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Shoshana Speiser

Kevin Outterson

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DEDUCTIONS FOR DRUG ADS? THE CONSTITUTION DOES NOT REQUIRE CONGRESS TO SUBSIDIZE DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISEMENTS

Shoshana Speiser* and Kevin Outterson**

TABLE OF CONTENTS

Introduction

- I. Summary of the Facts and Law
 - A. A Brief History of DTCA Regulation
 - B. Pharmaceutical Industry Promotion and its Effects
 - C. The Tax Code: A Potential Lever for Congress
 - D. Objections to Removing the Tax Deductions
 - 1. Policy: Unfair to the Drug Industry
 - 2. Unconstitutional: First Amendment Limitation on Congressional Power
 - II. Discussion
 - A. Revocation of Tax Deductions is Constitutional
 - B. Policy
 - 1. Negative Effects of DTCA
 - 2. Lobbying
 - C. Increased FDA Regulation as an Alternative Solution
 - D. Disincentivizing DTCA Through the IRC Would Not Cause an Administrative Burden
 - E. Potential Problems
- Conclusion

INTRODUCTION

According to the Internal Revenue Code (IRC or Tax Code), “ordinary and necessary” business expenses are

* May 2011 graduate of Boston University School of Law and currently a Legal Fellow for the Northeast Regional Office of the Federal Trade Commission.

** Associate Professor and Co-Director of the Health Law Program, Boston University School of Law.

tax deductible.¹ Traditionally, most advertising costs are specifically included within these tax deductions.² While advertising generally serves as a useful channel to inform consumers, the direct-to-consumer advertising (DTCA) of prescription drugs should not, and need not constitutionally, be treated the same as other advertising. As the Magazine Publishers' Association put it, "You can learn all you need to know about beer in [thirty] seconds. But, a prescription drug?"³ Prescription drugs have the ability to improve people's health when appropriately prescribed, but can have a range of negative short- and long-term consequences when inappropriately used. Prescribing decisions should therefore be based on scientific evidence with the goal of obtaining the best possible treatment, instead of making additional profits for the drug companies.⁴ Thus, Congress could consider revoking the tax deductions for DTCA as a means of imposing a "sin tax"⁵ to disincentivize spending on DTCA without running afoul of regulating speech.⁶

Proponents of DTCA argue that it provides important benefits, such as improving public health by encouraging viewers to speak with their doctors about health problems that might otherwise go untreated.⁷ Opponents, however,

1. 26 U.S.C. § 162(a) (2006).

2. See 26 U.S.C. § 162(j) (saying that "certain foreign advertising expenses" are explicitly excluded); see also, e.g., *Poletti v. Commissioner*, 330 F.2d 818, 822 (8th Cir. 1964).

3. Tamar V. Terzian, *Direct-To-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 164 (1999) (citing an advertisement which appeared in the *Wall Street Journal*).

4. See Ray Moynihan et al., *Selling Sickness: The Pharmaceutical Industry and Disease Mongering*, 324 BRIT. MED. J. 886, 886 (2002) [hereinafter Moynihan et al., *Selling Sickness*] (stating that "[i]nappropriate medicalization carries the dangers of unnecessary labelling, [sic] poor treatment decisions, iatrogenic illness, and economic waste, as well as the opportunity costs that result when resources are diverted away from treating or preventing more serious disease").

5. See Rachel E. Morse, *Resisting the Path of Least Resistance: Why the Texas "Pole Tax" and the New Class of Modern Sin Taxes Are Bad Policy*, 29 B.C. THIRD WORLD L.J. 189, 191 (2009) (explaining sin taxes as "targeted excise taxes imposed on the sale of disfavored goods or services" which are commonly used in connection with alcohol and tobacco).

6. See generally David I. Walker, *Suitable for Framing: Business Deductions in a Net Income Tax System*, 52 WM. & MARY L. REV. 1247, 1251 (2011) (discussing sin taxes and the common use thereof to encourage or discourage non-tax behavior).

7. This point, however, is undisputed. Indeed, some believe that DTCA has a positive impact. See, e.g., Mark B. McClellan, MD, Ph.D., FDA

argue that DTCA disperses deceptive information, hinders the patient-doctor relationship, encourages patients to choose drug-based solutions over lifestyle-based ones, reduces the amount spent on research and development, and increases spending on drugs without a corresponding health benefit.⁸ Indeed, DTCA spending has out-paced spending on research and development⁹ and the prevalence of Food and Drug Administration (FDA) warning letters demonstrates pharmaceutical companies' frequent failures to comply with advertising regulations that the FDA is under-resourced to police.¹⁰ During September 2010 alone, the FDA issued eleven warning letters to pharmaceutical companies primarily regarding "internet marketing of unapproved and misbranded drugs."¹¹ The problem with DTCA has "attracted

Commissioner, Speech before First International Colloquium on Generic Medicine (Sept. 25, 2003), *available at* <http://www.fda.gov/NewsEvents/Speeches/ucm053614.htm> (stating that "on net [DTC] advertising benefits the public health" and also arguing that "although the ads are highly visible, they account for less than 2 percent of U.S. pharmaceutical spending, and so they can't be a key driver of drug costs"); *see also* Frank Lichtenberg & Gautier Duflos, *Time Release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing and Utilization by the Public*, 11 MED. PROGRESS REP. 1, 12 (2009) (explaining that "marketing has a significant impact on utilization" which in turn improves public health and therefore restrictions on advertising should be carefully considered).

8. *See, e.g.*, Marcia Angell, *Relationships with the Drug Industry: Keep at Arm's Length*, 338 BRIT. MED. J. b222 (2009) [hereinafter Angell, *Relationships*] (explaining that DTCA is often aimed at "me-too drugs and are designed to convince viewers that one is better than another, despite the fact that these drugs are seldom compared in clinical trials at equivalent doses. Many seek to convince people that they have chronic disorders that require lifelong drug treatment . . . with the implication that it needs to be treated to prevent serious complications . . . We need to stop accepting the fiction that marketing, whether to prescribers or patients, is good education.").

9. *See* MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 132-33 (2004) [hereinafter ANGELL, *THE TRUTH*]. U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-07-54, *PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING* 5, 12 (Nov. 2006) [hereinafter GAO-07-54], *available at* <http://www.gao.gov/new.items/d0754.pdf>.

10. *See, e.g.*, *Bad Ad Program: FDA Aims to Keep Drug Promotion Truthful*, U.S. FOOD & DRUG ADMIN. (Apr. 5, 2011), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm211791.htm>; Susan Heavey & Lisa Richwine, *Special Report: Outgunned FDA Tries to Get Tough with Drug Ads*, REUTERS (Sept. 3, 2010), <http://www.reuters.com/article/2010/09/03/us-drugs-advertising-idUSTRE6821PN20100903>.

11. *Warning Letters 2009*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm>

enough congressional attention to warrant at least six bills in the 110th Congress as well as concerns from members in the 111th.”¹² For instance, the Say No to Drug Ads Act of 2009 proposed the removal of tax deductions specifically for DTCA.¹³ Yet, to the relief of the drug companies and the marketing industry, multiple bills introduced to Congress proposing to remove the tax deductions have not been passed.¹⁴ Neither this Article nor the proposed legislation discussed herein suggests that pharmaceutical companies’ ability to advertise should be revoked. As Congressman Daniel Lipinski said, “I am not looking to infringe upon any company’s right to advertise, only to help assure that the American taxpayers are not subsidizing these industries in our health care system.”¹⁵

055773.htm (last updated June 27, 2011).

12. SUSAN THAUL, CONG. RESEARCH SERV., R40590, DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS 3 (2009) [hereinafter THAUL, CRS REPORT], available at http://assets.opencrs.com/rpts/R40590_20090520.pdf (“Members of the 111th Congress have indicated interest in DTC advertising in the context of drug safety, tax treatment of advertising expenses, risk communication, and general FDA-activity authority and oversight, sometimes in the context of broader discussions of health care costs and reform.”).

13. H.R. 2966, 111th Cong. (2009) (stating that “[n]o deduction shall be allowed . . . for any amount paid or incurred for a direct-to-consumer advertisement of a prescription drug”); S. 2842, 111th Cong. (2009) (stating that “[n]o deduction shall be allowed . . . for expenses relating to direct to consumer advertising in any media for the sale and use of prescription pharmaceuticals for any taxable year”); S. 2873, 111th Cong. (2009) (same). Some of the proposed legislation, such as the Protecting Americans from Drug Marketing Act of 2009, proposed revoking tax deductions for all pharmaceutical advertising and promotion. H.R. 3979, 111th Cong. (2009) (stating that “[n]o deduction shall be allowed . . . for expenses relating to advertising or promoting the sale and use of prescription pharmaceuticals for any taxable year” and defining “advertising or promoting” to include “direct to consumer advertising in any media and any activity designed to promote the use of prescription pharmaceutical directed to providers or others who may make decisions about the use or prescription pharmaceuticals”); S. 1763, 111th Cong. (2009) (same); H.R. 2917, 111th Cong. (2009) (stating that “[n]o deduction shall be allowed . . . with respect to (1) any advertisement primarily for purpose of promoting the sale or use of any prescribed drug”).

14. H.R. 2917; John Eggerton, *Health Care Bill Won’t End Tax Deductions for Prescription Drug Ads*, BENTON FOUND. (July 15, 2009), <http://www.benton.org/node/26474>.

15. Letter from Representative Daniel Lipinski to Representative Charles B. Rangel and Representative Dave Camp (July 15, 2009) [hereinafter Lipinski Letter]. For more information on Congressman Daniel Lipinski, see his website, <http://www.lipinski.house.gov/>.

The First Amendment protects the pharmaceutical industry's commercial free speech and right to advertise, and prevents Congress from either imposing content- and speaker-based restrictions¹⁶ or prohibiting industry from spending on DTCA. Also, as previously mentioned, DTCA proponents present several compelling arguments more thoroughly discussed below. It is not necessary, however, to continue to allow tax deductions for DTCA in order to maintain those benefits and the constitution does not require the continued allowance of a tax deduction. The arguments for disincentivizing DTCA apply regardless of the content. The focus is on the listener, not the speaker. The tendency of drug advertising to mislead merely provides a facially-neutral justification for revoking the deductions.¹⁷

The Tax Code is regularly and frequently used for social engineering to affect non-tax behaviors.¹⁸ Congress allows tax breaks for actions or behaviors they want to encourage and denies them, or imposes sin taxes for those they wish to discourage or believe have low social value.¹⁹ Even constitutionally important topics such as religious donations and gun purchases may be taxed, or exempted, by legislative decision. Here, forcing the pharmaceutical industry to internalize the full cost of advertising by removing the subsidy may encourage them to consider more carefully whether their ads' content complies with FDA regulations aimed at accurate portrayals of the drugs. Thereby, Congress could reduce DTCA without violating the First Amendment through outright bans or restrictions based on an ad's content or speaker. Further, removing tax deductions also results in administrative simplification and is therefore a preferred means of attempting to address non-tax behaviors.²⁰ One such bill was estimated to raise

16. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011) ("State[s] may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That [a s]tate finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.").

17. Advertising pharmaceuticals directly to consumers is suspect regardless of who is responsible for the advertisement. Particularly in light of *Sorrell*, Congress must be wary of focusing on a particular viewpoint or speaker. *See id.* at 2663–64.

18. *See generally* Walker, *supra* note 6, at 1251.

19. *See, e.g.*, I.R.C. § 162 (2006).

20. *See* David A. Weisbach & Jacob Nussim, *The Integration of Tax and*

approximately \$37 billion in revenue, which would not prevent the industry from advertising, but could help cover the cost of other government programs and likely reduce the overall prominence of DTCA.²¹ Thus, removing the tax deductions for DTCA is constitutionally permissible, properly aligned with public policy,²² and Congress could remove the deductions.

