doctrine as an important doctrinal step forward, but who, at the same time, criticize the Court for going only half-way by failing to bestow full First Amendment protection to commercial speech.⁴ Although Professor Shiffrin is no fan of “hierarchies” of First Amendment protection, he sees the pro-protectionist approach as too simplistic.⁵ For one thing, this approach disregards the reality that, at times, the government must regulate speech in the course of legitimate economic regulations (e.g., regulation of the sale of securities), and that full constitutional protection for such speech might inhibit the government's ability to advance important societal interests.⁶ For another, pro-protectionist theorists overlook the complicated definitional issues that arise when the government regulates economic activity that has an effect on speech—complexities that in Professor Shiffrin's view make the commercial speech doctrine an incomplete answer to a poorly framed question.⁷

Professor Shiffrin spends even more energy challenging those who argue that expanding the domain of the First Amendment to cover commercial speech is ill-conceived.⁸ These commentators—

2. *E.g.*, Shiffrin, *supra* note 1, at 1224.

3. *Id.*

4. *Id.* at 1261 (arguing that depending on its context, the Court permitting restrictions on speech is appropriate); *see, e.g.*, Martin H. Redish, *The Value of Free Speech*, 130 U. PA. L. REV. 591, 634–35 (1982) (arguing that the distinction between commercial and other forms of expression is unjustified beyond the regulation of false and misleading advertising).

5. *See* Shiffrin, *supra* note 1, at 1223–24.

6. *Id.* at 1260–61.

7. *See, e.g., id.* at 1217; *see also* STEVEN H. SHIFFRIN, *DISSENT, INJUSTICE, AND THE MEANINGS OF AMERICA* 41 (Princeton Univ. Press 1999) (faulting the Court's commercial speech jurisprudence for failing “to make a distinction between commercial *information* and commercial *advertising*”). Professor Shiffrin suggests that commercial advertisers “deserve some free speech protection, but no special protection.” *Id.* at xii.

8. Shiffrin, *supra* note 1, at 1224.

“anti-protectionists”—contend that providing *any* First Amendment protection to commercial speech, even the less-than-complete protection afforded by the doctrine, risks weakening the First Amendment’s core value of providing ample breathing room for personal political, social, and artistic expression.⁹ For these commentators, equating detergent ads by profit-seeking corporations with core political speech by individuals inevitably dilutes the protection afforded to speech that lies at the heart of the First Amendment.¹⁰

Professor Shiffrin rejects the anti-protectionist approach as well. As he sees it, much of what is labeled commercial speech deserves First Amendment protection because it does in fact implicate core political or social values.¹¹ Simply tarring speech with a “commercial” label to avoid wrestling with difficult questions about the nature of the speech and the speech’s role in political and social discourse is, in Professor Shiffrin’s view, itself an affront to the First Amendment.¹²

Ever the iconoclast, Professor Shiffrin carves out his own path in the commercial speech debate, rejecting general theories as formulaic, rigid, imprecise, and ultimately unhelpful. Professor Shiffrin instead calls for a careful, highly context-sensitive, case-by-case balancing of interests when government seeks to regulate speech relating to economic activity.¹³ He has little tolerance for paternalistic government regulation and believes the courts should exercise probing and skeptical review of government justifications for speech regulation.¹⁴ But, as his later writings drive home, he is also deeply suspicious of concentrated corporate power, and the ability of large, unchecked, corporate interests to monopolize debate on important issues.¹⁵ He diverges from pro-protectionist First

9. See, e.g., C. Edwin Baker, *Commercial Speech: A Problem in the Theory of Freedom*, 62 IOWA L. REV. 1, 3 (1976) (“[A] complete denial of first amendment protection for commercial speech is not only consistent with, but is required by, first amendment theory.”).

10. *Id.*

11. See Shiffrin, *supra* note 1, at 1238–39.

12. *Id.* at 1241–52.

13. *Id.* at 1251–52.

14. *Id.* at 1223.

15. Professor Shiffrin’s more recent writings focus on a dissent-informed conception of the First Amendment and suggest that the exercise of corporate power often goes unchecked and is often enabled by government. SHIFFRIN, *supra* note 7, at 37–43, 93, 107–09.

Amendment theorists by acknowledging that, at times, the government's interest in regulating speech relating to economic activity extends beyond restraining speech that is demonstrably false, misleading, or deceptive.¹⁶ In Professor Shiffrin's view, the government's interest in regulating even *truthful* speech is, at times, sufficiently substantial such that the government's interest should prevail.¹⁷

In the introduction to *Away from a General Theory*, Professor Shiffrin summarizes his mission in this way:

I offer neither a bold new methodology, nor any creative "solution" to the commercial speech problem here. It is precisely because the problem is so difficult that both courts and commentators have been groping to find their way. If I have a contribution to make, it is to show why this difficulty exists, why the commercial speech problem is in fact many problems, and why the small questions will not go away.¹⁸

This essay takes as its starting point Professor Shiffrin's observation that "the commercial speech problem is in fact many problems."¹⁹ It focuses on commercial speech problems that bedevil First Amendment theorists and the courts alike: what constitutional protections should be afforded to speech promoting a product that poses significant risks to the product's users and does so by making health or safety claims that omit information about the product's risks or are not susceptible to empirical verification?

This is not an idle question. Consider one example. There has already been substantial litigation over Congress's efforts to prohibit dietary supplement manufacturers and food purveyors from disseminating ads that claim that their products cure, treat, or mitigate a disease where there is no significant scientific agreement that the claim is true.²⁰ The Federal Food, Drug, and Cosmetic Act²¹

16. See, e.g., Shiffrin, *supra* note 1, at 1260–61.

17. *Id.* at 1260–61 (stating that values other than freedom of speech can cause the government to restrict speech); see also *id.* at 1214–15 (listing various forms of accepted government regulation of presumably truthful commercial speech).

18. *Id.* at 1216.

19. *Id.*

20. These claims include: "omega-3 fatty acids reduce the risk of heart disease," "vitamin C reduces the risk of influenza," "SAM-e [a dietary supplement] treats depression and arthritis."

requires “significant scientific agreement” before such claims can be made.²² But sellers frequently make claims about their products that, because the scientific evidence is not definitive, cannot be proven true or false. The statute forbids sellers from making these claims, but they have objected on First Amendment grounds. To avoid First Amendment difficulties, lower courts have refused to read the statute literally, ruling instead that the government, not the seller, bears the burden on the question of “truth.”²³ Where the government cannot prove falsity, the government may require that sellers use disclaimers to counter consumer confusion.²⁴ The government may resort to more stringent regulation or prohibition only if it can prove that disclaimers would “bewilder” consumers.²⁵

To bring this discussion into focus, this essay concentrates on a question of exceptional importance—as yet unexplored by the courts—that is before Congress as of this writing and is likely to fuel the commercial speech debate: whether direct-to-consumer (“DTC”) advertising of prescription drugs should be permitted, and if so,

See David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson v. Shalala*, 54 *FOOD & DRUG L.J.* 535, 542 (1999).

21. 21 U.S.C. § 343 (2000).

22. For health claims regarding foods, the Act says that they may be made only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Id. § 343(r)(3)(B)(i). Congress did not specify a standard for health claims for dietary supplements, but instead directed the FDA to set a standard “respecting the validity of such claim[s].” *Id.* § 343(r)(5)(D). The FDA by regulation adopted the “significant scientific agreement” standard for health claims for dietary supplements. See 21 C.F.R. §§ 101.14(c), 101.70(f)(B).

23. See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (holding that the FDA must explain what it means by “significant scientific agreement”). Cf. *Whitaker v. Thompson*, 239 F. Supp. 2d 43 (D.D.C. 2003), *aff’d*, 353 F.3d 947 (D.C. Cir. 2004) (upholding FDA’s rejection of health claim for saw palmetto, a dietary supplement).

24. See, e.g., *Pearson*, 164 F.3d at 658–59.

25. *Id.* at 659–60. See generally Vladeck, *supra* note 20, (criticizing *Pearson*). To avoid further litigation, the FDA has established a procedure to permit sellers of foods and dietary supplements to make “qualified” health claims—that is, health claims that do not meet the “significant scientific agreement” standard set out in the statute—but are “qualified” by a disclaimer. See 68 Fed. Reg. 41, 387 (2003); see also CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FDA, *FINAL GUIDANCE: FDA’S IMPLEMENTATION OF “QUALIFIED HEALTH CLAIMS”* (May 12, 2006), <http://www.cfsan.fda.gov/~dms/qhcqagui.html>.

whether these ads should be subject to any limits?²⁶ How one answers these questions—the “small questions” that Professor Shiffrin says will not go away—depends on one’s conception of the role the First Amendment plays in the regulation of economic activity. For instance, does it matter that consumers may not purchase these products on their own, but instead must have a doctor prescribe the drug for them? Does it matter that evaluating the risks and benefits of prescription medication is a task fraught with complexity and generally beyond the competence of consumers? Does it matter that empirical evidence suggests that DTC ads are highly effective in influencing consumer choice but often fail to disclose adequately the risks of the drug? Does it matter that the Food and Drug Administration (“FDA”) lacks the statutory tools and resources to police the DTC advertising marketplace effectively? Let us now turn to the “commercial speech problem” and see whether, as Professor Shiffrin claims, the “small questions” it raises will not go away.

II. A BRIEF OVERVIEW OF THE COMMERCIAL SPEECH DOCTRINE

To set the stage, it is useful to recall the evolution of the modern commercial speech doctrine. The basic story is a familiar one. Prior to the Supreme Court’s landmark 1976 ruling in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,²⁷ “commercial speech” was generally not entitled to protection under the First Amendment.

The key case was *Valentine v. Chrestensen*.²⁸ In 1940, Mr. Chrestensen sailed into the New York harbor in a “former U.S. Navy Submarine S-49,” a two-million-dollar “fighting monster,” intending to put the submarine on public display.²⁹ Mr. Chrestensen distributed handbills offering tours of the submarine for a fee. But New York’s anti-littering ordinance prohibited the distribution of handbills for the purpose of “commercial and business advertising,” and the police

26. Congress is considering a substantial overhaul of our nation’s drug safety laws, and direct-to-consumer ads are squarely in Congress’s sights. See Food and Drug Administration Revitalization Act, S.1082, 110th Cong. § 202 (as passed by Senate, May 9, 2007); Enhancing Drug Safety and Innovation Act of 2007, H.R. 1561, 110th Cong. (as introduced in House, Mar. 19, 2007). At this writing, it does not appear that Congress will restrict DTC ads.

27. 425 U.S. 748 (1976).

28. 316 U.S. 52 (1942).

29. *Chrestensen v. Valentine*, 122 F.2d 511, 512 (2d Cir. 1941).

ordered Mr. Chrestensen to desist.³⁰ Undeterred, Mr. Chrestensen resurfaced with a new, two-sided handbill. One side advertised tours of his submarine. The other detailed Mr. Chrestensen's complaint against the city for denying him permission to moor his submarine at a city dock convenient to visitors. Unpersuaded that the modification changed the commercial nature of the handbill, the police again ordered Mr. Chrestensen to stop distribution. Mr. Chrestensen brought suit. After a short-lived victory in the Second Circuit, his case came before the Supreme Court, which scuttled his promotional efforts once and for all.

To call Justice Robert's opinion for the unanimous Court perfunctory is an overstatement. The 875 word opinion (125 of which quote the relevant provision of the New York City anti-littering law) contains not a single case citation and nothing approaching analysis. It simply announces that "the Constitution imposes no . . . restraint on government as respects purely commercial advertising" and chastises Mr. Chrestensen for attempting to *evade* the ordinance by merging his political attack on the City with his commercial appeal.³¹ Justice Roberts said, "If that evasion were successful every merchant who desires to broadcast advertising leaflets in the streets need only append a civic appeal, or a moral platitude, to achieve immunity from the law's command."³²

The rule of *Valentine v. Chrestensen*, that speech proposing a commercial transaction receives no constitutional protection, stood essentially unchallenged for three decades. Although the opinion was, at times, criticized by individual Justices as "casual, almost offhand,"³³ it was not until the Court's 1975 ruling in *Bigelow v. Virginia*³⁴ that it became clear that *Valentine*'s days were numbered. *Bigelow* was decided in the wake of *Roe v. Wade*.³⁵ *Bigelow* held that a state could not forbid advertising for abortion services,

30. *Valentine*, 316 U.S. at 53 n.1.

31. *Id.* at 54.

32. *Id.* at 55.

33. See Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 629 nn.4-8 (1990) (cataloguing criticisms of *Valentine*); see also Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376, 401 & n.6 (Stewart, J., dissenting); *id.* at 404 (Blackmun, J., dissenting); *Cammarano v. United States*, 358 U.S. 498, 514 (1959) (Douglas, J., concurring) (observing that *Valentine* "has not survived reflection").

34. 421 U.S. 809 (1975).

35. 410 U.S. 113 (1973).

signaling the Court's view that *Valentine* was a "limited" ruling that "obviously does not support any sweeping proposition that advertising is unprotected per se."³⁶

The following year marked the birth of the modern commercial speech doctrine. It bears noting that several of the pivotal commercial speech cases involved speech restrictions incidental to the regulation of drugs. *Virginia Board of Pharmacy*³⁷ struck down a Virginia law forbidding pharmacists from advertising the price of prescription drugs. The Court held explicitly, for the first time, that speech proposing a commercial transaction is entitled to some measure of constitutional protection.³⁸ The Court observed that the "consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate," and thus society has "a strong interest in the free flow of commercial information."³⁹ And it found the Virginia statute to be "highly paternalistic."⁴⁰ But the Court did not articulate a standard for assessing restraints on commercial speech, but instead, in a Delphic footnote, left the question of how much protection such speech deserves for another day.⁴¹

For our purposes, what is significant about the Court's opinion in *Virginia Board of Pharmacy* is not just the Court's path-breaking holding, but also the dissent by then-Justice Rehnquist. Aligning himself with the anti-protectionist camp, Justice Rehnquist rejected the Court's view that commercial expression falls within the protective sphere of the First Amendment. Instead, he argued that the First Amendment's purpose is to enlighten "public decision making as to political, social, and other public issues," not "the decision of a particular individual as to whether to purchase one or another kind of shampoo."⁴² With remarkable foresight, Justice Rehnquist predicted that the Court's ruling would pave the way to DTC advertising of prescription drugs, and he forecast that an

36. 421 U.S. at 819–20 (emphasis omitted).

37. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council Inc.*, 425 U.S. 748 (1976).

38. *Id.* at 770.

39. *Id.* at 763–64.

40. *Id.* at 770.

41. *Id.* at 771 n.24 ("suggest[ing] that a different degree of protection" should be afforded to commercial speech).

42. *Id.* at 787.

enterprising pharmacy might soon run an advertisement that said “Don’t spend another sleepless night. Ask your doctor to prescribe Seconal [a powerful prescription sleeping medication] without delay.”⁴³ Justice Rehnquist warned that ads like these were an inevitable consequence of the majority opinion:

Unless the State can show that these advertisements are either actually untruthful or misleading, it presumably is not free to restrict in any way commercial efforts on the part of those who profit from the sale of prescription drugs to put them in the widest possible circulation. But such a line simply makes no allowance whatever for . . . a considered legislative judgment in most States that while prescription drugs are a necessary and vital part of medical care and treatment, there are sufficient dangers attending their widespread use that they simply may not be promoted in the same manner as hair creams, deodorants, and toothpaste.⁴⁴

The question raised by DTC advertising is precisely Justice Rehnquist’s question: i.e., does the First Amendment make an allowance for a legislative judgment that prescription drugs, “a necessary and vital part of medical care,” not be “promoted in the same manner as hair creams, deodorants, and toothpaste”?⁴⁵

Four years after *Virginia Board of Pharmacy*, the Court handed down its decision in *Central Hudson*,⁴⁶ which established the now-familiar four part test for evaluating the constitutionality of restrictions on commercial speech. The test inquires whether:

- (1) The speech is false or misleading, or concerns an unlawful activity, such that it may be suppressed outright;
- (2) The asserted governmental interest is substantial;
- (3) The regulation directly advances the asserted governmental interest; and
- (4) The regulation is more extensive than necessary.⁴⁷

43. *Id.* at 788.

44. *Id.*

45. *Id.*

46. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557 (1980).

47. *Id.* at 566. Even before the ink was dry on *Central Hudson*, it was subject to extensive criticism, from both within the Court and the academic community. Justice Powell’s majority opinion mustered the support of only five Justices: Justice Blackmun, the author of *Virginia State Board of Pharmacy*, complained that “the test now evolved and applied by the Court is not

As I have explained elsewhere, although the Court has never formally abandoned *Central Hudson*, it has slowly transformed the test without explicitly doing so.⁴⁸ As initially articulated, the *Central Hudson* test was a genuinely intermediate standard of scrutiny, with courts giving legislative judgments considerable deference.⁴⁹ The theory, of course, was that commercial speech merits constitutional protection to enable consumers to get information they need to make informed choices.⁵⁰ Consumers are only interested in truthful information; false, misleading, deceptive, or unreliable information subverts the interest in informed decision making. The theory did not seek to advance the expressive interests of the speaker; indeed, the early cases are remarkably devoid of any mention of the speaker's interest.⁵¹ Applying the *Central Hudson* test as first formulated, the Court upheld a number of laws that restrained commercial speech: the Court thought that the restraints served sufficiently strong governmental interests and did not needlessly intrude on protected speech.⁵² In more recent cases, however, the Court has tightened the standard considerably. No longer do courts

consistent with our prior cases and does not provide adequate protection for truthful, non-misleading, noncoercive commercial speech." *Id.* at 573 (Blackmun, J., concurring). In an opinion that fits well with Professor Shiffrin's theory, Justice Stevens argued that the Court's efforts to formulate a one-size-fits-all test was misguided and that the speech at issue in *Central Hudson*—the utility's promotion of off-peak pricing—concerned important economic matters and thus was entitled to rigorous First Amendment protection. *Id.* at 579–81 (Stevens, J., concurring). And Justice Rehnquist again dissented, arguing against constitutionalizing speech unrelated to social and political discourse. He accused the Court of "return[ing] to the bygone era of *Lochner v. New York*, in which it was common practice for this Court to strike down economic regulations adopted by a State based on the Court's own notions of the most appropriate means for the State to implement its considered policies." *Id.* at 589 (Rehnquist, J., dissenting) (citation omitted). Typical of the academic criticism of *Central Hudson* is Professor Robert Post's, who called the test "so vague and abstract as to fail entirely to express any specific constitutional values." Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. REV. 1, 5 (2000); see also Ronald A. Cass, *Commercial Speech, Constitutionalism and Collective Choice*, 56 U. CIN. L. REV. 1317, 1374–77 (1988).

48. See generally David C. Vladeck, *Lessons from a Story Untold: Nike v. Kasky Reconsidered*, 54 CAS. W. RES. L. REV. 1049 (2004); see, e.g., *Posadas de P.R. Assoc. v. Tourism Co. of P.R.*, 478 U.S. 328 (1986).

49. Vladeck, *supra* note 48, at 1055.

50. *Central Hudson*, 447 U.S. at 563 ("The First Amendment's concern for commercial speech is based on the informational function of advertising.") (citing *First Nat'l Bank v. Bellotti*, 435 U.S. 765 (1978)).

51. See Vladeck, *supra* note 48, at 1070 n.92 (and authorities cited therein); see, e.g., *First Nat'l Bank*, 435 U.S. at 779–80 (1978).

52. See, e.g., *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618 (1995); *United States v. Edge Broad. Co.*, 509 U.S. 418 (1993); *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469 (1989).

give deference to legislative judgments or uphold restraints that are reasonable and proportionate to the interests they serve.⁵³ Rather, the test applied today is a demanding one—akin to strict scrutiny—that results in the virtually automatic invalidation of laws restraining commercial speech that is not demonstrably false, misleading or deceptive.⁵⁴

III. DIRECT-TO-CONSUMER ADVERTISING

Just as Justice Rehnquist predicted, *Virginia Board of Pharmacy* unleashed a wave of DTC advertising for prescription medications. These days, DTC advertising for drugs designed to treat ailments ranging from insomnia, anxiety, hair loss, and high blood pressure to sexual dysfunction and arthritis, is a standard feature on all media, but increasingly on television.⁵⁵ Drug companies often launch mass marketing campaigns for their drugs as soon as they obtain FDA approval. Drug companies now spend over \$29 billion annually to promote their products,⁵⁶ including \$11.4 billion on advertising.⁵⁷ Nearly forty percent of the advertising expenditures—over \$4 billion per year—pay for DTC ads that are designed to encourage patients to ask their doctors to prescribe the advertised drug.⁵⁸ As a result, the

53. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371–74 (2002); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555–64 (2001).