This Article first discusses the factual and legal background leading up to the proposed DTCA tax deduction removal, including: a brief history of DTCA regulation, pharmaceutical industry promotion and its effects, the relevant IRC provisions and constitutional limits on Congress' power. Next, this Article examines the legal and policy reasons why the removal of the tax deductions is advisable and permissible. Specifically, the removal would not infringe upon the First Amendment-protected commercial free speech, even under heightened-scrutiny as recently applied in *Sorrell v. IMS Health Inc.*²³ In *Sorrell*, the Court maintained that regulatory differences between industries would still survive a constitutional challenge if there was reason to believe that fraud was more likely in one industry.²⁴ The Court also suggested that it might be more flexible with respect to consumer protection matters.²⁵ This reasoning should apply to the revocation of deductions for DTCA which generally does not explain alternative therapies and may interfere with the doctor-patient relationship leading to excess prescribing, thereby contributing to the cost of health care without a correspondingly healthier population.²⁶ Additionally, Congress has disallowed, and the Supreme Court has approved, the revocation of deductions in many

Spending Programs, 113 YALE L.J. 955, 958 (2004) [hereinafter Weisbach & Nussim, *Tax and Spending*].

21. See Ryan J. Donmoyer, *House Considering \$37 Billion Drug Tax*, *Rangel Says*, BLOOMBERG (June 16, 2009), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aeEJZicjYE60>.

22. See generally Walker, *supra* note 6, at 1251–53.

23. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

24. *Id.* at 2672.

25. *Id.*

26. See Walker, *supra* note 6 at 1251–53; *RxP Weekly Reader: Bailout Edition*, POSTSCRIPT (Oct. 2, 2008), <http://postscript.communitycatalyst.org/?p=223> (“The FDA has warned five drug makers about false or misleading advertisements of five ADHD drugs, according to the Bureau of National Affairs Health Care Daily Report.”).

other instances as within Congress' broad authority under the Sixteenth Amendment to both tax the public and revoke deductions.²⁷ Further, lobbying, which like DTCA occurs in the ordinary course of business and aims to persuade people, is specifically not tax-exempt due to Congress' concern over "undue influence[.]"²⁸ Yet Congress allows full tax deductions for DTCA.

This Article also addresses why implementing a disincentive through the IRC would be preferable to increasing FDA regulation. First, utilizing the IRC would be more practical and involve fewer administrative costs. Second, FDA faces constitutional limitations on its ability to monitor advertisements' content. Finally, this Article acknowledges several potential problems with the deductions' removal and offers that while a complete removal is preferred, Congress should in the alternative consider instituting a cap on the amount deductible for DTCA spending.

I. SUMMARY OF THE FACTS AND LAW

A. *A Brief History of DTCA Regulation*

Richard G. Frank, Professor of Health Economics at Harvard Medical School, defines DTCA as "any promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media."²⁹ This "includes advertisements targeted toward consumers through magazines, newspapers, television, radio, and outdoor advertising."³⁰ DTCA encompasses three categories:

27. See, e.g., 26 U.S.C. § 162 (2006); *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (approving removal of tax exempt status); *New Colonial Ice Co. v. Helvering*, 292 U.S. 435, 440 (1934); *Knight v. Commissioner*, 552 U.S. 181, 192 (2008) ("noting the familiar rule that an income tax deduction is a matter of legislative grace" (citing *INDOPCO, Inc. v. Commissioner*, 503 U.S. 79, 84 (1992) (internal quotations omitted))).

28. Lloyd Hitoshi Mayer, *What Is This "Lobbying" That We Are So Worried About?*, 26 *YALE L. & POL'Y REV.* 485, 496 (2008) [hereinafter Mayer, *Lobbying*].

29. Michael S. Wilkes, Robert A. Bell & Richard L. Kravitz, *Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, and Implications*, 19 *HEALTH AFF.* 110, 112 (2000), available at <http://content.healthaffairs.org/content/19/2/110.full.pdf>.

30. KAISER FAMILY FOUND., *IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON PRESCRIPTION DRUG SPENDING* 4 (2003), available at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14378>.

help-seeking ads, reminder ads, and product-claim ads.³¹ Help-seeking ads aim to get viewers to see their doctor about a particular condition, but do not mention any specific drug or treatment.³² Reminder ads state the name of the drug—but do not discuss the condition it treats or make health claims—and the FDA does not require full risk disclosure.³³ Finally, product-claim ads include both the drug's name and therapeutic claims and must include full risk information.³⁴

In recognition of the weaknesses of the Pure Food and Drugs Act of 1906 and Federal Food, Drugs and Cosmetics Act of 1938 to address advertising, Congress passed the 1962 Kefauver-Harris Amendments. These amendments, directed at advertising to physicians, transferred regulatory authority for pharmaceutical marketing from the Federal Trade Commission (FTC) to FDA.³⁵ These amendments required that ads not be false or misleading, present a fair balance of the drug's risks and benefits, contain facts relevant to the advertised and approved use, list contraindications, and be submitted to FDA upon publication.³⁶ DTCA first attracted the FDA's attention in the early 1980s.³⁷ Following a brief voluntary moratorium to study the practice, FDA deemed the 1960s regulations regarding physician advertising adequate

31. THAUL, CRS REPORT, *supra* note 12, at 4–5.

32. *Id.* at 4. Please note that these ads tend to be coordinated by the company to coincide with heavy marketing to doctors about a particular drug. U.S. GEN'L ACCOUNTING OFFICE, Report, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 11 (Oct. 2002) (stating that “DTC advertising is concentrated among a small number of drugs for chronic conditions and many of these same drugs are also promoted to physicians, both factors that may lead to increased sales.”).

33. THAUL, CRS REPORT, *supra* note 12, at 4–5. The Report also notes that these ads are primarily directed towards providers who already have a base knowledge of the product. *Id.*

34. *Id.* at 5.

35. 21 U.S.C. § 352(n) (2006).

36. For a more in-depth discussion of the history of regulation, see Victor E. Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-To-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 333, 336–40 (2009) [hereinafter Schwartz, *Viability*]; THAUL, CRS REPORT, *supra* note 12, at 8–14.

37. Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 491–92 (1999) [hereinafter Pines, *DTC History*]; see also Schwartz, *Viability*, *supra* note 36, at 336–37 (stating that “[c]ompanies that sell medications have advertised their products directly to consumers since the beginning of medicine”).

to apply to DTCA.³⁸ As a result of the cumbersome summary requirements, these regulations effectively prohibited broadcast DTCA.³⁹

Interestingly, one study conducted by the FDA in the 1980s, which in-part led to the allowance of DTCA, found that consumers retained more information regarding the drug's benefits than its risks, and that print ads are relatively more effective than broadcast ones at conveying risk information.⁴⁰ Yet, the FDA deemed that presenting only a "fair balance" of the risks and benefits was necessary to inform consumers effectively.⁴¹ Other than a January 2009 guidance regarding what device manufacturers, drug manufacturers or representatives may disseminate regarding off-label usage,⁴² the regulations have remained relatively constant and there remains no distinction between the FDA's regulations for physician and consumer advertising.⁴³

Initially, the FDA did not allow product-specific advertisements.⁴⁴ Drug companies could either advertise symptoms with a message for consumers to see their doctor or mention the name of a product, but could not indicate

38. Pines, *DTC History*, *supra* note 37, at 492; *Prescription Drug Promotion: Hearing Before the Subcomm. on Consumer Affairs, Foreign Commerce & Tourism of the S. Comm. on Commerce, Sci. & Transp.*, 107th Cong. (2001) [hereinafter *Ostrove Testimony*], available at <http://www.fda.gov/NewsEvents/Testimony/ucm115206.htm> (statement of Nancy M. Ostrove, Ph.D., Deputy Director, Food & Drug Admin.) ("On September 9, 1985, FDA withdrew the moratorium in a Federal Register (FR) Notice (50 FR 36677), which stated that the 'current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers.'").

39. See *Ostrove Testimony*, *supra* note 38.

40. Pines, *DTC History*, *supra* note 37, at 492; see also Joel J. Davis, *Consumers' Preferences for the Communication of Risk Information in Drug Advertising*, 26 HEALTH AFF. 863, 863-64 (2007) (citing Kathryn Aikin, *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship* (Sept. 22, 2003)).

41. The FTC has also recognized potential problems with the conveyance of risk information to consumers in advertisements. See *FTC Staff Provides Comments to FDA on Direct-to-Consumer Drug and Device Ads*, FED. TRADE COMM'N (May 12, 2004), <http://www.ftc.gov/opa/2004/05/dtcdrugs.shtm>.

42. See FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES (2009), available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm>.

43. See *Ostrove Testimony*, *supra* note 38.

44. Pines, *DTC History*, *supra* note 37, at 494.

its purpose.⁴⁵ For example, these regulations permitted a commercial advertising the prescription drug Claritin, featuring only a singer crooning about “blue skies” and a “kind voice instruct[ing] the viewer to ‘see your doctor about Claritin.’”⁴⁶ Incidentally, this ad does not educate the public regarding a disease or treatment thereby failing to satisfy the pharmaceutical industry’s primary justification for DTCA.

Rather than educate the public, the message appeals to the individual’s emotions.⁴⁷ Calm, cloudless, blue skies present a soothing image and a carefree outlook. The advertisement, for an allergy medication, could just as easily promote a statin or antipsychotic drug. These advertisements grab viewers’ attention, but not because they suffer from a debilitating allergy. Curious, the viewer will ask his doctor and as a result may discover some low-grade allergy.⁴⁸ In American culture, with the promotion of perfection and quick-fixes, those with very mild symptoms would likely disregard the side effects and opt to take the drug when no treatment or a generic, cheaper drug would also suffice. In 1995, “[c]oncerned that consumers were confused by the choppy nature of broadcast DTC advertising,” the FDA held a “hearing on the putative risks and benefits of easing its regulation” and in 1997 began to allow product-specific advertisements.⁴⁹

Simultaneously, the FDA also released the “Guidance for Industry: Consumer-Directed Broadcast Advertisements.”⁵⁰ For print ads, the guidance still required a “brief summary” listing all the risks in the drug’s prescribing information and at least one FDA-approved use.⁵¹ Alternatively, recognizing

45. *Id.*

46. *Id.*

47. See, e.g., Sidney M. Wolfe, Editorial, *Direct-to-Consumer Advertising—Education or Emotion Promotion?*, 346 NEW ENG. J. MED. 524, 525 (2002).

48. According to Claritin’s website, about fifty million Americans are affected by allergies. *Questions & Answers*, CLARITIN, <http://www.claritin.com/claritin/learn/questions-answers.jspa#question4> (last visited Oct. 4, 2011).

49. Jeremy A. Greene & David Herzberg, *Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the Twentieth Century*, 100 AM. J. PUB. HEALTH 793, 800 (2010).

50. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf> [hereinafter FDA 1999 GUIDANCE]; see also *Ostrove Testimony*, *supra* note 38.

51. FDA 1999 GUIDANCE, *supra* note 50, at 1.

that the not-so-brief summary information presented an insurmountable challenge in a thirty- or sixty-second commercial, the FDA eased the requirements for broadcast ads.⁵² This change allowed industry to include only an “adequate provision” with a “major statement” of the most important risk information that informs viewers or listeners where to find the full FDA-approved prescribing information.⁵³ In the wake of the DTCA regulatory relaxation, the pharmaceutical industry spends the majority of its DTCA budget on television commercials.⁵⁴

In 2004, FDA issued a draft Guidance for Industry entitled “Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.”⁵⁵ The guidance again distinguishes between print and broadcast advertisements, requiring a brief summary for print ads, but not for broadcast ads. This, however, may be a distinction without a difference.⁵⁶ While the guidance “strongly encourages the use of consumer-friendly language in all consumer-directed materials,” the “FDA cannot object . . .

52. *Id.*

53. *Id.* at 2.

54. See CONG. BUDGET OFFICE, PROMOTIONAL SPENDING FOR PRESCRIPTION DRUGS 3 (2009) [hereinafter CBO REPORT]; Peter Lurie, *DTC Advertising Harms Patients and Should Be Tightly Regulated*, 37 J.L. MED. & ETHICS 444, 444 (2009) (describing the FDA’s removal of the brief summary requirement as the “regulatory change that produced the growth in DTC advertising”); Caroline L. Nadal, *The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Consumers Become the Learned*, 9 J.L. & POL’Y 451, 479–80 (2001) (explaining that as result of the FDA “relax[ing] its guidelines for product-specific television and radio ads DTC marketing [grew] exponentially with pharmaceutical manufacturers spending almost \$1.9 billion on DTC advertisements in 1999, more than triple what they spent in 1996”); Shannon Pettypiece, *Less Sex, Rock-n-Roll as Drugmakers React to FDA TV Ad Scrutiny*, BLOOMBERG (Jan. 27, 2010), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aVe6AAgRw_0Y.

55. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: BRIEF SUMMARY: DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS (2004) [hereinafter FDA 2004 DRAFT GUIDANCE], available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069984.pdf>. While the FDA refers to the guidance as a “draft,” it reflects the Administration’s current practice. THAUL, CRS REPORT, *supra* note 12, at 11.

56. See, e.g., *DDMAC Frequently Asked Questions*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090308.htm> (last updated June 18, 2009) (The “FDA has also heard concerns about the lack of value of the required information [in the brief summary] from some individuals and groups.”).

solely on the basis that the risk information is not presented in consumer-friendly language.”⁵⁷ Accordingly, to satisfy the brief summary requirement many manufacturers include the full FDA-approved labeling.⁵⁸ Nevertheless, as the FDA astutely points out, providing the full labeling information “is less than optimal.”⁵⁹ In effect, the FDA admits that while this approach complies with the regulations, it fails to convey the information necessary to educate consumers appropriately.⁶⁰ Thus, the additional brief summary requirement in print ads does not prove any more effective in communicating appropriate use, benefit, and risk information to consumers.

In 2006, Congress amended the Lanham Act designed to prevent false advertising claims.⁶¹ The Act provides, in part, a civil penalty for anyone who “in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities.”⁶² The statute further allows for “action by any person who believes that he or she is or is likely to be damaged by such act.”⁶³

Congress also addressed DTCA in the Food and Drug Administration Amendments Act of 2007 (FDAAA).⁶⁴ First, the FDAAA authorized the FDA to charge industry a fee to review DTCA prior to publication in order to fund the additional staff essential to that task.⁶⁵ In January of 2008, however, the FDA announced it would not implement this

57. FDA 2004 DRAFT GUIDANCE, *supra* note 55, at 1.

58. *Id.* at 3.

59. *Id.* at 2.

60. *Id.* (“Although this approach complies with the brief summary requirement, FDA believes it is less than optimal for consumer-directed print advertisements because many consumers do not have the technical background to understand this information. Moreover, the volume of the material, coupled with the format in which it is presented (i.e., very small print and sophisticated medical terminology) discourages its use and makes the information less comprehensible to consumers. In general, FDA believes that exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks. FDA also believes that information intended for a consumer should optimally be communicated in language fully understandable by a lay reader and presented in an easily readable format.”).

61. 15 U.S.C. § 1125(a)(1)(B) (2006).

62. *Id.*

63. *Id.*

64. Food and Drug Administration Amendments Act (FDAAA) of 2007, Pub. L. No. 110–85, 121 Stat. 823 (codified as amended at 21 U.S.C. & 42 U.S.C.).

65. 21 U.S.C.A. § 379h-1.

program.⁶⁶ Second, the FDAAA authorized the FDA to require submission of television ads at least forty-five days before their airdate, after which the Secretary may recommend, but not require or actually make, changes to the advertisement.⁶⁷ This expanded authority has also not been utilized. Third, the FDAAA sets forth civil penalties for the sponsoring of false or misleading DTCA.⁶⁸ Finally, the FDAAA required all DTCA to include a statement encouraging the reporting of negative side effects.⁶⁹

FDA only reviews ads once published, but even then does not review all ads.⁷⁰ When the FDA discovers a violation, their enforcement options include: sending an untitled letter or a warning letter, imposing a civil monetary penalty, criminally prosecuting the company, seizing a product, or withdrawing their approval for sale.⁷¹ Upon finding a problem with an ad, the FDA typically responds first with an untitled letter, also known as a notice of violation, then a warning letter, and finally an injunction.⁷² Despite the FDA's contention that warning letters serve as a sufficient threat to prevent the need for further action, their prevalence indicates that by themselves they are an insufficient regulatory tool.⁷³

66. User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Program Will Not Be Implemented, 73 Fed. Reg. 2924 (Jan. 16, 2008).

67. 21 U.S.C.A. § 353b.

68. 21 U.S.C.A. § 333. The FDAAA established that the maximum penalty would be \$250,000 for the first offence, and \$500,000 for any subsequent offence in a three-year period. However, the repeated dissemination of the same ad only counts as one violation.

69. 21 U.S.C.A. § 352(n). The statute requires that the following statement be included: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088." *Id.*

70. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-54, PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 5 (2006), available at <http://www.gao.gov/new.items/d0754.pdf>.

71. *Id.* at 11.

72. DONNA U. VOGT, CONG. RESEARCH SERV., RL32853, DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS 29 (2005), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3285303252005.pdf> (stating that "FDA believes that the . . . warning letter is a powerful tool in its regulatory arsenal").

73. See *Warning Letters*, FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (last updated Oct. 4, 2011); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-03-177, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 21-22 (2002) [hereinafter FDA OVERSIGHT], available at <http://www.gao.gov/new.items/d03177.pdf>.

B. *Pharmaceutical Industry Promotion and its Effects*

Following the 1997 DTCA regulatory relaxation, promotional spending across the pharmaceutical industry increased from \$11.4 billion in 1996 to \$29.9 billion in 2005.⁷⁴ In 2008, the pharmaceutical industry spent \$20.5 billion, placing them second only to the auto industry in advertising.⁷⁵ The rate of increase in promotional spending has out-paced spending on research and development.⁷⁶ Currently, the United States spends 17.3% of the Gross Domestic Product on healthcare, outpatient pharmaceuticals accounting for approximately 10% of those costs.⁷⁷ While DTCA, at about \$4.2 billion, represents only a small fraction of pharmaceutical industry spending, it is continually expanding and, as proponents and opponents of DTCA agree, effective.⁷⁸

Despite attempts by the FDA to require a balanced portrayal of the risks and benefits of each drug, such a balance is unlikely.⁷⁹ The pharmaceutical industry has a

74. Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 673 (2007) [hereinafter Donohue, *A Decade of DTCA*], available at <http://www.nejm.org/doi/full/10.1056/NEJMsa070502>.

75. Noreen O'Leary, *Sen. Bill Nelson Backs off on Drug Ads*, ADWEEK (Sept. 16, 2009), <http://www.adweek.com/news/advertising-branding/sen-bill-nelson-backs-drug-ads-100360>. This number actually represents a decline from the industry's peak spending in 2006, which amounted to \$5.2 billion. See CBO REPORT, *supra* note 54, at 2. *But see* ANGELL, *THE TRUTH*, *supra* note 9, at 122 (explaining that the exact amount spent yearly by industry is unclear, but higher than they report).

76. GAO-07-54, *supra* note 9, at 5, 12; Lipinski Letter, *supra* note 15 (explaining that "[s]pending by drug companies on consumer advertising has quadrupled since 1996, even outpacing spending on research and development"); FDA OVERSIGHT, *supra* note 73, at 9.

77. See Micah Hartman et al., *Health Spending Growth at a Historic Low in 2008*, 29 HEALTH AFF. 147, 148 exhibit 1 (2010).

78. See ANGELL, *THE TRUTH*, *supra* note 9, at 123; Donohue, *A Decade of DTCA*, *supra* note 74, at 675 (stating that at \$4.2 billion "[i]n 2005, only 14% of total industry expenditures on pharmaceutical promotion were devoted to such advertising."); Faith McLellan, *US Government Report Released on Deceptive Drug Advertisements*, 360 LANCET 1951, 1951 (2002), available at <http://www.lancet.com/journals/lancet/article/PIIS0140-6736%2802%2911947-7/fulltext> (stating that every year approximately 8.5 million people request and receive prescriptions as a result of DTCA).

79. Cf. Joanna K. Sax, *Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications*, 37 AM. J.L. & MED. 203, 205 (2011). Sax found that even the research used to support drugs tends to be slanted. *Id.*

clear financial incentive to aggressively promote their products. Drug companies are for-profit businesses and spend billions each year to advertise because the industry receives a high return on this investment.⁸⁰ Studies have shown that each \$1 spent on advertising yields between about \$4.20 and \$6.50 in drug sales.⁸¹ The Congressional Budget Office (CBO) reported that “the [ten drugs] with the highest DTC expenditures in 2008 accounted for [thirty] percent of expenditures for DTC advertising industrywide.”⁸² This increase in drug use and profits, however, does not correlate with a healthier population.⁸³ Rather, pharmaceutical advertising results in the overuse of brand-name prescription drugs and more expensive treatments instead of

Previous studies demonstrate that industry publications have a bias in that they tend to report positive results of clinical trials. This is not surprising because industry has a profit-seeking motive and companies are likely to closely monitor the progress and process of a research study in such a way that adverse results may be suppressed leading to the publication of biased results.

Id.

80. Terzian, *supra* note 3, at 166–67; *see also* Schwartz, *Viability*, *supra* note 36, at 335; Lichtenberg & Duflos, *supra* note 7, at 12 (stating that “marketing has a significant impact on utilization”); QIUPING GU ET AL., NAT’L CTR. FOR HEALTH STATISTICS, NCHS DATA BRIEF NO. 42, PRESCRIPTION DRUG USE CONTINUES TO INCREASE: U.S. PRESCRIPTION DRUG DATA FOR 2007–2008 1 (2010), *available at* <http://www.cdc.gov/nchs/data/databriefs/db42.pdf>.

81. Lipinski Letter, *supra* note 15; THAUL, CRS REPORT, *supra* note 12, at 25. *But see Heavy Drug Ad Spending Doesn’t Pay Off*, MARKETINGCHARTS (Apr. 12, 2010), <http://www.marketingcharts.com/television/heavy-drug-ad-spending-doesnt-pay-off-12554/> (stating that advertising spending does not necessarily correlate with profits).

82. CBO REPORT, *supra* note 54, at 4–5 (discussing the drugs in the CBO’s data set); *see also* Donohue, *A Decade of DTCA*, *supra* note 74, at 676 (“The 20 drugs with the highest spending made up 54.4% of total industry spending on advertising in 2005 . . .”).

83. *See, e.g.*, THAUL, CRS REPORT, *supra* note 12, at 1, 21 (noting that DTCA “are susceptible to marketing needs that interfere with objective presentations” and “the American Medical Association (AMA) Council on Ethical and Judicial Affairs . . . found . . . that 44% of promotional material to physicians ‘would lead to improper prescribing,’” and recommended that providers “remain vigilant to ensure that DTC advertising does not promote expectations”); Jared A. Favole, *FDA Warns Drug Companies On Promotional Material*, DOW JONES NEWSWIRES, Feb. 3, 2010 (noting warnings issued to major pharmaceutical companies Eli Lilly & Co., United Therapeutics Corp. and Sanofi-Aventis SA for misleading promotional materials). *But see generally*, Frank R. Lichtenberg, *Effects of New Drugs on Overall Health Spending: Frank Lichtenberg Responds*, 26 HEALTH AFF. 887 (2007) (finding “that, in general, using newer drugs has reduced nondrug costs more than it has increased drug costs . . .”).

equally effective, cheaper options, thereby raising the cost of healthcare for everyone.⁸⁴

“The great majority of DTC ads are for very expensive me-too drugs that require a lot of pushing because there is no good reason to think they are any better than drugs already on the market.”⁸⁵ DTCA also often aims to raise the significance of a relatively innocuous temporary problem to something far more serious. For instance, “heartburn is elevated to gastrointestinal reflux disease, with the implication that it needs to be treated to prevent serious complications.”⁸⁶ Once “people [are] convinced they have a treatable medical condition, then it is an easy step to sell them drugs to treat it.”⁸⁷ Moreover, the pharmaceutical industry optimizes the effect of DTCA by first heavily advertising to physicians.⁸⁸ While industry and DTCA supporters refer to these efforts as education, Marcia Angell, former *New England Journal of Medicine* Editor-in-Chief, noted the fact that this “‘education’ comes out of the drug companies’ marketing budgets should tell you what is really going on.”⁸⁹

The for-profit pharmaceutical companies consider their promotional activities’ potential benefits and liabilities. Even if a company knows they will have to pay a penalty after, in light of the expected revenue resulting from every dollar

84. See, e.g., Barry Meier et al., *Medicine Fueled by Marketing Intensifies Trouble for Pain Pills*, N.Y. TIMES, Dec. 19, 2004, § 1, at 1 (explaining how Celebrex and Vioxx costing \$2 or \$3 per pill, were prescribed to many patients could have received the same effect, more safely, from over the counter drugs for only pennies per pill).

85. ANGELL, THE TRUTH, *supra* note 9, at 124.

86. Angell, *Relationships*, *supra* note 8.

87. *Id.*

88. See, e.g., Donohue, *A Decade of DTCA*, *supra* note 74, at 679 (explaining that “PhRMA, the industry trade group, has recommended that manufacturers delay such campaigns for new drugs until after health professionals have been sufficiently educated, although no details have been provided on how long a period was deemed necessary”); ANGELL, THE TRUTH, *supra* note 9, at 126. For more information on drug detailing, see, e.g., Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL’Y L. & ETHICS 785, 808–09 (2005); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. AM. MED. ASS’N 373, 377–79 (2000).

89. ANGELL, THE TRUTH, *supra* note 9, at 135 (the comment was made by Angell in the context of discussing “educational meetings arranged by pharmaceutical companies for physicians,” but similarly applies to DTCA).

spent on DTCA, the risk may be worth it to the company.⁹⁰ In tort cases, manufacturers will generally be held directly liable to consumers for failure to warn. By contrast, as a result of the learned intermediary doctrine, premised on the notion that physicians are in the best position to analyze an individual patient's particular circumstances and the drug's risks and benefits, pharmaceutical manufacturers are shielded from direct liability to consumers.⁹¹ Practically, however, the doctrine effectively allows the pharmaceutical industry to blame doctors for the manufacturer's inadequate warnings.⁹² In *Perez v. Wyeth Laboratories, Inc.*, the New Jersey Supreme Court revoked the doctrine's applicability for DTCA, recognizing that DTCA fundamentally impacts the doctor-patient relationship and therefore the initial policy justifications for the doctrine no longer applied.⁹³ Since most states have not adopted a DTCA exception, industry shields itself from liability in many cases and does not calculate the full extent of potential harm from their advertisements.⁹⁴

90. See Ozlem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?*, 81 U. DET. MERCY L. REV. 267, 267–70 (2004); Schwartz, *Viability*, *supra* note 36, at 356 & n.121 (explaining the doctrine and noting that it has been abolished, at least with respect to DTCA, in New Jersey, West Virginia, etc.).

91. *Id.*

92. See Bordes, *supra* note 90, at 278; Erin Lenhardt, *Why So Glum? Toward a Fair Balance of Competitive Interests in Direct-To-Consumer Advertising and the Well-Being of the Mentally Ill Consumers It Targets*, 15 HEALTH MATRIX 165, 166 (2005) [hereinafter Lenhardt, *Why So Glum?*] (arguing that even physicians “sometimes do not realize the persuasive effect of the spin contained [in drug advertisements]”).

93. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999). Note also that this decision follows *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208 (D. Mass. 1991), in which the court in a footnote allowed for an exception to the learned intermediary doctrine anytime a manufacturer advertises directly to consumers. *Id.* at 211 n.4. See also *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007) (rejecting the learned intermediary doctrine entirely, but focusing on DTCA in particular).

94. *But see* Schwartz, *Viability*, *supra* note 36, at 364–69 (arguing that creating a DTCA exception “represent[s] unsound policy”); Victor E. Schwartz et al., *West Virginia As a Judicial Hellhole: Why Businesses Fear Litigating in State Courts*, 111 W. VA. L. REV. 757, 778–82 (2009) (discussing West Virginia's 2007 wholesale rejection of the learned intermediary doctrine and thereby placing it “firmly at odds with fundamental tort principles expressed in the Second and Third Restatements”).

Similarly, in two recent cases, *Bruesewitz v. Wyeth*⁹⁵ and *Pliva v. Mensing*,⁹⁶ the Supreme Court held that federal laws preempt products liability cases against vaccine and pharmaceutical manufacturers, respectively. These two cases represent a departure from the 2009 decision in *Wyeth v. Levine* in which the Court held that federal law did not preempt state strict liability tort suits.⁹⁷ In declining to find preemption, the *Levine* court considered the benefits of state tort litigation including “help[ing] the FDA in its oversight function by revealing important and previously unknown information about product-related risks, especially during the postapproval [sic] period, and by deterring manufacturers from acting irresponsibly and engaging in business tactics aimed at increasing product sales at the expense of patient safety.”⁹⁸ Accordingly, raising costs associated with manufacturing and promotion of drugs may lead the industry to more carefully consider the practice.

C. *The Tax Code: A Potential Lever for Congress*

The Sixteenth Amendment broadly authorizes Congress to tax incomes.⁹⁹ Generally, the IRC taxes businesses and individuals only on net income. Accordingly, the IRC allows for the deduction of numerous expenses to try to achieve that result, including “ordinary and necessary” business expenses.¹⁰⁰ The Internal Revenue Service’s (IRS) definition of ordinary corresponds with a common sense understanding of ordinary. “An ordinary expense is one that is common and accepted in your trade or business.”¹⁰¹ Necessary, on the other hand, is defined as to not require the expense to be “indispensable,” but rather “one that is helpful and

95. 131 S. Ct. 1068 (2011).

96. 131 S. Ct. 2567 (2011).

97. 555 U.S. 555 (2009).

98. Aaron Kesselheim, *Safety, Supply, and Suits — Litigation and the Vaccine Industry*, 364 NEW ENG. J. MED. 1485, 1486 (2011), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1102182>.

99. U.S. CONST. amend. XVI (“Congress shall have power to lay and collect taxes on incomes, from whatever source derived, without apportionment among the several States, and without regard to any census or enumeration.”).

100. 26 U.S.C. § 162 (2006).

101. *Deducting Business Expenses*, INTERNAL REVENUE SERVICE, <http://www.irs.gov/businesses/small/article/0,,id=109807,00.html> (last updated June 10, 2011) [hereinafter *IRS Business Expenses*]; see also *Welch v. Helvering*, 290 U.S. 111, 113–14 (1933); 26 C.F.R. § 1.162-1 (2004).

appropriate for your trade or business.”¹⁰² Unlike tax deductions for individuals, deductions for corporations do not phase out at any income bracket.¹⁰³

Despite the general deductible rule, a deduction is not a matter of right. As courts have repeatedly stated, Congress has the authority to tax gross income. In *New Colonial Ice Co. v. Helvering*, the Supreme Court refused to infer a deduction where Congress had not explicitly allowed one.¹⁰⁴ As the Court explained, “[w]hether and to what extent deductions shall be allowed depends upon legislative grace.”¹⁰⁵ IRC section 162 exempts certain expenses as a means of regulating and discouraging relevant non-tax behaviors.¹⁰⁶ For instance, neither treble damage payments under the antitrust laws, nor certain foreign advertising expenses are deductible.¹⁰⁷ Additionally, home mortgages are deductible, but rental payments are not and tax credits are given for installing solar panels, but not for wood-burning stoves.¹⁰⁸ Advertising in general, however, is deductible.¹⁰⁹ But expenses that may produce a future benefit must be capitalized.¹¹⁰ The IRS, however, allows for the deduction of advertising expenses despite the fact that a particular campaign may last several years.¹¹¹ Removing this deduction would increase the cost of advertising thereby discouraging industry from advertising as heavily.¹¹² At the very least, it would cease the taxpayer subsidy of DTCA.

102. *IRS Business Expenses*, *supra* note 101; *Welch*, 290 U.S. at 113.

103. *See, e.g.*, I.R.C. § 151(d)(3) (phasing out the allowance of a deduction for personal exemptions when the taxpayer’s adjusted gross income exceeds a certain amount); *cf., e.g.*, I.R.C. § 162 (not providing any phase out amount for allowable trade or business deductions).

104. *New Colonial Ice Co. v. Helvering*, 292 U.S. 435, 440 (1934).

105. *Id.*

106. *Walker*, *supra* note 6, at 1257.

107. I.R.C. § 162(g), (j).

108. I.R.C. § 162.

109. *Id.*

110. I.R.C. § 263A.

111. 26 C.F.R. § 1.162-20 (2004).

112. *See Walker*, *supra* note 6, at 1251 (explaining that the effect of certain other disallowances of tax deduction “discourage[s] [the] disfavored activity”).

D. Objections to Removing the Tax Deductions

1. Policy: Unfair to the Drug Industry¹¹³

Proponents of DTCA defend the increase in prescription drug spending and healthcare costs by arguing that these practices lead to an overall healthier population.¹¹⁴ Specifically, DTCA increases consumer knowledge, encourages people to see their doctors by removing the stigma, leads to the diagnosis of more diseases, reminds patients to refill and take their prescriptions, and helps individuals “achieve the maximum degree of material satisfaction.”¹¹⁵ As many have observed, however, while the consumer may be *more* informed after viewing an advertisement, they are not necessarily *better* informed.¹¹⁶ In light of the frequency with which FDA issues warning letters for failure to present a fair balance of a drug’s risks and benefits, it is clear that the quality of the information conveyed leaves something to be desired. Moreover, even when risks and benefits are evenly presented, consumers retain more information regarding the advantages than the side effects.¹¹⁷

113. See Pat Kelly, *DTC Advertising’s Benefits Far Outweigh Its Imperfections*, HEALTH AFF. (Apr. 28, 2004), <http://content.healthaffairs.org/content/early/2004/04/28/hlthaff.w4.246.full.pdf+html>.

114. See Kelly, *supra* note 113; *Keeping Watch Over Direct-to-Consumer Ads*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm> (last updated Sept. 09, 2011) [hereinafter *FDA Keeping Watch*]; *DTC Prescription Drug Advertising*, AM. ADVERTISING FED’N, <http://www.aaf.org/default.asp?id=248> (last updated Sept. 2008); Peter J. Pitts, *Turning Point or Tipping Point: New FDA Draft Guidance and the Future of DTC Advertising*, HEALTH AFF., W4-259 (Apr. 28, 2004), <http://content.healthaffairs.org/content/suppl/2004/04/27/hlthaff.w4.259v1.DC1>.

115. Martin H. Redish, *The First Amendment in the Marketplace: Commercial Speech and the Values of Free Expression*, 39 GEO. WASH. L. REV. 429, 433 (1971); see also *FDA Keeping Watch*, *supra* note 114.

116. See, e.g., Jon D. Hanson and Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1456 (1999); but see Kathryn J. Aikin, *Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results* (2003), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM148277.pdf> (reporting physician survey results that most doctors found that DTCA did help educate consumers about their health problems).

117. Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 FOOD DRUG COSM. L.J. 497, 500 (1984).

Proponents also point out that advertising can lead to lower drug prices.¹¹⁸ Even if advertising drives down its cost, when a drug is unnecessary, that expenditure is wasteful. Pharmaceutical companies are for-profit businesses; if advertising actually led to overall reduced costs, or more specifically, did not help increase their profits, they would stop advertising. As many economists have noted, the “recent growth in DTC advertising has persuaded consumers to substitute new, more expensive drugs for older, lower-priced ones”¹¹⁹ thereby increasing profits for industry.

2. *First Amendment Limitations on Congressional Power*

Under the First Amendment, government may not censor speech.¹²⁰ The 1942 Supreme Court in *Valentine v. Chrestensen*, however, held that the First Amendment protections did not extend to “purely commercial advertising.”¹²¹ Commercial speech, along with obscenity, fighting words, incitement, and defamation, remained unprotected as a result of “low social value,” failure to “contribute to the exchange of ideas and the search for truth, and because the social interests in order and morality outweigh any benefit that [it] produce[s].”¹²²

Thirty years later, the Supreme Court narrowly interpreted *Valentine* in *Bigelow v. Virginia*, revoking commercial speech’s *per se* unprotected status.¹²³ Justice Blackmun announced that “speech is not stripped of First Amendment protection merely because it appears in [the] form [of commercial advertisements].”¹²⁴ The Court further

118. See Lee Benham, *The Effect of Advertising on the Price of Eyeglasses*, 15 J.L. & ECON. 337, 344–45 (1972) (noting that advertising correlates with lower prices).

119. THAUL, CRS REPORT, *supra* note 12, at 25 (citing Stephen Heffler et al., *Health Spending Growth Up in 1999; Faster Growth Expected in The Future*, 20 HEALTH AFF. 193 (2001)); see also Angell, *Relationships*, *supra* note 8 (explaining that DTCA promotes me-too drugs).