54. *Thompson*, 535 U.S. at 373–74 (2002); *Lorillard Tobacco Co.*, 533 U.S. 525 (2001). *But see* *Tenn. Secondary Sch. Athletic Ass'n v. Brentwood Acad.*, 127 S. Ct. 2489 (2007) (upholding restraint on in-person recruitment of high school athletes).

55. From 1997 to 2001, the percentage of DTC advertising for print ads declined from 74 to 35, while the percentage of spending on television ads increased from 25 to 64. Government Accounting Office, *PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS* 10 (GAO-03-177) (Oct. 2002) [hereinafter 2002 GAO REPORT]. For a history of the FDA's regulation of DTC ads, see Timothy S. Hall, *The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet*, 7 *DEPAUL J. HEALTH CARE L.* 1 (2003).

56. Julie M. Donohue, et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 *JAMA* 673 (Aug. 16, 2007).

57. KAISER FAMILY FOUND., *PRESCRIPTION DRUG TRENDS* 2 (May 2007), available at http://www.kff.org/rxdrugs/upload/3057_06.pdf.

58. A 2005 study found that \$4.2 billion was spent on DTC advertising annually, or 37 percent of total pharmaceutical advertising. *Id.* To put these expenditures in context, the pharmaceutical industry now spends nearly as much money on advertising as the tobacco industry spends on all of its product promotion (including price reductions and samples). *Cf.* FEDERAL TRADE COMMISSION *CIGARETTE REPORT FOR 2003* 2 (2005), available at <http://www.ftc.gov/reports/cigarette05/050809cigrpt.pdf> (reporting that the tobacco industry spent a total of \$15.15 billion in 2003 to promote its products).

average American now views “as many as 16 hours of prescription drug advertisements per year, far exceeding the average time spent with a primary care physician.”⁵⁹

DTC advertising is highly targeted. Indeed, “[a]lmost all spending on DTC advertising is concentrated among a small number of drugs that treat chronic conditions and therefore must be taken repeatedly.”⁶⁰ According to the Government Accountability Office (GAO), “in 2005, the top 20 DTC advertised drugs accounted for more than 50 percent of all spending on DTC advertising”⁶¹—a total of more than \$2 billion devoted to advertising 20 drug products.

DTC advertising has proven to be highly successful in stimulating demand for drugs. An assessment by the National Institute for Health Care Management found that between 1999 and 2000, the number of prescriptions written for the 50 most advertised drugs rose 24 percent, as compared to a 4 percent increase in prescriptions for all other drugs, although this study did not take into account the likelihood that these drugs were also heavily promoted to doctors.⁶² A patient who requests a specific medication is more likely to receive medication—and the particular drug requested—than a patient who does not ask for a specific drug, even when the two present the same symptoms.⁶³ According to an FDA study, between 74 and 77 percent of doctors prescribed the requested drug when a specific drug was requested.⁶⁴ The same study reported that

59. Dominick F. Frosch et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 ANNALS OF FAM. MED. 6, 6 (2007) (citing Erica D. Brownfield et al., *Direct-to-Consumer Drug Advertisements on Network Television: An Exploration of Quantity, Frequency, and Placement*, 9 J. HEALTH COMM. 491, 496 (2004)).

60. 2002 GAO REPORT, *supra* note 55, at 12; *see also* Government Accountability Office, *PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA’S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 14* (GAO-07-54) (Nov. 2006) [hereinafter *NOV. 2006 GAO REPORT*].

61. *NOV. 2006 GAO REPORT*, *supra* note 60, at 14.

62. *Id.*; *see also* 2002 GAO REPORT, *supra* note 55, at 16 (“surveys . . . consistently show that DTC advertisements have an impact on whether consumers request and receive a specific brand-name prescription”).

63. Richard L. Kravitz, *Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants*, 293 J. AM. MED. ASS’N 1995, 1999 (2005) (reporting results of randomized trial in which actors were sent to doctor’s offices presenting symptoms of depression. Those who asked for a specific antidepressant were more likely to get medication than those who did not, and were likely to get a prescription for the requested medication).

64. K. Aiken, et al., *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Results*, 7 (Nov. 19, 2004) available at <http://www.fda.gov/cder/ddmac/Final%20Report/DTCPhysicianSurvey%20Materials3.pdf> (last viewed on Oct. 4, 2007).

65 percent of physicians believe patients misunderstand the relative risks and benefits of DTC advertised drugs and 75 percent say that the ads cause patients to overestimate the drug's benefits.⁶⁵ In 2006, the Government Accountability Office reported that its review of many studies showed that "about 90 percent of consumers report having seen a DTC advertisement," and that between 2 and 7 percent of consumers who have seen DTC ads say that they requested and received a prescription for the advertised drug from their physician.⁶⁶ Based on "[s]urveys conducted by the FDA and private organizations," the GAO concluded that DTC advertisements "have an impact on whether consumers request and receive a specific brand-name prescription from their physician."⁶⁷

The FDA also has problems regulating the content of these ads.⁶⁸ The Food, Drug and Cosmetic Act does not directly address DTC advertising. The FDA derives its authority to regulate prescription drug advertising from its general responsibility to regulate written or graphic materials that accompany a regulated product.⁶⁹ Ads must contain "information in brief summary relating to side effects, contraindications . . . and effectiveness" (the "brief summary" requirement).⁷⁰ For broadcast advertising, the company must state the drug's major risks and either provide a "brief summary" or make "adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast

65. *Id.* at 8.

66. NOV. 2006 GAO REPORT, *supra* note 60, at 14–15.

67. 2002 GAO REPORT, *supra* note 55, at 16; *see also* NOV. 2006 GAO REPORT, *supra* note 60, at 14. The Institute of Medicine has reached a similar conclusion. It reports that DTC "advertising may lead to more rapid uptake of a new drug . . . which could potentially dramatically increase the exposure to that particular drug, even among patients who are not good candidates for it." Inst. of Medicine, *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC*, 158 (Nat'l Academies Press 2006). Available at http://books.nap.edu/catalog.php?record_id=11750#toc. [hereinafter IOM REPORT].

68. *See* 2002 GAO REPORT, *supra* note 60, at 23 ("[R]eviews of draft regulatory letters from FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before FDA issued the letters.").

69. 21 U.S.C. § 321(m) (2000); *see also* Direct-to-Consumer Promotion; Public hearing, 60 Fed. Reg. 42,581 (Aug. 16, 1995) (FDA Notice of Public Hearing to discuss regulation of DTC advertising and brief explanation of the FDA's policies regarding DTC ads); FDA, DIVISION OF DRUG MARKETING, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (Aug. 9, 1999), available at <http://www.fda.gov/cber/gdlns/advrts.pdf>.

70. 21 C.F.R. § 202.1 (e)(1) (2007).

presentation.”⁷¹ “Reminder” ads, which can disclose the name of the drug but not its indication, do not have to include risk information.⁷²

Drug ads most frequently run afoul of FDA regulations for DTC advertising in two situations: the ad either fails to give adequate safety information about a drug; or the ad overstates the effectiveness of the drug, often by claiming incorrectly that the drug compares favorably with other drugs in the same class.⁷³ In either case, consumers receive messages about a drug that are false or misleading and designed to stimulate demand for the drug.

The FDA has only a limited ability to police the DTC advertising market. Drug companies have no legal duty to submit ads to the FDA prior to dissemination. Rather, FDA regulations require companies to submit advertising materials to the agency when the ad is first aired.⁷⁴ Some manufacturers neglect to submit ads at all, apparently hoping that the FDA will not catch them.⁷⁵ Even when companies submit their advertising materials when an ad is first aired, the FDA lacks the personnel and resources to review all of the thousands of advertisements it receives. And this problem has intensified as the number of DTC ads continues to increase.⁷⁶ Indeed, the FDA has admitted that it cannot review DTC ads in a timely way,

71. *Id.*

72. 2002 GAO REPORT, *supra* note 55, at 8. Several companies have encountered problems with the FDA over these reminder ads, however. The manufacturer of the nasal allergy drug Flonase received a regulatory letter from the FDA in 1999 after it aired an advertisement that did not directly state the indication of the drug. Rather, the ad showed “a person in an environment that contains allergens, such as flowers, grasses, and trees, and then show[ed] the person taking a deep breath.” *See* Letter from FDA to Glaxo Wellcome (Sept. 17, 1999), <http://www.fda.gov/cder/warn/sep99/wl091799.pdf>.

73. 2002 GAO REPORT, *supra* note 55 at 20 tbl.4.

74. *Id.*

75. For instance, in 1998 and 1999, the makers of Flonase, a nasal spray for relief from allergy symptoms, aired a commercial in Puerto Rico that was never submitted to the FDA and contained “no risk information at all.” *See* Warning Letter from FDA to Glaxo Wellcome (August 18, 1999), <http://www.fda.gov/cder/warn/aug99/wl081899.pdf>. Once the FDA learned of the ad, it sent a warning letter to the manufacturer in August 1999. This was not an isolated occurrence. In recent years, the FDA has had to issue a number of warning letters to companies that have failed to submit advertising material to the FDA. *See* 2002 GAO REPORT, *supra* note 55, at 20 tbl.4.