120. U.S. CONST. amend. I; Brienne T. Greiner, *Tough Pill to Swallow: Does the First Amendment Prohibit WV from Regulating Pharmaceutical Companies’ Advertising Expenses to Lower the Cost of Prescription Drugs*, 109 W. VA. L. REV. 107, 120–21 (2006).

121. *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942).

122. Greiner, *supra* note 120, at 123.

123. *Bigelow v. Virginia*, 421 U.S. 809 (1975).

124. *Id.* at 818 (citing *Pittsburgh Press Co. v. Human Relations Comm’n*, 413

emphasized the protection of commercial speech with respect to prescription drugs in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*¹²⁵ Writing for the majority, Justice Blackmun stated that “even if the First Amendment were thought to be primarily an instrument to enlighten public decision making in a democracy, we could not say that the free flow of information does not serve that goal.”¹²⁶ Accordingly, economic motives are irrelevant and even “speech [that] does no more than propose a commercial transaction” receives First Amendment protection.¹²⁷

Simultaneously, the Court stressed that “[u]ntruthful speech, commercial or otherwise, has never been protected.”¹²⁸ Justice Rehnquist’s dissent, however, astutely predicted the then-future problematic nature of DTCA that the majority had not anticipated.¹²⁹

In 1980, the Supreme Court provided a test to determine whether the government can regulate a particular instance of commercial speech.¹³⁰ Specifically, the *Central Hudson* test states that protected speech must: (1) “concern lawful activity and not be misleading”; (2) concern a substantial “asserted governmental interest”; (3) “directly advance[] the governmental interest asserted”; and (4) “not [be] more extensive than is necessary to serve that interest.”¹³¹

U.S. 376, 384 (1973); *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 266 (1964) (“The fact that the particular advertisement . . . had commercial aspects or reflected the advertiser’s commercial interests did not negate all First Amendment guarantees.”).

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

126. *Id.* at 765.

127. *Id.* at 762 (citing *Pittsburgh Press Co.*, 413 U.S. at 385) (stating that “we may assume that the advertiser’s interest is a purely economic one”).

128. *Id.* at 771.

129. *Id.* at 788 (“In the case of ‘our’ hypothetical pharmacist, he may now presumably advertise not only the prices of prescription drugs, but may attempt to energetically promote their sale so long as he does so truthfully. Quite consistently with Virginia law requiring prescription drugs to be available only through a physician, ‘our’ pharmacist might run any of the following representative advertisements in a local newspaper: ‘Pain getting you down? Insist that your physician prescribe Demerol. You pay a little more than for aspirin, but you get a lot more relief’ ‘Can’t shake the flu? Get a prescription for Tetracycline from your doctor today.’ ‘Don’t spend another sleepless night. Ask your doctor to prescribe Seconal without delay.’”).

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

131. *Id.* at 566.

Applying that test, in *Thompson v. Western States Medical Center*, the Court struck down a provision of the FDA Modernization Act that required physicians and pharmacists to refrain from advertising in order to compound a drug.¹³²

The Supreme Court remains steadfast in holding drug advertising constitutional and preventing states and Congress from regulating its content. Most recently, in *Sorrell v. IMS Health*, the Court struck down a Vermont law restricting the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors. In enacting this law, “Vermont articulated three objectives: avoiding harm to the public health associated with the overprescription of new drugs, controlling costs by stemming practices that promote expensive, branded drugs over generics, and protecting physicians’ privacy.”¹³³ The Court found pharmaceutical data mining to be protected speech in aid of pharmaceutical advertising.¹³⁴ The statute at issue in *Sorrell* imposed both content and speaker-based restrictions by prohibiting the sale of physician prescribing patterns to pharmaceutical manufacturers and detailers for marketing purposes, but allowing the sale of the same records to certain other entities. While the Court determined heightened-scrutiny to be the correct standard, it simultaneously held that the statute failed even under the intermediate *Central Hudson* test. In another decision only days later, however, the Supreme Court held that all content-based restrictions trigger strict scrutiny,¹³⁵ thereby leaving the exact level of scrutiny to be applied in future cases unclear.¹³⁶

132. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 376–77 (2002); THAUL, CRS REPORT, *supra* note 12, at 15–16 & n.51.

133. Michelle M. Mello & Noah A. Messing, *Restrictions on the Use of Prescribing Data for Drug Promotion*, 365 NEW ENG. J. MED. 1248, 1248 (2011).

134. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2670–72 (2011).

135. *Brown v. Entm’t Merch. Ass’n*, 131 S. Ct. 2729, 2738 (2011).

136. Mello & Messing, *supra* note 133, at 1250 (“[T]he term ‘heightened scrutiny’ is critical and pointedly ambiguous. It might be a mere synonym for the midlevel scrutiny applied under the *Central Hudson* test — but it might mean far more. In a prior opinion, Justice Kennedy cited First Amendment cases that applied ‘strict scrutiny,’ the most rigorous kind, as examples of ‘heightened scrutiny,’ suggesting that he may have intended this meaning when he used the same term in *Sorrell v. IMS Health, Inc.* . . . *Sorrell* might thus portend that commercial speech will no longer receive lesser protection than political and social speech.” (internal citations omitted)).

In the wake of this ruling and as noted in Justice Breyer's dissent, the Court has opened the gates to the possibility of striking down most FDA regulations since they generally discriminate based on conduct and speaker.¹³⁷ For instance, off-label promotion by industry members, currently prohibited by FDA regulations faced a First Amendment challenge by Allergan several years ago. While Allergan dropped the claim and that case ultimately settled,¹³⁸ in light of *Sorrell's* application of heightened scrutiny to content- and speaker-based regulations, the regulation would likely not survive today. Thus, there are significant constitutional concerns with strong content-based limitations on DTCA.¹³⁹

II. DISCUSSION

The problem with DTCA has "attracted enough congressional attention to warrant at least six bills in the 110th Congress as well as concerns from members in the 111th."¹⁴⁰ Among these bills is the Say No to Drug Ads Act, which aimed to alter the IRC such that "[n]o deduction shall be allowed . . . for any amount paid or incurred for a direct-to-consumer advertisement of a prescription drug."¹⁴¹ Part II evaluates the strengths and weaknesses of this particular strategy concerning DTCA.

As Representative Daniel Lipinski, sponsor of one of the bills to revoke the DTCA tax deduction, said, "I am not looking to infringe upon any company's right to advertise, only to help assure that the American taxpayers are not subsidizing these industries in our health care system."¹⁴² By

137. See Kevin Outterson, *Higher First Amendment Hurdles for Public Health Regulation*, 365 NEW ENG. J. MED. e13, e13(2) (2011); *Sorrell*, 131 S. Ct. at 2676–80 (Breyer, J., dissenting).

138. Settlement Agreement between United States, et al. and Allergan, Inc. ¶ 19 (Sept. 1, 2010); see also Press Release, U.S. Department of Justice, Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox, No. 10-988 (Sept. 1, 2010) available at <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>.

139. See Sax, *supra* note 79, at 216 (advocating to institute the content-based Truth in Marketing Act).

140. THAUL, CRS REPORT, *supra* note 12, at 1.

141. H.R. 2966, 111th Cong. (2009).

142. Lipinski Letter, *supra* note 15. *But see* Walker, *supra* note 6, at 1251–52 (arguing that "the disallowance on 'public policy' grounds of deductions . . . is best understood as a response to an appearance of subsidy" and noting that not all deductions are actually subsidies).

allowing a tax deduction for DTCA, the government is reducing the cost of advertising and encouraging DTCA spending.¹⁴³ “[The pharmaceutical companies] already have plenty of incentives to spend that money As Congress looks for ways to repair our health care system, this is one simple reform that ought not to be overlooked.”¹⁴⁴

Increasing the financial burden on industry marketing may reduce the frequency and enhance the accuracy of DTCA content since there will be a greater monetary loss to companies when they are forced to cease broadcasting a misleading ad.¹⁴⁵ The recent Pfizer marketing abuse resulting in a multibillion-dollar fine further supports the need to encourage accurate advertising from the outset.¹⁴⁶ Moreover, eliminating the DTCA tax deduction would not prevent the pharmaceutical industry, ranked by Fortune magazine as one of the top thirty most profitable industries in 2009,¹⁴⁷ from advertising.¹⁴⁸ Thus, any benefits from advertising would be maintained while decreasing negative effects.

Removing the tax deduction would not cease all DTCA by creating a practical barrier. Rather, the removal would serve three main purposes. First, it would signal Congressional unwillingness to subsidize DTCA through the Tax Code.

143. See Walker, *supra* note 6, at 1251–52 (arguing that “the disallowance on ‘public policy’ grounds of deductions . . . is best understood as a response to an appearance of subsidy” and noting that not all deductions are actually subsidies).

144. Lipinski Introduces Bill to End Tax Break for Marketing and Advertising By Drug Companies, CONGRESSMAN DAN LIPINSKI (June 17, 2009), http://web.archive.org/web/20110406164620/http://www.lipinski.house.gov/index.php?option=com_content&task=view&id=917&Itemid=9 (internal quotations omitted).

145. *Cf.* The distortions to the healthcare market as a result of insurance such that consumers do not fully appreciate the cost of their decisions.

146. Gardiner Harris, *Pfizer Pays \$2.3 Billion to Settle Marketing Case*, N.Y. TIMES, Sept. 2, 2009, at B4, available at <http://www.nytimes.com/2009/09/03/business/03health.html>; see also Kesselheim, *supra* note 98, at 1486.

147. *Global 500 2009: Top Performers — Fast Growing Industries: Growth in Revenues*, CNNMONEY, <http://money.cnn.com/magazines/fortune/global500/2009/performers/industries/fastgrowers/> (last visited Oct. 5, 2011) (ranking the pharmaceutical industry number six in growth in profits and number twenty-seven in growth in revenue).

148. See, e.g., Lipinski Letter, *supra* note 15 (explaining that pharmaceutical companies earn approximately \$4.20 for each dollar spent on advertising and “neither need nor deserve to have their marketing expenditures subsidized by taxpayers”).

Second, making advertising more expensive would alter the drug companies' cost-benefit analysis as to how much money to spend on DTCA, likely leading them to cut back and reduce the overall quantity of DTCA. Third, the removal of the deductions may find favor with the public by resulting in increased revenue of approximately \$37 billion over ten years.¹⁴⁹

A. *Revocation of Tax Deductions is Constitutional*

Even in the wake of the Supreme Court's recent decision in *Sorrell*, which "expand[ed] the First Amendment's reach and power to strike down government regulation of health care information[,]"¹⁵⁰ revocation of the deductions for DTCA remains constitutionally viable. As Justice Kennedy noted in writing for the majority, *Sorrell* did not alter the proposition that "a State may choose to regulate price advertising in one industry but not in others, because the risk of fraud . . . is in its view greater there."¹⁵¹ Rather, the Court focused on content- and speaker-based restrictions in access to or use of information. Unlike the Vermont statute in *Sorrell*,¹⁵² revocation of the deductions for DTCA does not impose a content- or viewpoint-based restriction since it neither affects the industry's use of, or access to, information nor pertains to the content of its advertisements. Drug manufacturers can still publish the exact same advertisements that could be published with a deduction. Conversely, imposing a direct regulation on truthful, non-misleading DTCA would not likely survive a First Amendment challenge.

Revoking the deductions also does not impose speaker-based discrimination since it would apply to all DTCA, regardless of the person or entity engaging in the practice or his motivation. While the revocation may have the effect of discriminating based on speaker since only pharmaceutical manufacturers engage in DTCA, the revocation does not

149. Rich Thomaselli, *Industry Mobilizes to Fight Off Congress' \$37 Billion Ad Tax*, ADVERTISING AGE (June 22, 2009), <http://adage.com/article/news/big-pharma-media-cos-4a-s-defend-threat-dtc/137476/>.

150. Outterson, *supra* note 137, at e13(1).

151. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011) (citing *R.A.V. v. City of St. Paul, Minn.*, 505 U.S. 377, 388–89 (1992)).

152. *Id.* at 2663 ("Vermont's law . . . has the effect of preventing detailers—and only detailers—from communicating with physicians in an effective and informative manner.").

involve the facial discrimination apparent in the Vermont statute.