76. *See Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Subcomm. on Health of the Comm. on Energy and Commerce H.R.*, 107th Cong. 10 (2002) (responses of the Food and Drug Administration for the record). In its 2006 report, the GAO found that the DTC Review Group at the FDA suffered from under-staffing and was not equipped to handle the 4,600 final DTC materials in received in 2005. NOV. 2006 GAO REPORT, *supra* note 60, at 17–19.

and has estimated that it would need to nearly double the number of reviewers it has on staff just to keep pace with DTC ads.⁷⁷

The FDA's problems extend beyond resource limitations. The agency has only limited authority to sanction companies for false or misleading ads. The FDA has no statutory authority to impose civil penalties for misleading ads, and the only real sanction it has (apart from bringing a misbranding action in court) is to issue public warning letters that detail the violation and threaten legal action if the violation is not rectified.⁷⁸ But the process of issuing warning letters has fallen victim to internal FDA politics. As a result of a 2002 policy change, all regulatory letters now have to be reviewed by the FDA's Office of Chief Counsel.⁷⁹ The change has had two consequences. One is that the number of warning letters has dropped markedly. According to the GAO, "[s]ince the policy change, FDA has issued fewer regulatory letters per year than it did in any year prior to the change."⁸⁰ From 1997 to 2001, the FDA issued 15 to 25 letters per year related to DTC ads; from 2002 to 2005, only 8 to 11 letters were issued per year.⁸¹ The second, and perhaps more problematic, consequence is delay. In 2002, the GAO raised questions about the speed with which regulatory letters were being processed.⁸² Although the FDA promised reform, the process is still mired in delay.⁸³ Between 2002 and 2005, it took an average of 4 months for the FDA to issue a regulatory letter; prior to the policy

77. *Id.* Legislation currently before Congress would ameliorate this problem. In provisions reauthorizing the FDA's "user fee" program, in which drug companies pay a fee to defray the cost of the FDA reviewing applications for new drugs, Congress has proposed giving companies the right to pay a new user fee to have the FDA review an ad before it is aired. The pending legislation would also give the FDA new authority, including the ability to impose civil money payments, for certain violations of the Act, including those involving drug promotion. See generally CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, FDA LEGISLATION IN THE 110TH CONGRESS: A GUIDE TO S.1082 AND H.R. 2900 (July 18, 2007).

78. On occasion, the FDA directs companies to issue "corrective advertising materials." But the FDA has little control of the timing of corrective ads, and there is generally a lengthy delay. In one example cited by the GAO, the FDA found an ad that had run from April through October 2004 to be in violation of the Act. The FDA issued a letter in April 2005 requiring the company to correct the misleading ad. But the company did not issue the corrective ad until January 2006. NOV. 2006 GAO REPORT, *supra* note 60, at 31.

79. *Id.* at 2.

80. *Id.* at 21.

81. *Id.* at 21.

82. *Id.* at 3.

83. *Id.* (discussing GAO recommendations for reform and resulting FDA goals).

change, issuing a letter took about two weeks.⁸⁴ As a result, misleading ads remain on the air for extended periods of time, and the FDA often sends out warning letters after an advertising campaign has run its course.⁸⁵

DTC ads have been identified as a key culprit in several serious recent public health debacles, most notably with Vioxx and Celebrex.⁸⁶ These drugs belong to a class of drugs known as “COX-2 inhibitors.”⁸⁷ They were developed as part of a new generation of pain relievers for patients with arthritis and rheumatism, equally effective as older painkillers like ibuprofen in blocking pain, but with less risk of gastrointestinal bleeding.⁸⁸ Recognizing that these drugs might mark a significant therapeutic advance, the FDA accelerated its approval of them, with approvals for Celebrex and Vioxx coming in 1998 and 1999, respectively.⁸⁹ COX-2 drugs were not marketed simply as improved versions of older treatments. Instead, they were marketed as entirely new drugs that were more effective, lower-risk treatments for pain and inflammation associated with common ailments, ranging from mild muscle aches to arthritis. As has now been shown, not only were these claims overstated, but the drugs also increase a patient’s risk of heart attack and stroke, especially when used for extended periods. Because of these risks, Vioxx was

84. *Id.* at 21, 28. One congressional study found that in 2003 it took the FDA an average of 177 days from initial placement of a prescription drug advertisement to an enforcement action, if any. MINORITY STAFF OF U.S. H.R. COMM. ON GOV’T REFORM, FDA ENFORCEMENT ACTIONS AGAINST FALSE AND MISLEADING PRESCRIPTION DRUG ADVERTISEMENTS DECLINED IN 2003 4 (2004), available at http://drugsafetyresearch.com/downloads/House_Dem_Rept_Advertising.pdf.

85. NOV. 2006 GAO REPORT, *supra* note 60, at 28. One signal that the FDA’s oversight is not an effective deterrent is the fact that “FDA regulatory letters do not always prevent the same drug companies from later disseminating violative DTC materials for the same drug, sometimes using the same or similar claims” the FDA had previously found misleading. *Id.* at 31. Of the 89 drugs for which the FDA sent regulatory letters between 1997 and 2005, 25 drugs had DTC advertising materials that were cited in more than one letter. *Id.*

86. See generally Barry Meier et al., *Medicine Fueled by Marketing Intensified Trouble for Pain Pills*, N.Y. TIMES, Dec. 19, 2004, at A1.

87. *Id.*

88. *Id.*

89. Drugs that are approved on an accelerated basis are cleared by the FDA with less safety and efficacy information than other drugs, and there is a greater chance that unforeseen risks will emerge as the drug is used in larger populations for longer durations. See GOVERNMENT ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS (GAO-06-402) 11 (Mar. 2006), available at www.gao.gov/new.items/d06402.pdf.

withdrawn from the market in 2004 and warnings were added to alert patients using Celebrex of the drug's cardiovascular risks.⁹⁰

As soon as the drugs were approved by the FDA, they were heavily promoted directly to patients as safer and more effective substitutes for the older generation of anti-inflammatory drugs.⁹¹ Merck, for example, trumpeted the FDA's approval of Vioxx with what the company proclaimed to be its biggest, fastest, and best launch ever.⁹² In 2000, just its second year on the market, Vioxx was the number one DTC-advertised drug—\$160 million for DTC ads,⁹³ more than spent that year to advertise Budweiser or Pepsi—and retail sales quadrupled.⁹⁴ Until 2002, the ads made no mention of an increased risk of heart attack or stroke.⁹⁵ In the first nine months of 2004, Pfizer spent over \$71 million on DTC ads for Celebrex, even though doubts about the safety of the drug had already begun to emerge.⁹⁶

These ads were highly successful. After just a year on the market, the COX-2 drugs (mainly Vioxx and Celebrex) had captured about 40 percent of the market from traditional anti-inflammatory drugs, despite costing an average of two to three dollars per pill, while the older generation anti-inflammatory drugs cost just a few pennies each.⁹⁷ More than 19 million prescriptions for Celebrex

90. Both companies are now embroiled in extensive product liability litigation over these risks. See, e.g., Bloomberg News Service, *Vioxx Damage Award*, N.Y. TIMES, June 6, 2007, at C8, available at <http://nytimes.com/2007/06/06/business/06vioxx.html?ex=1338782400&en=be8ff02278a25d25&ei=5088&partner=rssnyt&emc=rss> (estimating that Merck faces over 27,000 lawsuits over Vioxx).

91. See Meier, *supra* note 86, at 1.

92. See Robert Langreth, *Merck's Vioxx Arthritis Drug Gets Approval*, WALL ST. J., May 24, 1999, at B3.

93. THE EUROPEAN CONSUMERS ORGANISATION, CONSUMERS SAY NO TO UNETHICAL DRUG PROMOTIONS 4 (2006).

94. NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT, PRESCRIPTION DRUGS AND MASS MEDIA ADVERTISING, 2000 5 (2001), available at <http://www.nihcm.org/~nihcmor/pdf/DTCbrief2001.pdf>.

95. The FDA warned Merck in 2001 that its advertising campaign for Vioxx (including DTC ads) improperly minimized the risks of heart attack and stroke. After protracted negotiations between the FDA and Merck, the agency in 2002 required Merck to add warnings about heart attack and stroke to Vioxx's labeling. See Barry Meier, *For Merck, Defense of a Drug Crumbles at a Difficult Time*, N.Y. TIMES, Oct. 1, 2004, at C1.

96. Meier, *supra* note 86, at 1.

97. *Id.* at 38.

were written its first year on the market.⁹⁸ An estimated 105 million prescriptions were written for Vioxx in the United States between May 20, 1999 and September 30, 2004, involving 20 million patients.⁹⁹ At the height of their sales, Celebrex brought in about \$3.3 billion a year for Pfizer and Vioxx brought in over \$2.5 billion for Merck.¹⁰⁰

According to medical experts, the effect of the DTC advertising was “to drive consumer demand for COX-2 drugs far beyond the bulk of those patients who really benefit from them.”¹⁰¹ Use of Vioxx and Celebrex extended well beyond what could be justified medically.¹⁰² And, the experts contend, the problem is not one limited to the COX-2 market. “Too often, marketing can drown out medical science” because “the lure of the new drug can run ahead of the science.”¹⁰³ As *The New York Times* put it, the COX-2 example is “perhaps the clearest instance yet of how the confluence of medicine and marketing can turn hope into hype.”¹⁰⁴

IV. THE SMALL ARGUMENTS THAT WILL NOT GO AWAY

There have been a number of proposals by Congress to limit DTC advertising or to ban it outright.¹⁰⁵ I will not try to canvass all of those efforts here. Instead, I will focus only on two proposals, each of which has recently received serious consideration by Congress. The first would give the FDA authority to require disclaimers on DTC ads and, in some cases, impose a two-year moratorium on DTC advertising for specific, potentially high-risk

98. Diedtra Henderson, *How Safe Is Celebrex?*, BOSTON GLOBE, Feb. 25, 2007 at D1 available at http://www.boston.com/yourlife/health/diseases/articles/2007/02/25/how_safe_is_celebrex/.

99. *In re Vioxx Prods. Liab. Litig.*, 2007 U.S. Dist. LEXIS 48367 (E.D. La. July 3, 2007).

100. Meier, *supra* note 86, at 1.

101. *Id.* at A38.

102. *Id.* (“A big problem with COX-2 drugs . . . has been the tendency of doctors to use them indiscriminately”) (quoting Dr. Guerkipal Singh).

103. *Id.* (quoting Dr. James F. Fries, Director, Stanford Arthritis Group); *see also* NOV. 2006 GAO REPORT, *supra* note 60, at 16–17.

104. Meier, *supra* note 86, at A1.

105. Some of the pre-2002 proposals are addressed in Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 434–36 (2002).

drugs.¹⁰⁶ The second would ban outright all DTC advertising in broadcast media.¹⁰⁷

Both proposals reflect a deep-seated concern that DTC advertising artificially creates demand for drugs that may pose special dangers to consumers. The underlying worry is that the FDA's testing and evaluation of drugs prior to approval is based on clinical studies that are conducted over relatively brief periods of time—maybe a year or so—and involve small groups—at most a few thousand—of relatively homogenous patients. Pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect sub-populations not included or adequately represented in the studies (e.g., the elderly, ethnic minorities, and pregnant women).¹⁰⁸ For these reasons, the FDA's approval of a drug is not a warrant that the drug will not cause serious adverse effects even if used for its intended purposes. And experience shows that many unforeseen risks emerge in the first year or so that a drug is marketed for general use.¹⁰⁹ To proponents of the efforts to restrict DTC advertising, Vioxx and Celebrex are the poster children for these dangers.¹¹⁰

A. *The First Proposal*

The first proposal, floated by Senator Kennedy during Congress's recent debates on pending drug safety legislation, was designed to clarify and expand the FDA's regulatory authority over DTC advertising.¹¹¹ Under the proposal, the FDA would be

106. See discussion *infra* Part III.A.

107. See discussion *infra* Part III.B.

108. IOM REPORT, *supra* note 67, at 38.

109. See generally David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008); see also IOM REPORT, *supra* note 67, at 38; Bruce M. Psaty & Curt D. Furberg, *COX-2 Inhibitors—Lessons in Drug Safety*, 352 NEW. ENG. J. MED. 1133, 1134 (2005) (“In the initial evaluation of the COX-2 inhibitors [the class of drugs that includes Vioxx and Celebrex] the use of small, short-term trials, the exclusion of high-risk patients, and the methodological inattention to cardiovascular events all minimized the possibility of uncovering evidence of cardiovascular harm.”)

110. They are not, however, the only examples. More recently, the FDA came under fire for taking a year to require the manufacturers of two widely sold diabetes drugs, Avandia and Actos, to carry prominent “black box” warnings for the risk of heart attack. See, e.g., Gardiner Harris, *F.D.A. Issues Strictest Warning on Diabetes Drugs*, N.Y. TIMES, June 7, 2007, at A1; Gardiner Harris, *Potentially Incompatible Goals at F.D.A.*, N.Y. TIMES, June 11, 2007, at A1.

111. The proposal is based on an amendment to S. 1082, 110th Cong., offered by Senator Kennedy, that was taken out of the bill during mark-up by the Senate Committee on Health, Education and Labor. Senator Kennedy's proposal, in turn, was an effort to build upon the

authorized to “pre-review” DTC ads.¹¹² If accepted, the FDA would have to complete its review within forty-five days.¹¹³

The proposal would then empower the FDA to regulate DTC advertising in situations where the proposed advertising lacks a specific disclosure of when the drug was approved and an acknowledgment that existing information “may not have identified or allowed for full assessment of all serious risks” relating to the drug.¹¹⁴ This disclosure would respond directly to the concern that consumers may be unaware that pre-approval testing of new drugs is no guarantee that adverse effects will not emerge once the drug has been used in larger patient populations for a year or more.¹¹⁵ For that reason, the proposal authorizes the FDA to direct that DTC advertisements contain disclaimers alerting consumers that the drug has only recently been approved by the FDA and thus the products’ risk profile is still uncertain. In the exceptional case where the FDA determines that the disclaimers would not, on their own, be adequate “to protect public health and safety,” and that “additional information about serious risks” needs to be compiled, the proposal would give the FDA the power to prohibit DTC ads for the drug for a fixed period not to exceed two years.¹¹⁶ In exercising that power, the FDA would have to consider a host of factors, including a patient’s ability to obtain substitute products and the “extent to which clinical trials used to approve the drug may not have identified serious risks that might occur among patients expected to be treated with the drug.”¹¹⁷

The question is whether such a proposal, if enacted into law, would survive First Amendment review.¹¹⁸ Let me start with the

recommendation of the National Academy of Sciences’ Institute of Medicine that, in widely publicized 2006 report, urged Congress to impose a two year ban on DTC advertising for all new drugs. See IOM REPORT, *supra* note 67, at 158.

112. Food and Drug Administration Revitalization Act, S. 1082, 110th Cong. § 202(5)(O)(N) (2005).

113. *Id.*

114. *Id.* at § 202(4)(G)(i).

115. See Kessler & Vladeck, *supra* note 109, at 471.

116. S. 1082, 110th Cong. § 202 (o)(5)(F) (as reported by Sen. Kennedy, Apr. 24, 2007).

117. *Id.* at § 202 (o)(5)(F)(v).

118. I will put to the side any claim that the First Amendment would bar Congress from giving the FDA the power to “prereview” DTC ads for new drugs. Courts have rejected the argument that the prior restraint doctrine applies in the commercial speech context. *E.g., Va. State Bd. of Pharmacy*, 425 U.S. at 771 n.24 (finding prior restraint doctrine “inapplicable” to commercial speech). And the Food, Drug, and Cosmetic Act already gives the agency ample

basic arguments in favor of its constitutionality, and then I will sketch out the arguments against.¹¹⁹

1. Arguments Supporting Constitutionality

The first and most powerful argument in favor of the first proposal is the core public health justification Congress would invoke in enacting it—namely, that DTC advertising of prescription drugs artificially and improperly stimulates demand for drugs that, by definition, pose a serious health threat to patients. That risk greatly increases with newly approved drugs whose safety profiles are uncertain.¹²⁰ As noted above, there is substantial empirical evidence underlying Congress's determinations that DTC ads pose a real threat to the public health, and that disclaimers or the temporary elimination of DTC advertising for specific high-risk drugs would materially advance the government's interest in safeguarding consumers from inappropriately taking drugs whose risks are unknown but potentially grave.¹²¹ *Virginia Board of Pharmacy* sought to further the consumers' interest in receiving truthful information about products. That rationale does not extend to information that may be as misleading as it is helpful.

With that general submission as a backdrop, the defense of the disclaimer provision becomes simple. Authorizing the FDA to require disclaimers on advertisements that, in the agency's view, fail to adequately address the risks posed by the drug or to inform consumers about the risks that inhere in taking a newly approved drug easily passes constitutional muster. Ever since *Zauderer v. Office of Disciplinary Counsel*,¹²² it has been settled that disclaimers

authority to screen a product's labeling before a drug is approved by the FDA, and the label and accompanying advertising is made public. See Kessler & Vladeck, *supra* note 109.

119. My purpose here is not to exhaustively review the arguments that could be made in support of or in opposition to the constitutionality of these proposals. My purpose is more modest, which is simply to show the complexity of the problems that confront courts in commercial speech cases, and, later on, to explain why this illustration bears out Professor Shiffrin's concerns.

120. See generally Kessler & Vladeck, *supra* note 109.

121. See, e.g., *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (requiring the government to "demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree.").

122. 471 U.S. 626 (1985); see also *Va. State Bd. of Pharmacy*, 425 U.S. at 771 n.24.

are a favored First Amendment remedy.¹²³ Indeed, in *Shalala v. Pearson*,¹²⁴ the United States Court of Appeals for the District of Columbia Circuit ruled that, rather than place more restrictive restraints on speech, the FDA was *required* to use disclaimers and warnings to solve the problem of potential consumer deception, if at all possible.¹²⁵

The more serious objection would be to authorizing the FDA to impose a moratorium on DTC ads for up to two years. Moratorium proponents would begin their argument by pointing out that Congress has drawn the FDA's authority as narrowly as possible to address a serious, but infrequently occurring problem. To ensure that the FDA did not use its authority inappropriately, Congress would carefully circumscribe the agency's authority to restrict DTC ads. First, the FDA may impose a moratorium only if it determines that DTC advertising for a particular drug poses an unreasonable risk to public health and that disclaimers would be "inadequate to protect public health and safety."¹²⁶ Second, the authorization applies only after the FDA determines that "additional information about serious risks" needs to be compiled.¹²⁷ And finally, in making this determination, the FDA must consider a host of factors going to the drug's risk, a patient's ability to obtain substitute products, and the "extent to which clinical trials used to approve the drug may not have identified serious risks that might occur among patients expected to be treated with the drug."¹²⁸

The constitutional argument would be strengthened by the practical necessity of giving the FDA this authority. After all, the extensive safeguards that are built into the provision contemplate a

123. 44 *Liquormart v. R.I.*, 517 U.S. 484, 501 (1996) (plurality opinion) (observing that state regulation to "require[] the disclosure of beneficial consumer information" should not be subject to demanding scrutiny); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 492 (Stevens, J., concurring). More recently, the Court has held that some compelled, non-factual claims must be subject to First Amendment scrutiny. This can be seen for example in *United States v. United Foods*, 533 U.S. 405, 411 (2001). But the Court has also held that *government* speech, even if subsidized by a private party, is not subject to First Amendment analysis. *Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550 (2005).

124. 164 F.3d 650 (D.C. Cir. 1999).

125. *Id.* at 658–60.

126. Enhancing Drug Safety and Innovation Act of 2007, H.R. 1561, 110th Cong. § 101(O)(4)(H) (2007).

127. *Id.*

128. *Id.* at § 101(O)(4)(H)(i) to (v).

situation in which the FDA has to make a tough decision—whether to approve for marketing a drug that holds promise for some patients, but whose risks are not fully understood and are deemed serious. If the FDA’s only choice is to approve the drug, and in so doing, permit unrestrained DTC advertising, then the prudent choice may well be to hold off on approval until those risks are better understood, even though that choice will deprive some patients of a new and perhaps more effective drug. A powerful justification for this provision is that it offers the agency another, perhaps more rational, choice—approve the drug, but dampen unwarranted consumer demand by restricting DTC advertising until the drug’s risk profile is better understood.¹²⁹

2. Arguments Against Constitutionality

There are, of course, serious constitutional objections to such a proposal, most of which go to the FDA’s power to block DTC ads for up to two years. Drug companies invest heavily in DTC advertising because the ads influence patient-consumer behavior.¹³⁰ Supporters of DTC ads cite their informational and educational role as a distinct advantage—that is, they get critical information in the hands of patients and not just their doctors.¹³¹ DTC ads empower patients to take control over their own health care and make better informed choices, goals plainly in keeping with the autonomy and self-expression values embedded in the First Amendment.¹³²

The argument against any kind of advertising ban—even one of limited duration—would find support in the case law. Most important would be the Court’s decision in *Thompson v. Western*

129. This is just what happened when the FDA approved the new diabetes drug Symlin. As part of the negotiations over the drug’s approval, the company agreed not to engage in DTC advertising for two years and to forego advertising in journals for one year. Although the company has not complained, the FDA has been criticized by industry for pushing the company to limit its advertising as part of the approval process. *See, e.g.,* Scott Gottlieb, *Drug Safety Proposals And the Intrusion of Federal Regulation into Patient Freedom and Medical Practice*, 26 HEALTH AFF. 664, 671 (2007).