Another reason to differentiate DTCA from the data mining at issue in *Sorrell* is that data mining provides useful, educational information to doctors.¹⁵³ While DTCA also purports to educate, it targets consumers whose protection presents a greater concern to the court. As Kevin Outterson explained in his recent article in the *New England Journal of Medicine*, the *Sorrell* Court also indicated that the constitutional standard applied to regulations aimed at protecting consumers might be more relaxed.¹⁵⁴ According to Outterson, this means that:

FDA regulation of [DTCA] could be given more leeway than marketing to physicians, especially if medical education programs focused on helping physicians evaluate such claims. Similarly, more leeway could be given under special circumstances, such as if the FDA restricted [DTCA] as part of a Risk Evaluation and Mitigation Strategy.¹⁵⁵

While Congress cannot limit protected speech, they are not required to ease its financial burden. In *Bob Jones University v. United States*, the Supreme Court noted that “[i]n an area as complex as the tax system, the agency Congress vests with administrative responsibility must be able to exercise its authority to meet changing conditions and new problems.”¹⁵⁶ It is “well established that Congress is not required to subsidize the exercise of constitutional rights through the allowance of tax deductions, and may withdraw such subsidies if it chooses to do so.”¹⁵⁷ Tax deductions are

153. *Id.* at 2683 (Breyer, J., dissenting); Mello & Messing, *supra* note 133, at 1251.

154. Outterson, *supra* note 137, at e13(2) (“The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good These precepts apply with full force when the audience, in this case prescribing physicians, consists of ‘sophisticated and experienced’ consumers.” (quoting *Sorrell*, 131 S. Ct. at 2671)).

155. *Id.*

156. *Bob Jones Univ. v. United States*, 461 U.S. 574, 596 (1983).

157. Brief for Appellee at 28, *Branch Ministries v. Rossotti*, 211 F.3d 137 (D.C. Cir. 2000) (No. 99-5097), 1999 WL 34835366 (citing *Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 545–46 (1983); *Cammarano v. United States*, 358 U.S. 498, 513 (1959)) (discussing tax deduction and exceptions). Also consider, Congress’ removal of lobbying, a protected speech, from the class of deductible ordinary and necessary business expenses under

matters of legislative grace¹⁵⁸ and Congress “[u]nquestionably . . . has the power to condition, limit, or deny deductions.”¹⁵⁹

For instance, the IRC specifically exempts deductions for certain political expenditures, despite First Amendment implications.¹⁶⁰ This section also differentiates between local and non-local legislation. Note, however, that Congress would not be permitted to revoke deductions only for a particular political party. Such a restriction would be an impermissible speaker- and content-based restriction under *Sorrell*.¹⁶¹ The IRC also excludes deductions for expenses related to a redemption, certain passive real estate investments, net capital losses in excess of three thousand dollars, certain group health plans, and stock reacquisition, to name just a few.¹⁶² Most importantly, Congress has exempted certain foreign advertising expenses from the category of deductible expenses.¹⁶³ In *Bob Jones University*, the Supreme Court held that Congress had the power to revoke tax deductions on the basis of racial discrimination.¹⁶⁴

The Supreme Court, however, has held that preventing companies from spending money on protected speech violates the First Amendment.¹⁶⁵ In *First National Bank of Boston v. Bellotti*, the Court struck down a Massachusetts state law criminalizing contributions or expenditures by certain corporations for the purpose of influencing a vote.¹⁶⁶ The

the IRC remains constitutional in the wake of the *Bellotti* decision. I.R.C. § 162(e) (2006); *see also* *First Nat'l Bank of Bos. v. Bellotti*, 435 U.S. 765, 784 (1978).

158. *See, e.g.*, 26 U.S.C. § 162 (2006); *Bob Jones Univ.*, 461 at 574 (approving removal of tax exempt status); *New Colonial Ice Co. v. Helvering*, 292 U.S. 435, 440 (1934); *Knight v. Commissioner*, 552 U.S. 181, 192 (2008) (“noting the familiar rule that an income tax deduction is a matter of legislative grace” (citing *INDOPCO, Inc. v. Commissioner*, 503 U.S. 79, 84 (1992) (internal quotations omitted))).

159. *Helvering v. Indep. Life Ins. Co.*, 292 U.S. 371, 381 (1934).

160. I.R.C. § 162(e).

161. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011) (finding that the Vermont Law violates the First Amendment since “[t]he State’s interest in burdening the speech of detailers . . . turns on nothing more than a difference of opinion”).

162. I.R.C. § 162(k), (l).

163. I.R.C. § 162(j).

164. *Bob Jones Univ. v. United States*, 461 U.S. 574, 585 (1983); *see also* *Interstate Transit Lines v. Commissioner*, 319 U.S. 590, 593 (1943).

165. *First Nat'l Bank of Bos. v. Bellotti*, 435 U.S. 765, 784 (1978).

166. *Id.* at 765. The Court also explained that the lower court erred in holding that “First Amendment rights of a corporation are limited to issues that

Bellotti Court stressed the importance of the “exacting scrutiny” applied to “legislative prohibition[s] . . . directed at speech itself and speech on a public issue” since the First Amendment protects speech regardless of the source.¹⁶⁷ Indeed, the Supreme Court drew particular attention to advertising, reaffirming its holding in *Virginia State Board of Pharmacy*.¹⁶⁸ Specifically, the Court noted that “[a] commercial advertisement is constitutionally protected . . . because it furthers the societal interest in the ‘free flow of commercial information.’”¹⁶⁹ Congress has no authority to limit protected speech.¹⁷⁰ While the removal of the tax deductions may increase the cost of advertising and thereby reduce its prevalence, it does not prevent manufacturers from spending money to exercise their First Amendment right.

Recently, the Supreme Court issued a decision “reflect[ing] its willingness to expand significantly the justifications for regulating campaign financing, the First Amendment notwithstanding.”¹⁷¹ Professor Richard Briffault¹⁷² observed that the Court reframed the issue of regulating the finances away from “a threat to freedoms of speech and association and therefore a challenge to constitutional values . . . [instead] giv[ing] great weight to the interests in fair, informed democratic decision-making it found to be advanced[.]”¹⁷³ This reasoning for increasing regulations should similarly apply to DTCA. Rather than promote, DTCA, facilitated by tax deductions, hinders the free flow of information. DTCA influences consumers to pressure their over-burdened doctor whose reasoning cannot

materially affect is [sic] business, property, or assets.” *Id.* at 767. Even if the protections were limited to this subset, pharmaceutical advertising would still be allowed. This Article, however, discusses this case to emphasize that the amount of money a corporation may spend on advertising cannot be restricted.

167. *Id.* at 766.

168. *Id.* at 765–66.

169. *Id.* at 783.

170. *Id.* at 784–85.

171. Gregg D. Polsky & Guy-Uriel E. Charles, *Regulating Section 527 Organizations*, 73 GEO. WASH. L. REV. 1000, 1002 (2005) (discussing *McConnell v. FEC*).

172. Professor Briffault is the Vice Dean and Joseph P. Chamberlain Professor of Legislation at Columbia Law School.

173. Polsky & Charles, *supra* note 171, at 1002 n.19 (citing Richard Briffault, *McConnell v. FEC and the Transformation of Campaign Finance Law*, 3 ELECTION L.J. 147, 148 (2004)).

compete with the alluring ads to prescribe a more expensive medicine.¹⁷⁴

B. Policy

1. Negative Effects of DTCA

In their comments on the 2004 FDA DTCA draft guidance, FTC noted “the important role that DTC advertising *can* play in keeping consumers better-informed about their healthcare and treatment options.”¹⁷⁵ FTC highlighted the importance of providing consumers with risk information they can easily understand and “improv[ing] the facilitation of truthful, non-misleading information.”¹⁷⁶ Thus, FTC implicitly recognizes that DTCA, in its current state, fails to promote public welfare as demonstrated by the industry’s repeated violations of FDA guidance.¹⁷⁷

Improving consumer knowledge by providing information through DTCA is an honorable, yet impractical, aspiration. Drug companies often provide technically accurate information framed to mislead viewers.¹⁷⁸ The general public

174. See, e.g., Patrick Cohoon, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. TEX. L. REV. 1333, 1357 (2001) (“There is no justification for concluding that DTC advertising does not interfere with the doctor-patient relationship.”); Terzian, *supra* note 3, at 158 (“Moreover, industry critics of DTC advertisements argue that the advertisements distort doctor-patient relationships and may actually increase the use of prescription drugs.”); David C. Vladeck, *The Difficult Case of Direct to Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 284 (2007) (stating that “doctors often succumb to patient pressure, or patients ‘doctor-shop’ until they find a doctor willing to write the prescription the patient wants” and that “[m]edical organizations generally see DTC ads as a threat to the doctor-patient relationship for just that reason”).

175. BUREAU OF CONSUMER PROT., BUREAU OF ECON. & OFFICE OF POLICY PLANNING OF THE FTC, DOCKET NO. 2004D-0042, IN THE MATTER OF REQUEST FOR COMMENTS ON AGENCY DRAFT GUIDANCE DOCUMENTS REGARDING CONSUMER-DIRECTED PROMOTION 13 (2004), available at <http://www.ftc.gov/os/2004/05/040512dtcdugscomment.pdf> (emphasis added).

176. *Id.*

177. See sources cited *supra* notes 11, 73, 83, 146.

178. See, e.g., Lipinski Letter, *supra* note 15 (“In health care reform we should be striving to provide consumers with more information, but this information should be unbiased information that gives a clear understanding of the choices available to them.”); see also Terzian, *supra* note 3, at 165 (explaining that “even though DTC advertisements may be technically truthful, these advertisements mislead consumers because consumers lack the specialized knowledge needed to evaluate the information effectively”);

with no medical training cannot fully appreciate the implications of a particular drug as presented by the pharmaceutical companies.¹⁷⁹ An FDA survey revealed that 75% of patients overestimate drug's efficacy based on DTCA.¹⁸⁰ Many viewers assume that advertisements are preapproved and all advertised drugs are "completely safe."¹⁸¹ DTCA generally does not list alternate treatment options or include the full list of potential side effects and consumers typically lack the independent knowledge to appreciate an ad in its proper context.

Despite the instruction to viewers in every broadcast ad to consult additional sources for the full list of side effects, consumers are unlikely to comply. Rather than rationally process the information that should be relevant, consumers respond to the images designed to evoke a positive association in the consumer's mind. Alternatively, the ads sometimes aim to incite fear in the viewer to make the viewer believe that a relatively minor problem is a serious problem requiring immediate attention. Regardless of the marketing strategy, DTCA consistently emphasizes the drug's benefits to outweigh the side effects.

Accordingly, some argue that DTCA creates a "disease mongering" problem whereby patients decide they have the problem mentioned in an ad (e.g. restless leg syndrome) and request the miracle cure from their doctor.¹⁸² This increases prescription drug use, and consequently, the cost of health care, but does not lead to a healthier population.¹⁸³ When

Lenhardt, *Why So Glum?*, *supra* note 92, at 167–68.

179. See Davis, *supra* note 40, at 863–64.

180. KATHRYN J. AIKIN ET AL., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS: SUMMARY OF FDA SURVEY RESEARCH RESULTS 8 (2004), *cited in* Vladeck, *supra* note 174.

181. THAUL, CRS REPORT, *supra* note 12, at 26. *Cf.* *DTC Prescription Drug Advertising*, *supra* note 114.

182. Susan Heylman, *Widely Advertised 'Restless Legs' Drugs Move into Court*, 44 TRIAL 14, 14, 16 (2008) (explaining disease mongering and that while Consumer Reports, for example, has identified restless leg syndrome as an example of disease mongering, it is a real disease according to the National Institute of Neurological Disorders and Stroke); *see also* Moynihan et al., *Selling Sickness*, *supra* note 4, at 886.