130. *See*, NOV. 2006 GAO REPORT, *supra* note 60, at 12–14.

131. *See generally, id.* at 16.

132. There is empirical evidence that supports the proposition that DTC ads have some educational benefit; they spur patients to ask their doctors about prescription drug treatments, and, on occasion, get a diagnosis for a previously unknown medical condition—some of which involve high priority conditions such as asthma and high blood pressure. *See, e.g.,* DONNA V. VOGT, CONG. RESEARCH SERV., REPORT FOR CONG., *DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS* (Mar. 25, 2005); K. Aikin, *supra* note 64, at 3–4.

States Medical Center,¹³³ where a divided Court struck down a federal law authorizing pharmacists to “compound” drugs, but prohibiting pharmacists from advertising their services. The law had been crafted to permit pharmacists to compound specialty drugs not generally on the market but needed by a handful of patients.¹³⁴ But Congress was wary that pharmacies were not equipped to engage safely in the mass compounding of drugs and wanted to ensure that pharmacy compounding was limited to special circumstances.¹³⁵ In ruling against the FDA, the majority discounted Congress’s judgment that public health imperatives justified the advertising restraint. The majority concluded instead that Congress would have to find non-speech means to achieve its objective of limiting compounding activities by pharmacies.¹³⁶ In so ruling, the majority gave considerable emphasis to the free speech rights of the pharmacists, so much so that those rights took precedence over public health objectives deemed by the Court to be valid and significant.¹³⁷

Supporters of DTC ads would likely contend as well that a blanket restriction on DTC advertising, even a targeted one of limited duration, runs afoul of the Court’s well-known hostility to categorical bans on speech that is not demonstrably false, misleading, or deceptive. Although the Court could not find

133. 535 U.S. 357 (2002).

134. *Id.* at 357–58.

135. *Id.*

136. *Id.* at 372. It may be hazardous to read too much into the *Western States* decision, especially since the impact of the ruling was to void the statute in its entirety. The ruling resulted in the *withdrawal* of authority for pharmacists to engage in compounding. This somewhat odd result came about because the Ninth Circuit ruled that, although the statute violated the First Amendment rights of pharmacists, the statutory authorization for compounding was not severable from the advertising ban, and thus the entire statute was invalid. *See* 535 U.S. at 366. Remarkably, the pharmacists did not challenge the severability ruling in the Supreme Court. *Id.* Thus, when the Supreme Court affirmed the Ninth Circuit’s judgment, the pharmacists’ victory became a pyrrhic one, and Congress has not revisited the compounding issue since the Court’s ruling.

137. *Id.* at 369. The Court’s newfound concern over the expressive rights of the speaker in economic regulation cases was also evident in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), where the Court invalidated a Massachusetts regulation restricting the outdoor advertising of tobacco products. The *Lorillard* majority based its ruling in part on the notion that the Massachusetts regulation went too far in interfering with the tobacco companies’ ability to get its selling message to willing adult smokers. *Id.* at 555–61. More recently, the Court’s decision in *FEC v. Wisconsin Right to Life*, 127 S. Ct. 2652 (2007), appears to require, at least in the election context, a constitutional regime in which non-profit corporations are entitled to the same First Amendment protections as individuals.

common ground over a rationale in *44 Liquormart, Inc. v. Rhode Island*,¹³⁸ each Justice made clear that an outright ban on truthful commercial speech that keeps consumers “in the dark” about a lawful product would come before the Court with a heavy burden of justification.¹³⁹ There are, it should be recognized, a number of salient differences between DTC advertising of drugs and *44 Liquormart*. For one thing, here, in contrast to *44 Liquormart*, it is at least arguable that the ban is not a categorical one because drug companies would face no restraint in advertising and promoting the drug to physicians. For another, drugs are subject to even more extensive regulation than alcoholic beverages, including a federal ban on their direct sale to patients in the absence of a prescription. But this paternalism argument would nonetheless carry weight with a court. After all, a court would have good reason to be skeptical about the government’s claim that it is in the *patient’s* best interest to be kept in the dark about a new medication that might be effective in treating the patient’s ailment.

Finally, DTC advertising supporters would invoke the Court’s First Amendment decision in *Lorillard Tobacco Co. v. Reilly*,¹⁴⁰ which overturned a Massachusetts regulation severely limiting outdoor tobacco advertising. A majority of the Justices found that the regulations satisfied the third part of the *Central Hudson* test by directly and materially advancing Massachusetts’ interest in deterring tobacco usage by minors.¹⁴¹ But a different majority concluded that the regulations failed to satisfy *Central Hudson’s* proportionality test because the regulations would effectively ban outdoor tobacco advertising in most of the State’s urban areas, thereby preventing the companies from communicating their sales messages to adults.¹⁴² Supporters of DTC advertising would argue that the FDA’s power to ban was no more constrained than the authority Massachusetts asserted in *Lorillard*, because an FDA-imposed ban would effectively cut off a company’s ability to communicate with the patients who are the ultimate consumers of their products.

138. 517 U.S. 484 (1996).

139. *Id.* at 501–04 (plurality opinion); *id.* at 526–28 (Thomas, J., concurring).

140. 533 U.S. 525 (2001).

141. *Id.* at 555–61.

142. *Id.* at 561–66.

B. *The Second Proposal*

The second proposal, offered by Representative Anna Eshoo, would enact a flat ban on DTC ads in broadcast media.¹⁴³ Under the second proposal, DTC ads in newspapers and magazines would not be restricted, nor would any restriction be placed on advertising and promotional campaigns directed at doctors or other health care professionals licensed to prescribe drugs.

1. Arguments Supporting Constitutionality

Representative Eshoo and her co-sponsors do not see a First Amendment problem with her proposal. They contend that prescription medication cannot be purchased directly by patients for a reason—questions about whether a drug should be prescribed at all, and, if so, which drug should be prescribed, are ones that should be decided by doctors with specialized medical judgment. Non-experts have no business making these determinations. DTC ads distort that judgment because they encourage patients to demand medications that may not be best-suited for them. They demand drugs not on the basis of a detailed understanding of the scientific factors that go into selecting drugs, but on the basis of thirty- or sixty-second commercials that are skillfully designed to stimulate demand. And doctors often succumb to patient pressure, or patients “doctor-shop” until they find a doctor willing to write the prescription the patient wants. Medical organizations generally see DTC ads as a threat to the doctor-patient relationship for just that reason.¹⁴⁴

Supporters of the proposal also contend that a DTC advertising ban limited to the broadcast media leaves open ample channels of communication. Drug companies would remain free to promote their drugs to doctors and other health care providers, and could reach consumers with print ads that, presumably, are more informative than brief broadcast ads. And they argue that cases like *Red Lion*

143. During the House deliberations on drug safety legislation, Rep. Anna Eshoo offered an amendment to ban DTC advertising by adding to section 301 of the Federal Food, Drug and Cosmetic Act a provision that said “[t]he sponsorship of direct-to-consumer broadcast advertising of any drug” is a prohibited act.

144. See, e.g., American College of Physicians, *Direct-to-Consumer Prescription Drug Advertising: Position Paper*, at 17 (2006) (opposing DTC advertising because, among other things, it “undermines the patient-physician relationship and often leaves patients confused and misinformed about medications.”) available at http://www.acponline.org/hpp/direct_prescript.pdf.

establish that the government is entitled to regulate broadcast advertising more strictly than advertising in other media, because the spectrum is a scarce public good that Congress has a right to supervise.¹⁴⁵ That justification was sufficient to uphold a ban on broadcast advertising of cigarettes, although the challenge to that ban came before *Virginia Board of Pharmacy*.¹⁴⁶

Nonetheless, the burden of justifying an advertising ban on a lawful product is a heavy one, and the Court has signaled its willingness to abandon the *Central Hudson* test in favor of a tougher standard when confronted with a product ban that effectively keeps consumers in the dark.¹⁴⁷ In response, the ban's proponents would make two related arguments. First, relying on a line of cases that includes *Tennessee Secondary School Athletic Ass'n v. Brentwood Academy*,¹⁴⁸ *Florida Bar v. Went for It, Inc.*,¹⁴⁹ and *Ohralik v. Ohio State Bar Ass'n*,¹⁵⁰ proponents of the ban would argue that the Court has often upheld restraints carefully tailored to shield vulnerable individuals from selling messages they may not be capable of evaluating or verifying on their own. This defense is not based on the nature of the message as much as it is based on the inability of the audience to evaluate it. For instance, in *Tennessee Secondary School*, the Court upheld a ban forbidding coaches from directly soliciting impressionable high school athletes; in *Florida Bar*, the Court upheld a ban on lawyers soliciting recent accident victims and their families; and in *Ohralik*, the Court upheld a ban on lawyers

145. See *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969); see also *Columbia Broad. Sys., Inc. v. Democratic Comm.*, 412 U.S. 94, 101 (1973); *Broad. Co. v. United States*, 319 U.S. 190 (1943).

146. *Capital Broad. Co. v. Mitchell*, 333 F. Supp. 583 (D.D.C. 1971) (three-judge court), *aff'd without opinion sub nom.* *Capital Broad. Co. v. Kleindienst*, 405 U.S. 1000 (1972). It bears noting that no cigarette company challenged the ban after *Virginia Board of Pharmacy* ruled that commercial speech merits constitutional protection. A similar ban was put in place for advertising smokeless tobacco products on broadcast media in 1986, see 15 U.S.C. §4402(f), but the industry has not challenged that restriction either.