183. Ray Moynihan & David Henry, *The Fight Against Disease Mongering: Generating Knowledge for Action*, *Public Library of Science*, 3 PUB. LIBR. SCI. MED. e191, e191 (2006), *available at* <http://collections.plos.org/plosmedicine/pdf/plme-03-04-diseasemongering.pdf>.

doctors inappropriately prescribe medication, drug companies are shielded from blame by claiming the prescribing physician as a “learned intermediary” with the “ultimate responsibility for prescribing drugs.”¹⁸⁴

While “many physicians believe that educated patients are easier to treat and care for,” few “believe that DTC advertisements are educationally effective.”¹⁸⁵ Rather than promoting productive communications between doctors and patients, DTCA “create[s] unreasonable or inappropriate patient expectations for product effectiveness and often lead patients to request inappropriate products for their medical needs.”¹⁸⁶ “Physicians may relent to patient pressure, even if it is not in the [patient’s] best interest.”¹⁸⁷ One survey found that physicians prescribe the advertised and requested drug 39% of the time despite not “believ[ing it is] the best medical—or economic—option.”¹⁸⁸ In many cases, the providers felt another drug would have been equally effective, and in some cases, the physicians even stated that they believed that a different course of action would have been more beneficial.¹⁸⁹ For instance, doctors frequently prescribed the heavily-advertised Claritin despite it working only 11% better than a placebo and the existence of other more effective

184. Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising*, HEALTH AFF., W4-226 (Apr. 28, 2004), <http://content.healthaffairs.org/content/early/2004/04/28/hlthaff.w4.219.short>); Pines, *DTC History*, *supra* note 37, at 515; Terzian, *supra* note 3, at 161 (“The learned intermediary doctrine holds that an adequate warning by a prescribing physician discharges a manufacturer’s duty to warn.”) However, as seen in *Edwards v. Basel Pharmaceuticals*, the doctrine does not shield manufacturers from potential liability when the FDA mandates a direct warning to patients. Terzian, *supra* note 3, at 162.

185. Terzian, *supra* note 3, at 158.

186. *Id.*; see also Council on Ethical & Judicial Affairs of the Am. Med. Ass’n, *Direct-to-Consumer Advertisements of Prescription Drugs*, 55 FOOD & DRUG L.J. 119, 122–23 (2000) (noting that the American Medical Association believes that DTCA causes a time burden on physicians).

187. Terzian, *supra* note 3, at 157; see also Angell, *Relationships*, *supra* note 8 (explaining that doctors may go along with prescribing the requested medicine since it is easier than suggesting an alternate course of treatment).

188. THAUL, CRS REPORT, *supra* note 12, at 24.

189. *Id.* (citing Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising*, HEALTH AFF., W4-226 (Apr. 28, 2004), <http://content.healthaffairs.org/content/early/2004/04/28/hlthaff.w4.219.short>); see also Angell, *Relationships*, *supra* note 8 (explaining that “adverts are mostly for me-too drugs and are designed to convince viewers that one is better than another, despite the fact that these drugs are seldom compared in clinical trials at equivalent doses”).

medications.¹⁹⁰ In the event that the doctor refuses to prescribe the drug, the patient may just doctor-shop until he finds one who will comply with his demand. Refusal to prescribe may also generate tension between the doctor and the patient, who does not understand the rationale, thereby placing a strain on the doctor-patient relationship in which trust and honesty are critical.¹⁹¹ Thus, industry “may be creating demand where there is no need and thereby harming the doctor-patient relationship.”¹⁹²

The FDA’s use of the same regulatory standard for DTCA and physician advertising also presents a problem.¹⁹³ Doctors, by virtue of their basic professional requirements, may consider drug advertising in context and better comprehend risk information and research further.¹⁹⁴ As a third party, the physician will not experience the same emotional response as the patient. Despite the continuing medical education requirements, keeping up with the latest advances in the ever-evolving medical field presents a challenge for doctors. Thus, drug detailing alerting doctors to a new treatment option may serve as a useful additional means of keeping doctors current.¹⁹⁵ DTCA, on the other

190. THAUL, CRS REPORT, *supra* note 12, at 25.

191. Terzian, *supra* note 3, at 157.

192. *Id.* at 165.

193. *But see* Schwartz, *Viability*, *supra* note 36, at 350 (arguing that “[b]ecause DTC marketing of prescription drugs has not fundamentally altered the playing field, traditional rules of law should remain fully viable”).

194. *But see* Lenhardt, *Why So Glum?*, *supra* note 92, at 166 (arguing that doctors are sometimes unknowingly deceived by DTCA). Additionally, physicians are human and some are persuaded by the perks offered by the drug companies, and some are unavoidably influenced by the inundation of the pharmaceutical representatives who flood their offices, a practice known as detailing. Accordingly, there is currently a rising concern with detailing and an increased focus on attempting to institute academic detailing which involves unbiased sources providing doctors with summaries of the best treatments with a focus on quality and a consideration of costs. For a more detailed discussion, please see Mark Navin, *Program to Inform Doctors about Drugs at Risk*, RADIO BOSTON (Jan. 8, 2010), <http://www.radioboston.org/2010/01/08/program-to-inform-doctors-about-drugs-at-risk/>.

195. Advertising to physicians is still problematic and academic detailing should be implemented to replace pharmaceutical advertising to physicians. *See, e.g.*, Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2659 (2011) (explaining detailing as a process through which pharmaceutical salespersons, generally armed with background information on the physician’s prescribing patterns, to persuade the physician to prescribe a particular drug). “Detailers bring drug samples as well as medical studies that explain the ‘details’ and potential advantages of various prescription drugs. Interested physicians listen, ask

hand, targets patients who lack the specialized knowledge to comprehend and appropriately weigh a drug's risks and benefits.¹⁹⁶

Yet, currently the government appears more focused on the undue influence of the industry on doctors rather than consumers. Recently, Congress enacted the Physician Payment Sunshine Act, which requires, among other things, drug companies to disclose gifts and payments to doctors, as Congress believes they generate conflicts of interest and biases.¹⁹⁷ While industry influence over the medical profession presents legitimate concerns, it should not be the sole legislative focus.

DTCA also results in increased healthcare spending since only the brand drugs advertise and the advertising reduces consumer price sensitivity.¹⁹⁸ Even when a consumer requests and receives a medically necessary drug as a result of DTCA, the ad often leads to wasteful spending by convincing patients they need the brand name drug, when a cheaper generic would be equally effective.¹⁹⁹ This effect is magnified by the fact that most consumers have health insurance and thus do not absorb the full cost of the drug. Accordingly, the irrational preference for brand over generic drug is another way in which DTCA increases unnecessary healthcare spending.

Allowing an advertising tax deduction also incentivizes the industry to invest additional resources in advertising to increase the life and profitability of their existing drugs rather than invest in research and development for new drugs.²⁰⁰ The patent system already provides drug companies with incentives to create drugs by allowing exclusivity periods for the first drug manufacturer to get a New Drug Application

questions, and receive follow-up [sic] data." *Id.*

196. Terzian, *supra* note 3, at 165.

197. S. 301, 111th Cong. (2009); H.R. 3138, 111th Cong. (2009).

198. See generally John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*, 42 J.L. & ECON. 89, 89–91 (1999) (primary effect of advertising drugs is to reduce consumer price sensitivity).

199. THAUL, CRS REPORT, *supra* note 12, at 1.

200. See, e.g., Aaron S. Kesselheim et. al., *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 HEALTH AFF. 1637, 1638 (2006) (explaining the pharmaceutical manufacturers' practice of using various tactics to extend the life of their existing "blockbuster" drugs known as "evergreening").

and the first generic drug to get an Abbreviated New Drug Application. Accordingly, these exclusivity periods, put in place to encourage research and development, allow the industry to profit from the drugs they make. Yet incentives are misaligned when more money is spent on administrative costs than research and development. Thus, removing the tax deduction may help shift the incentives from encouraging companies to invest in prolonging the profitability of existing drugs to investing the money into new drugs.²⁰¹

2. Lobbying

Unlike DTCA, Congress specifically exempts most lobbying from the deductible category of “ordinary and necessary business expenses.”²⁰² Like advertising, the First Amendment and several Supreme Court decisions limit Congress’ ability to regulate lobbying.²⁰³ Nevertheless, Congress removed the tax deductions for lobbying as a means of regulating and limiting the activity to “reduc[e the] possible nefarious effects.”²⁰⁴ The line of reasoning applied by Congress to the allowance and removal of the deductions for lobbying expenses, and grassroots lobbying specifically, also applies to DTCA.²⁰⁵

Originally, Congress recognized lobbying expenses as included within the IRC’s definition of ordinary and necessary business expenses and permitted their deduction.²⁰⁶ Like advertising, Congress observed that permitting the deduction for lobbying “would improve the flow of information.”²⁰⁷ In spite of that belief, Congress did not find

201. Terzian, *supra* note 3, at 165 (stating that critics of DTCA “argue that the money spent on expensive television advertising could be better spent on research and development of products, or to reduce the price of pharmaceutical products, thereby promotion public health and welfare”).

202. Mayer, *Lobbying*, *supra* note 28, at 495. For a discussion of the definition of lobbying in the tax context and exactly what is and is not included, see generally *id.* at 508–18.

203. *See id.* at 492.

204. *Id.* at 492–96, 507–08, 517–18.

205. *Cf. id.* at 492–96.

206. *See id.* at 498 (citing H.R. REP. NO. 87-1447, at 17 (1962)).

207. Mayer, *Lobbying*, *supra* note 28, at 498 (citing H.R. REP. NO. 87-1447, at 17; S. REP. NO. 87-1881, at 24 (1962)). They also noted that this “would reduce the administrative burden.” Mayer, *Lobbying*, *supra* note 28, at 498. *But see infra* Part II.D (discussing how removing tax deductions does not necessarily substantially increase administrative burdens).

value in extending deductibility to grassroots lobbying that targets the public to assist with lobbying activities.²⁰⁸ That distinction implicitly recognized the susceptibility of the general public to persuasion on topics about which they likely have little base knowledge. If Congress, however, attempted to distinguish between deductible and non-deductible lobbying based on the identity of the speaker or the content of the lobbying, that would violate the First Amendment under *Sorrell*.²⁰⁹

Additionally, Congress did not extend the revocation of the deductibility of lobbying expenses to charities, distinguishing between those who stand to profit from their efforts and those who do not.²¹⁰ This reflects Congress' concern for both influence over the public and the actors' motivation in attempting to influence. Despite the importance of prescription drugs, the pharmaceutical industry is not in the same class as charities. Thus, the DTCA tax deductions could similarly be revoked.²¹¹

C. *Increased FDA Regulations as an Alternative Solution*

The FDA, the agency in charge of regulating DTCA under the Federal Food, Drug and Cosmetic Act, should be the appropriate agency to implement changes to the current system and solve the DTCA problem. If indeed DTCA is misleading or not truthful, then the FDA has ample constitutional room to regulate it. FDA, however, has failed to rise to the challenge of sufficiently regulating DTCA and has left legislators concerned with current DTCA practices and searching for a solution.²¹² This failure stems from two major roadblocks: 1) the FDA lacks the necessary funding and resources; and 2) the FDA would have difficulty specifically identifying non-truthful or misleading speech, and therefore

208. Mayer, *Lobbying*, *supra* note 28, at 498–99.

209. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2670–72 (2011).

210. Mayer, *Lobbying*, *supra* note 28, at 517 (“Congress felt that charities were more likely to exercise their influence in a positive way, particularly with respect to providing information to government actors and to the public.”); *see also* I.R.C. § 162(e)(3) (2006).

211. For example, the potential for disease mongering and the potential negative impact on the doctor-patient relationship. *See* Moynihan & Henry, *supra* note 183, at e191; Terzian, *supra* note 3, at 158.

212. *See, e.g.,* ANGELL, THE TRUTH, *supra* note 9, at 124 (“Obviously, given the nature of the ads we’re subjected to, the [FDA] fails at [its] job.”).

would face practical difficulties in constitutionally increasing DTCA content regulation. FDA requires an average of forty-five days to review ads once they air.²¹³ A 2006 Government Accounting Office (GAO) report indicated that sometimes by the time FDA issues a warning on a misleading ad, its publication has already concluded.²¹⁴ Even when the FDA condemns an ad and the company ceases publication of the misleading ad, during the lag time inevitably some viewers saw the original advertisement and will either not see or disregard, the corrected version.²¹⁵ Further, in a 2009 Congressional Research Service report, the problem was recognized specifically in an area in which the FDA already has authority, but has failed to utilize.²¹⁶ The FDA lacks the manpower to review every advertisement prior to public viewing or to create a user fee program.²¹⁷ FDA staffing has not kept pace with the increase in number of drugs or advertisements.²¹⁸ As a result, in 2004, the FDA only reviewed approximately 32% of advertisements submitted before airing.²¹⁹

Following the passing of the Food and Drug Administration Amendments Act of 2007 (FDAAA), on March 14, 2007, then FDA Commissioner Andrew C. von Eschenbach issued a statement including a discussion of “a new program to assess fees for advisory reviews of DTC television advertisements.”²²⁰ In addressing the concerns

213. THAUL, CRS REPORT, *supra* note 12, at 13.

214. Schwartz, *Viability*, *supra* note 36, at 348.

215. Tim Kelly & John Busbice, *Measuring the Effectiveness of DTC Advertising*, 18 PRODUCT MGMT. TODAY 20, 21 (2007) (“TV advertising drives a sharp increase in new therapy starts for the first week or two after exposure and a more gradual increase in cumulative total prescriptions through week 36.”).

216. THAUL, CRS REPORT, *supra* note 12, at 27–29.

217. *Cf.* 21 U.S.C.A. § 353b (West 2010) (“The Secretary *may* require the submission of any television advertisement for a drug.”) (emphasis added).

218. *See* Donohue, *A Decade of DTCA*, *supra* note 74, at 679 (“[T]he number of staff members who are dedicated to reviewing advertisements has remained relatively stable, whereas the use of such advertising has grown substantially. In 2002, three FDA staff members were dedicated to reviewing direct-to-consumer advertisements. In 2004, four staffers were reviewing such advertisements, even though spending on this form of advertising (and probably the volume of ads to review) had increased by 45%, from \$2.9 billion to \$4.2 billion.”).

219. *Id.*

220. *Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 110th Cong. 7 (2007) [hereinafter Eschenbach statement] (statement of Andrew C. von

regarding the imbalance of risk and benefit information provided in DTCA, companies' ability to submit ads for review, and the industry's awareness of the benefits of the optional review, von Eschenbach also noted the FDA's increasing workload and the lack of a corresponding increase in staff.²²¹ As a solution, von Eschenbach proposed instituting a program where companies volunteering to have their ads reviewed by FDA would pay a user fee which would be used to "increase[] FDA resources to allow for . . . timely review . . . and ensure FDA input[.]"²²² FDA anticipated that these fees would generate several million in revenue and enable them to hire twenty-seven new employees to review ads.²²³ Under this arrangement, companies could get FDA approval prior to broadcasting their ads and thus not risk enforcement action against them.

On January 3, 2008, however, the Federal Register printed a notice that the "User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Program Will Not Be Implemented[.]"²²⁴ As a result, the FDA concluded that in lieu of a user fee, "[a]dvertisements voluntarily submitted for FDA review will be reviewed in as timely a manner as resources permit."²²⁵ Since the FDA by its own admission is incapable of reviewing the ads in a timely manner, few companies are likely to voluntarily submit ads.²²⁶

This failure of the law may not be quite as large a deficiency as it appears. First, the proposal was merely voluntary and thus would not solve the compliance problem.²²⁷ Second, the program would require significant resources to merely obtain a non-legally-binding FDA

Eschenbach, Comm'r, Food & Drug Admin.).

221. *Id.*

222. *Id.* at 8.

223. *Id.*

224. User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Program Will Not Be Implemented, 73 Fed. Reg. 2924 (Jan. 16, 2008).

225. *Id.*

226. Eschenbach statement, *supra* note 220, at 7 ("As a result, it is impossible for FDA to review all of the DTC television advertisement advisory submissions it receives in a timely manner.")

227. User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Program Will Not Be Implemented, 73 Fed. Reg. at 2924.

recommendation. Third, not even the FDA believed that the program would have received the \$11 million necessary to make the undertaking worthwhile.²²⁸ Finally, the FDA would also face First Amendment limits, as noted above, on its ability to regulate the content of the ads.

In an August 6, 2009 speech, FDA Commissioner Margaret Hamburg acknowledged a “steep decline in the FDA’s enforcement activity over the past several years.”²²⁹ Not surprisingly, the violations which “have gone unaddressed for far too long” include misleading advertising.²³⁰ As Hamburg noted, “[t]hese delays do not result from a lack of commitment by FDA career staff.”²³¹ FDA has recently demonstrated its promised commitment to enforcement of existing regulations by issuing more warning letters.²³² These efforts and good intentions, however, are insufficient. In light of its increased authority in recent years, the overburdened-FDA simply does not possess the means or funds to increase its enforcement power in order to make a substantial impact on the current situation.²³³

According to a January 2010 article, Thomas Abrams, Director of the Division of Drug Marketing, Advertising and Communications, reported that “[o]ver the last five years, the [FDA] has increased the number of people monitoring ads by 50% to 60% in an effort to keep” pace with advertising.²³⁴ Some may argue that the 4.7% decrease of DTCA in the first three quarters of 2009, compared to the previous year, indicates the FDA’s increased enforcement is already helping reduce the frequency of DTCA. The trend, however, can more likely be attributed to the current financial crisis and companies’ reluctance to spend money.²³⁵

228. *See id.*

229. Margaret A. Hamburg, Comm’r, U.S. Food & Drugs Admin., Remarks on “Effective Enforcement and Benefits to Public Health” at Food and Drug Law Institute (Aug. 6, 2009) [hereinafter Hamburg, Remarks], *available at* <http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm>.

230. *Id.*

231. *Id.*

232. Pettypiece, *supra* note 54 (“As a result, the agency issued 41 warning letters to drug makers, or almost double the number in 2008.”).

233. FDA expanded authority by the Bioterrorism Act of 2002 and Food and Drug Administration Amendments Act (FDAAA) of 2007.

234. Pettypiece, *supra* note 54.

235. *Id.* (noting the decrease in advertising spending and that “the recession has been partly to blame”).

Thus, there are problems with various aspects of the current DTCA regulation, which either cannot or will not be remedied by FDA action. Practical constraints prevent the FDA from serving as a realistic, practical, or sufficient solution to the DTCA problem. Any change to the FDA's responsibility would not only increase their responsibility, but also decrease available funds and resources for other programs. Moreover, constitutional concerns frustrate attempts to strengthen FDA regulation of DTCA content.

D. Disincentivizing DTCA Through the IRC Would Not Cause an Administrative Burden

Instituting an ex-ante user fee imposed through the FDA would accomplish the same goals, but would increase the FDA's work and responsibilities. Conversely, removing the tax deductions would not entail increasing the IRS' budget, resources, or responsibility, but would still raise revenue.²³⁶ As some scholars have pointed out, a benefit of instituting a disincentive through tax penalties in the IRC is low administrative cost.²³⁷ The taxable status of advertising is already at issue in the IRC and this approach is clearly feasible since its treatment varies among of different types of advertising.²³⁸ Also, for the targeted companies, the complexity will be small, especially considering the billions to be received. As a result of the low administrative cost, the IRC "includes numerous provisions that discourage particular non-tax behaviors."²³⁹ For instance, IRC section 162(m) imposes a tax penalty on certain executive salaries instead of having another agency directly regulate.

236. See Lipinski Letter, *supra* note 15 ("Each year pharmaceutical companies spend nearly \$18 billion for advertising, marketing, and promotion of prescription drugs, and the tax deduction these companies receive amounts to \$6.3 billion a year according to the Congressional Research Service.").

237. See, e.g., Weisbach & Nussim, *Tax and Spending*, *supra* note 20, at 958; Walker, *supra* note 6, at 1259–60 (explaining that under Eric Zolt's analysis of tax penalties, the low administrative costs "offset the crudeness of the incentives provided").

238. See I.R.C. § 162 (2006) (allowing a deduction for advertising in some instances, such as DTCA, but not allowing certain other instances, including certain foreign advertising).

239. Walker, *supra* note 6 (including several examples of tax disincentives and stating that the effect of these "provisions is to raise the effective cost of—and to discourage—the disfavored activity"); see also I.R.C. § 162.

For this reason, the removal of the deductions for DTCA has been widely supported as demonstrated by the proposed legislation and arguments from scholars. For instance, the 2009 CRS Report suggested removing the tax deduction for advertising as a means of “[m]ak[ing] DTC Advertising [l]ess [p]rofitable to [i]ndustry” which would thereby reduce the overall level of DTC.²⁴⁰ As one scholar argues, the Tax Code serves as a logical first place for Congress to attempt to regulate lobbying since it “requires spending money, and when money is spent, there is always the question of how to treat those expenditures for tax purposes.”²⁴¹ Alternatively, “[p]utting a program into the tax system makes the tax system look more complicated, but there is unseen simplification elsewhere.”²⁴² Moreover, the imposition of a monetary disincentive does not require any specialized knowledge.²⁴³ Thus, as a result of the faulty information portrayed in DTCA, the First Amendment hindering practical regulation of DTCA, and the FDA’s limited resources, taxation remains one policy mechanism constitutionally available to Congress to remedy the negative effects of DTCA.

E. Potential Problems

As with every piece of legislation, removing the tax deductions for DTCA presents several concerns. It is possible that even if DTCA becomes more expensive, the industry will not shift its spending to research and development. Rather, the drug companies could respond by shifting the spending to other promotional activities such as drug detailing, health outreach fairs, or grants to patient advocacy groups. The wealth of alternatives might strengthen the argument that the change in the Tax Code did not impermissibly constrain speech, since the companies retain many other ways to disseminate their messages. Indeed, the DTCA channel itself remains fully legal, with only the public subsidy removed.

240. THAUL, CRS REPORT, *supra* note 12, at 32–33.

241. Mayer, *Lobbying*, *supra* note 28, at 494.

242. Weisbach & Nussim, *Tax and Spending*, *supra* note 20, at 958.

243. *See id.* at 958–59. Authors explained that where specialization is not required for a particular task, there may be benefits to coordinating certain activities. *Id.* Accordingly, this would be an appropriate instance to use the Tax Code, which is already being used rather than to start trying to find another way to achieve the same result. *Id.*

Of course, if the industry reacted by increasing total drug advertising, some of the congressional policy objectives would not be met. While predicting the industry's next move if Congress eliminates the tax deduction presents a challenge,²⁴⁴ whether the policy achieves its goals will be an empirical question.

Additionally, the removal of the deductions for DTCA may either disproportionately impact different companies for the same conduct²⁴⁵ and may result in over deterrence of DTCA. Denying deductions is not intended to cease DTCA, but rather to remove the public subsidy. Proponents' arguments include some justifications for the practice that, if true, provide compelling reasons to ensure its continued existence. Accordingly, while the removal of deductions would probably not lead to complete deterrence²⁴⁶ this Article argues that some measure of deterrence through the IRC is the appropriate means to deter. Thus, in the alternative to the removal of the deductions, Congress should institute a cap on the amount which may be deducted for DTCA, just as they have done for certain executive compensation, to reduce spending.²⁴⁷

CONCLUSION

In the face of compelling public policy justifications, as judged by Congress, the Tax Code could be revised to deny tax deductions for DTCA. The removal of this public subsidy

244. See Donohue, *A Decade of DTCA*, *supra* note 74, at 677–78 (“Driven by increases in direct-to-consumer advertising, total promotion as a percentage of sales has increased substantially during the past 5 years, leading some observers to worry that consumers must bear these increased costs in the form of higher prices. Economic theory and evidence suggest that changes in marketing costs are unlikely to have a direct effect on pharmaceutical prices, which largely reflect perceptions of product value held by consumers, physicians, and payers. Of course, it is possible that advertising reduces the price responsiveness of demand and thus leads manufacturers to increase prices, but the empirical evidence on this point is mixed.”).

245. See Walker, *supra* note 6, at 1259–60 (explaining Eric Zolt’s article discussing the effect of tax penalties).

246. See, e.g., Walker, *supra* note 6, at 1275–79 (for an explanation of optimal and complete deterrence).

247. See I.R.C. § 162(m) (2006) (stating that “[i]n the case of any publicly held corporation, no deduction shall be allowed under this chapter for applicable employee remuneration with respect to any covered employee to the extent that the amount of such remuneration for the taxable year with respect to such employee exceeds \$1,000,000”).

would be constitutional and the likely resulting decrease in public exposure to DTCA is properly aligned with public policy. The First Amendment protects commercial-free speech and does not allow Congress to discriminate on the basis of content and speaker to restrict certain parties' use and access to information, but allows others. Under the First Amendment, Congress also may not institute a law preventing companies from spending money on protected speech. These protections, however, do not require Congress to continue to subsidize DTCA with a subsidy from the public fisc.