147. In *44 Liquormart*, noted above, at least four Justices indicated their willingness to replace *Central Hudson* with a stricter standard in cases involving categorical bans on truthful speech. See 517 U.S. at 501–04 (Stevens, J., concurring along with Kennedy and Ginsburg, JJ.); *id.* at 526–28 (Thomas, J., concurring). I say “at least” four Justices because Justice Scalia’s concurrence is less than clear on whether he intended to join the block of Justices calling for the overhaul of the doctrine. See *id.* at 517 (Scalia, J., concurring).

148. 127 S. Ct. 2489 (2007).

149. 515 U.S. 618 (1995).

150. 436 U.S. 447 (1978).

engaging in in-person solicitation of teenage accident victims. Arguably, this case is no different. Here, the ban is based on the judgment that ordinary consumers—unskilled in the intricate science of drug evaluation—are incapable of evaluating DTC claims on their own. If left to their own devices, consumers might easily be persuaded to choose less effective or riskier medications based not on sound medical judgment, but on brief but powerful television ads. Congress has a substantial interest in averting those judgment errors, especially since, as we learned with Vioxx and Celebrex, patients pay for errors not just with their wallets, but with their well-being.

The second argument would build on the first, but instead of focusing on the *audience* for the advertisements, it would focus on the *content* of the ads. Proponents contend that DTC advertising imperils the health of the American public by offering exaggerated, incomplete, and deceptive information about drugs. DTC ads are inevitably misleading because it is impossible to present accurate and balanced information about the benefits and risks of a drug in a commercial that is typically thirty to sixty seconds long. Moreover, the proponents would argue, the primary purpose of DTC advertising is not to educate consumers, but instead is to encourage them to actively seek out medication that their physician would not otherwise prescribe. The empirical evidence supports that claim.¹⁵¹ These reasons, the ban's supporters would claim, render all DTC advertising misleading and subject to plenary regulation by Congress.¹⁵²

151. See, e.g., Dominick L. Frosch, et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 ANNALS OF FAM. MED. 6 (2007) (empirical study of DTC ads; finding that they are aimed principally at making an emotional appeal to consumers, "possibly prompting consumers to request prescriptions that are clinically inappropriate or more expensive than equally effective alternatives") available at <http://www.annfammed.org/cgi/reprint/5/1/6> (last visited on Oct. 6, 2007); Mike Mitka, *Researchers Critical of TV Drug Ads*, 293 JAMA 939 (2007).

152. Because the commercial speech doctrine is aimed at fostering intelligent and well informed decisions by consumers, the Court has rejected efforts to extend protection to false, misleading or deceptive information. Justice Stewart's concurrence in *Virginia Board of Pharmacy* still best expresses the Court's view on this matter: "the elimination of false and deceptive claims serves to promote the one facet of commercial price and product advertising that warrants First Amendment protection—its contribution to the flow of accurate and reliable information relevant to public and private decisionmaking." 425 U.S. at 781 (Stewart, J., concurring). Similar statements are commonplace in the Court's decisions. See, e.g., *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 496 (1995) (Stevens, J., concurring); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002).

2. Arguments Against Constitutionality

Opponents of a DTC advertising ban would start their attack with *44 Liquormart*, which is emblematic of the Court's hostility to categorical restraints denying consumers information about lawful products. Their argument would be that the DTC advertising ban is a one-size-fits-all restraint on the dissemination of truthful information imposed to deprive consumers of important information relating to their own medical care. This, opponents would claim, is the height of paternalism—even worse than the paternalism criticized by the Court in *Virginia Board of Pharmacy*. At least in *Virginia Board of Pharmacy*, patients had access to information about what medication might best treat their ailment; only price information was subject to restraint. Here, the avowed purpose of the ban—to limit the ability of patients to be full participants in making decisions about their medical treatment—is its fatal First Amendment flaw. Many of the Court's cases support the view that bans on the dissemination of truthful information cannot, except in rare cases, survive First Amendment review.¹⁵³

Opponents of the ban would also argue that it fails *Central Hudson's* requirement that restraints must be proportional to the interests served. They would contend that a more narrowly drawn restraint could serve Congress's interests equally well. Congress has many less intrusive options. Congress could, for instance, give the FDA broader authority to identify and sanction DTC ads that are, in fact, false, misleading or deceptive. Congress could provide the FDA with greater resources to oversee DTC advertising. Or Congress could give the FDA the resources to educate consumers about the risks that newly approved drugs carry. Cases like *Lorillard Tobacco*, which held that Massachusetts' near-complete ban on outdoor tobacco advertising in urban areas was fatally overinclusive, would provide a strong foundation for these proportionality arguments.

V. WHAT WOULD A COURT DO?

Professor Shiffrin has recently been quoted in the *New England Journal of Medicine* as saying that “it's more likely than not that [a ban on DTC ads] will be struck down,” but it is unclear whether

153. *E.g.*, *Rubin*, 514 U.S. 476; *Thompson*, 535 U.S. 357.

Professor Shiffrin was speaking about a complete ban on broadcast ads or a more tailored, limited-duration ban of the kind outlined in the first proposal.¹⁵⁴ Professor Post, a leading First Amendment scholar and a participant in this Symposium, is quoted in the same article as saying that “[t]o ban direct-to-consumer drug advertising for new drugs, there would have to be something particularly unsafe about the drugs.”¹⁵⁵ Whether the standards set out in the first proposal would meet Professor Post’s test is unclear, but Professor Post’s formulation suggests that something more than uncertainty about a drug’s safety might be needed to justify a ban on DTC advertising for that drug.

My own view, although not strongly held, is that courts would likely uphold the first proposal as a carefully targeted restraint aimed at addressing a serious public health problem for which there is no other sensible solution. Congress must have some room to take reasonable and tailored measures to avoid a recurrence of the problems that were evident with the overzealous and less-than-accurate DTC promotions of Vioxx and Celebrex.¹⁵⁶ And it is hard to see how Congress could more carefully confine the FDA’s authority. As the Institute of Medicine and the Government Accountability Office have found,¹⁵⁷ the evidence demonstrates a clear link between DTC advertising and the overutilization of newly approved, potentially high-risk drugs. Courts would of course worry about the paternalistic nature of the restraint and would scrutinize carefully the claim that non-speech means would not effectively achieve the government’s objective. But they would also take seriously the concern that DTC ads threaten to strain the doctor-

154. Although the article is not clear on this point, Professor Shiffrin has confirmed that, in his opinion, courts would strike down both proposals on First Amendment grounds. His own view, however, is that neither proposal contravenes the First Amendment and, if enacted into law and challenged, should be upheld.

155. See Miriam Shuchman, M.D., *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?*, 356 NEW ENG. J. MED. 2236, 2236 (2007).

156. I recognize that *Central Hudson* stacks the deck against the government, and that the test, as currently applied by the Court, gives little deference to legislative judgments about the seriousness of the government’s interest, the fit between the governmental interest at stake and the restraint imposed, and the absence and ineffectiveness of non-speech alternatives. See generally Vladeck, *supra* note 48. Nonetheless, courts generally resolve commercial speech cases based on a pragmatic, context-specific, all-things-considered balancing of the interests at stake. *Id.* In this case, I think that these interests weigh in favor of the limited ban.

157. See *supra* text accompanying notes 76 & 85.

patient relationship and that DTC ads often persuade patients to take drugs that carry an unjustified risk to their health.

The closest case, in my view, is *Florida Bar v. Went for It, Inc.*,¹⁵⁸ where a divided Court, on the basis of a record far less developed than the one on DTC advertising, upheld a limited duration ban (there thirty days) prohibiting lawyers from contacting recent accident victims and their families.¹⁵⁹ In my view, the public health imperative at issue here is far more weighty than the privacy interest at stake in *Florida Bar*. Whether the Court would be willing to uphold a restraint that can last up to two years while the company and the FDA gather safety data is hard to predict, but on balance I think that the courts would see this statute as a sensible way to accommodate competing interests.

I am less sanguine that a court would uphold the second proposal's ban on broadcast DTC ads. There are, in my view, sound arguments supporting a ban on DTC advertising: the FDA's inability to fully assess a drug safety's prior approval; Congress's judgment to entrust prescribing decisions to physicians, not patients; and the rift DTC ads drive between patients and their doctors. But the fact that Congress gave physicians the sole power to select prescription drugs for their patients does not mean that Congress can deny patients information about newly approved drugs that might help them have informed interactions with their doctor while also allowing a patient to take a role in protecting their health and well-being. Moreover, after the Court's decision in *44 Liquormart*, I think it would be difficult for a court to uphold the kind of blanket ban described in the second proposal. On the other hand, although it has many opportunities to do so, the Court has not abandoned *Red Lion*. Thus, it is possible that a less intrusive form of scrutiny would be applied by the courts because the ban applies only to broadcast media, which might rescue the ban from invalidation.

VI. A PROBLEM THAT IS MANY PROBLEMS, AND THE SMALL QUESTIONS THAT WILL NOT GO AWAY

The preceding discussion highlights the complexity of the legal questions that would arise if Congress enacted a law limiting DTC

158. 515 U.S. 618 (1995).

159. *Id.* at 635.

ads and if that law were challenged on constitutional grounds. The point of the following discussion is to illustrate the enduring nature of Professor Shiffrin's observation that "the commercial speech problem is in fact many problems," and that "the small questions will not go away."¹⁶⁰

Perhaps most important, the DTC example illustrates the wisdom of Professor Shiffrin's critique of the pro-protectionist and anti-protectionist First Amendment theories. For the pro-protectionists who believe that there should be no distinction made between commercial and core speech, the DTC advertising example would be an easy one. In their view, no government-imposed restraints on DTC advertising are constitutional, except for restrictions that prohibit false, deceptive, or misleading ads. If the FDA alleged that an ad violated such a restriction, the burden would rest on the FDA to prove that the ad is in fact false, deceptive, or misleading. If the FDA cannot meet that burden, then it would have no business interceding. Accepting such a view would have two consequences. First, it would make it impossible for the government to invoke uncertainty—here, the unknown risks posed by a newly approved drug—as a justification for a speech restraint. Second, it would relegate government regulation of DTC advertising to ad-specific, after-the-fact, enforcement efforts by a resource-constrained agency.¹⁶¹ In my view, and I suspect Professor Shiffrin's as well, it makes little sense to significantly hamstring government's ability to protect consumers, especially when the Vioxx and Celebrex examples show the toll that unrestrained DTC ads can exact on the public's health.¹⁶²

For the anti-protectionists, who believe that commercial speech should be afforded little, if any, First Amendment protection, the example is an easy one as well, as Justice Rehnquist's dissent in

160. Shiffrin, *supra* note 1, at 1216.

161. Some drug industry lawyers contend that the First Amendment compels such a regime. See, e.g., George Evans & Arnold Friede, *FDA Regulation for Prescription Drug Manufacture Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365 (2003) (authors both serve as counsel to Pfizer).

162. See Shiffrin, *supra* note 7, at 48. (arguing that a "free country need not protect tobacco companies or alcoholic beverage companies when they encourage people to consume products that cause needless death and suffering."). I do not suggest that Professor Shiffrin would see DTC advertising in the same light. The point is simply that, given Professor Shiffrin's context-sensitive approach, the fact that DTC advertising poses serious risks to consumers would have to be considered in any balancing of interests.

Virginia Board of Pharmacy explained.¹⁶³ In their view, selling prescription drugs does not implicate the First Amendment's purpose of enlightening "public decision making as to political, social, and other public issues."¹⁶⁴ And for many anti-protectionists, the fact these ads are disseminated by profit-seeking corporations solely interested in persuading consumers to buy their drugs only reinforces the conclusion that the ads do not merit First Amendment protection. But these arguments overlook the powerful educational role that DTC ads can and, at times, do play and would turn back the clock to an era when paternalistic government regulation of speech was permitted by the Courts. I have no interest in returning to the days of *Valentine v. Chrestensen*, and I suspect that Professor Shiffrin shares that view as well.

The complexity of the issues surrounding DTC advertising also demonstrates that the commercial speech problem is not a unitary one, but "is in fact many problems."¹⁶⁵ Most of the commercial speech doctrine addresses speech relating to the sale of a product—advertising and promotion. But corporations engage in many forms of speech that are subject to strict government regulation, but may or may not fall within the conventional definition of "commercial speech"—that is, speech that proposes a commercial transaction.¹⁶⁶ DTC advertising provides examples of such speech. Suppose that a drug company runs a television ad addressing the advantages of a new class of drugs, but not urging consumers to buy the company's drug? Or suppose the company sends retirees copies of medical journal articles that discuss the benefits and risks of the company's arthritis drug? Or suppose a drug company takes out an ad to defend, in general terms, DTC advertising?¹⁶⁷ Are these examples of

163. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 781–790 (1976).

164. *Id.* at 787.

165. Shiffrin, *supra* note 1, at 1216.

166. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 767 (1993). The Court elaborated a more context-specific test in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66–68 (1983), which focuses on three factors: (1) whether the speech is directed at the speaker's customers; (2) whether the speech contains a promotional message about the speaker's product; and (3) whether the speech is aimed at persuading consumers to buy the speaker's product.

167. These examples are not far-fetched. For instance, Pfizer has produced and aired a 2.5 minute television and internet ad for Celebrex which discusses in depth the risks of gastrointestinal bleeding and cardiovascular events associated with both older-generation painkillers and COX-2s. Further, to give added credibility, the ad claims that it was developed in consultation with the FDA. The ad can be viewed here: <http://www.celebrex.com/content/>

commercial speech? The Supreme Court granted review in *Nike v. Kasky* to address these questions, but left them unresolved. Thirty years after the advent of the commercial speech doctrine we still do not know its metes and bounds.¹⁶⁸

Professor Shiffrin's caution that "the small questions will not go away" has also been borne out. The DTC example was intended to show how complicated and context-specific commercial speech cases are, and why the problem of categorization (i.e., determining whether speech falls within the boundaries of the commercial speech doctrine) is only the first of many questions that arise in assessing restraints on speech related to economic activity. The other questions arise because of the difficulty in balancing the myriad interests that invariably are in play in these cases. And no two cases are alike. Certainly the legal issues that arise with the regulation of DTC advertising are different from those that arise with advertising by lawyers and other professionals, advertising of so-called "sin" products (such as tobacco, alcohol, and gambling), and advertising the sale of securities.¹⁶⁹ Each produces its own specialized jurisprudence. States may restrain in-person solicitation of new

[index.jsp?setShowOn=../content/index.jsp&setShowHighlightOn=../content/index.jsp](#) (last visited on Oct. 6, 2007). The practice of drug companies disseminating favorable studies for unapproved uses was the subject of *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). There, a corporate-sponsored public interest organization sued the FDA for a declaratory judgment that drug companies had a First Amendment right to sponsor the distribution of medical journals to physicians. The court found the case non-justiciable. And although the pharmaceutical industry has not defended DTC ads in direct ads to consumers, it has heavily lobbied Congress to permit DTC advertising to continue without restraint.

168. See Shiffrin, *supra* note, 1 at 1214–15; see also *Nike*, 539 U.S. at 655 (2003) (dismissing the writ of certiorari as improvidently granted). *Nike* demonstrated the complexity of simply drawing the boundaries between "commercial" speech and core political speech—a line-drawing task that Shiffrin thought pointless. See generally *Symposium: Nike v. Kasky and the Modern Commercial Speech Doctrine*, 54 CASE W. RES. L. REV. 965–1299 (2004). Line-drawing problems are of course endemic to First Amendment jurisprudence. The First Amendment carves out domains based on categories—obscenity, fighting words, public forum, and so forth. In some instances, categorization determines whether speech receives First Amendment protection at all (political speech does, obscenity does not). In other instances, categorization defines the degree of First Amendment protection speech warrants (political speech deserves the most stringent protection, commercial speech somewhat less). See generally Frederick Schauer, *Categories and the First Amendment: A Play in Three Acts*, 34 VAND. L. REV. 265 (1981).

169. Compare, e.g., *Bates v. Arizona*, 433 U.S. 350 (1977), *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and *In re Primus*, 436 U.S. 412 (1978), with *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), and *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999), with *Lowe v. SEC*, 472 U.S. 181 (1985).

clients by lawyers but not by accountants.¹⁷⁰ The government may strictly regulate the promotion of securities but not of alcoholic beverages.¹⁷¹ And the government may restrict advertising for lotteries so long as it does so comprehensively and not in a piecemeal fashion.¹⁷² General First Amendment theories have had little success in taming the unruly cases that arise when government seeks to regulate commercial speech.

Perhaps most fundamentally, the DTC example shows that general First Amendment theories do not help us navigate the difficult problems that arise in commercial speech cases. Consider the first proposal to restrict DTC ads. Would broad legal rules provide much help in deciding whether it passes constitutional muster? I do not think so. My experience in litigating commercial speech cases suggests that rule-based approaches are generally too crude to resolve a difficult case.

VII. CONCLUSION

Professor Robert Post, another symposium participant and leading First Amendment scholar, recently said that the commercial speech doctrine is “a notoriously unstable and contentious domain of First Amendment jurisprudence. No other realm of First Amendment law has proved as divisive.”¹⁷³ There are, of course, many possible responses to such a provocative claim. One might be to observe that the doctrine, barely thirty years old, is still experiencing growing pains, and its instability is a reflection of the Court’s continued fine-tuning of a relatively new doctrine. However, another possible response might be to observe that perhaps the instability and contentiousness is symptomatic of the doctrinal flaws Professor Shiffrin identified over twenty years ago. Much of the divisiveness involves the definitional questions identified by Professor Shiffrin that have not been answered by the Court, and much of the instability reflects the Court’s struggle to address “the

170. Compare *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447 (1978), with *Edenfield v. Fane*, 507 U.S. 761 (1993).

171. Compare *Lowe v. SEC*, 472 U.S. 181 (1985), with *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

172. Compare *United States v. Edge Broad. Co.*, 509 U.S. 418 (1993), with *Greater New Orleans Broad. Co. Ass’n v. United States*, 527 U.S. 173 (1999).

173. Robert Post, *The Constitutional Status of Commercial Speech*, 48 *UCLA L. REV.* 1, 2 (2000).

small questions” that, as Professor Shiffrin predicted, have not gone away.

POSTSCRIPT

After this article was written, Congress enacted the Food and Drug Administration Amendments of 2007.¹⁷⁴ Congress gave extensive consideration to whether to impose more stringent rules for DTC advertising, and made three changes to the law that are pertinent here. First, the Amendments grant the FDA authority to require the submission of any television ad for a drug 45 days prior to broadcast.¹⁷⁵ The FDA must review the ad within this time frame.¹⁷⁶ The FDA may make recommendations to ensure that the ad is consistent with “consumer good and well-being,” and that the ad properly represents prescribing information and the efficacy of the drug in specific subpopulations (e.g., the elderly, children, ethnic and racial groups).¹⁷⁷ But the FDA may not require the sponsor to accept its recommendations.¹⁷⁸ If the agency determines that the ad may be false or misleading, the agency may require the sponsor to make affirmative disclosures about the drug’s risks or the date of the drug’s approval, but only for a period not to exceed two years.¹⁷⁹ Second, the Amendments give the FDA the power to impose civil money penalties against drug sponsors for disseminating DTC ads that are “false or misleading.”¹⁸⁰ Civil penalties can be as high as \$250,000 for the first violation and up to \$500,000 for each subsequent violation within three years.¹⁸¹ Civil penalties may be imposed only after providing the sponsor notice and an opportunity for a hearing, and no penalty may be imposed if the ad was pre-screened by the FDA and took into account comments received from the FDA.¹⁸² In that way, the Amendments strongly encourage companies to have their ads pre-screened by the FDA. Third, the

174. Pub. L. No. 110-85, 121 Stat. 823 (2007).

175. *See id.* sec. 901, § 503B(a), 121 Stat. at 939.

176. *Id.*

177. *Id.* sec. 901, § 503B(c), 121 Stat. at 939.

178. *Id.*

179. *Id.*

180. *Id.* sec. 901, § 503B(f)(4), 121 Stat. at 940.

181. *Id.*

182. *Id.* sec. 901, § 503B(g)(4)(A), 121 Stat. at 941.

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Amendments provide an authorization for over \$6 million annually in increased funding to enhance the FDA's resources for advertising reviews.¹⁸³

183. *Id.* sec. 104.

