NELLCO
NELLCO Legal Scholarship Repository

New York University Law and Economics Working Papers

New York University School of Law

2-5-2009

Drug Advertising Claims: Preemption's New Frontier

Catherine M. Sharkey
NYU School of Law, catherine.sharkey@nyu.edu

Follow this and additional works at: http://lsr.nellco.org/nyu_lewp

Part of the Administrative Law Commons, Litigation Commons, Products Liability Commons, and the Torts Commons

Recommended Citation
Sharkey, Catherine M., "Drug Advertising Claims: Preemption's New Frontier" (2009). *New York University Law and Economics Working Papers*. Paper 170.
http://lsr.nellco.org/nyu_lewp/170

This Article is brought to you for free and open access by the New York University School of Law at NELLCO Legal Scholarship Repository. It has been accepted for inclusion in New York University Law and Economics Working Papers by an authorized administrator of NELLCO Legal Scholarship Repository. For more information, please contact tracy.thompson@nellco.org.

DRUG ADVERTISING CLAIMS: PREEMPTION'S NEW FRONTIER

*Catherine M. Sharkey**

Preemption's frontier in the realm of products liability is fast-moving indeed. Prior to 1992, product manufacturers' preemption defenses to state common law tort actions met a brick wall. The Supreme Court's opinion in *Cipollone v. Liggett Group*[1] ushered in a new era for preemption in the realm of products liability by interpreting federal preemptive "requirements" to include common law tort actions. Between 1992 and 2009, the Court has addressed, in fits and starts, preemption under congressional statutes that cover the safety of automobiles, recreational boats, pesticides, medical devices, and pharmaceutical drugs.[2]

The current U.S. Supreme Court Term promises to be a true watershed for products liability preemption. For the first time in the decade and a half since the Court became active in this area, it is poised to fashion a comprehensive framework for products liability preemption. With *Riegel v. Medtronic, Inc.*,[3] a nearly unanimous (eight to one) Court handed preemption advocates a decisive victory in the medical devices realm. But any hopes for a spreading landslide into the pharmaceutical realm were dashed by the Court's per curiam summary affirmance by an equally divided (four to four) Court in *Warner-Lambert Co. v. Kent*.[4] Now, all eyes are on *Wyeth*

* Professor of Law, New York University School of Law. The D'Agostino/Greenberg Fund provided generous summer research support, and Sara Johnson provided helpful research assistance.

1. 505 U.S. 504 (1992).

2. The Supreme Court's products liability preemption jurisprudence is a small but expanding area that traces its beginnings to the early 1990s with *Cipollone*, 505 U.S. at 504, and continues, most recently, through the 2008 decision of *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

3. 128 S. Ct. 999.

4. 128 S. Ct. 1168 (2008).

v. Levine,[5] another pharmaceutical case pending this Term. *Riegel* and *Kent* will be on the minds of the Justices as they decide whether state-law tort claims alleging failure-to-warn can survive a preemption challenge where the U.S. Food and Drug Administration ("FDA") has approved the label on a prescription drug.

At this juncture, it is worth contemplating the next frontier: preemption of consumer fraud claims arising from prescription drug advertising. To date, the Supreme Court's focus has been on preemption of traditional tort claims impugning the safety of medical devices and drugs either through design defect or failure-to-warn claims. Even if the Court forecloses such tort claims, in whole or in part, most likely the nascent, but ever-expanding, realm of related consumer fraud claims will emerge unscathed.

Direct-to-consumer advertising ("DTCA") of prescription drugs is a significant public policy issue for the twenty-first century. Part I summarizes the relatively recent surge in expenditures on DTCA and explores the possibility of a concomitant increase in consumer fraud litigation stemming from drug advertisements.

Against this background, Part II focuses on the role of the FDA in regulating drug advertisements. Highlighting the regulatory role of the FDA is a prelude to consideration of the question whether federal regulation should preempt, or oust, competing state consumer fraud claims arising from drug advertisements. In prior work, I have proposed an institutional approach to products liability preemption, guided by what I termed an "agency reference model." Pursuant to this model, courts should look to agencies to supply the data and analysis necessary to determine when a uniform national regulatory policy with respect to a certain product makes the most sense or, instead, whether such regulation is better left to the states—in which case a plaintiff's common law claim should be permitted to proceed.[6]

5. 128 S. Ct. 1118 (2008) (No. 06-1249) (argued Nov. 3, 2008).

6. *See* Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008) [hereinafter, Sharkey, *Products Liability Preemption*]; *see also* Catherine M. Sharkey, *What* Riegel *Portends for State Law Products Liability Claims*, 102 NW. U.L. REV. COLLOQUY 415 (2008) [hereinafter, Sharkey, *What* Riegel *Portends*], *available at* http://www.law.northwestern.edu/lawreview/colloquy/2008/24/; Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Court*, 15 J. OF LAW & POL'Y 1013 (2007) [hereinafter Sharkey, *Federalism in Action*]; Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U.L. REV. 841 (2008); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) [hereinafter, Sharkey, *Preemption by Preamble*].

The role played by an agency might be significant in two respects. First, there is the degree of regulatory scrutiny employed by the agency in its review and approval of products.[7] Second, an agency may assume a distinct interpretive role as administrator of the congressional legislation and has a variety of means at its disposal to express its position on preemption.[8] These include official notice-and-comment rulemaking, less formal interpretive statements and preambles to rules, and amicus briefs filed before courts.[9] There is good reason to be chary of agencies acting in their interpretive, as distinct from regulatory, capacity.[10] Most of the arguments in favor of agencies' comparative expertise speak to the rigor of the product review and approval process.[11]

The preemption inquiry in the new realm of consumer fraud and drug advertising, taken up in Part III, hinges on an analysis of the FDA's regulatory review of advertising claims. A comparison of the FDA's regulatory scrutiny with respect to its approval of medical devices and pharmaceutical drugs to its review of advertisements reveals key weaknesses in product manufacturers' appeals to preemption in the latter context. A critical distinction emerges: in sharp contrast to medical devices and drug labels, which are subject to scrutiny *before* a company may market a product, direct-to-consumer advertisements are reviewed, but not preapproved, by the FDA.[12] Moreover, the FDA's review process for advertising provides, at most, a "floor" (or minimal) rather than a "floor and a ceiling" (or optimal) level of regulation.

I. DIRECT-TO-CONSUMER ADVERTISING OF DRUGS

A. Spending Surge

Spending on prescription drug marketing is the fastest growing component of the health care budget; total spending on

7. *See* Sharkey, *Products Liability Preemption*, *supra* note 6, at 479.

8. *See id.*

9. *See id.*

10. For a discussion of the FDA's regulatory and interpretive roles, *see* Sharkey, *What* Riegel *Portends*, *supra* note 6, at 420.

11. *See, e.g.*, Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73 (2008).

12. *See* PRESCRIPTION DRUGS: TRENDS IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING, at 1 (GAO-08-758T) (May 8, 2008) [hereinafter GAO 2008 REPORT].

pharmaceutical promotion increased from $11.4 billion in 1996 to $29.9 billion in 2005.[13] Annual spending (in real dollars) on direct-to-consumer advertising tripled between 1996 and 2005, when it reached a total of $4.2 billion.[14] While reaching out directly to consumers is by no means a new phenomenon,[15] there has been a revolution in the means—specifically the launch of television advertising of prescription drugs.

Prescription drug advertising is concentrated on remarkably few drugs. Indeed, for the vast majority of prescription drugs, the advertising budget is nil.[16] For a few select drugs, however (namely those within the classes of antidepressants, antihistamines, anti-inflammatory agents, anti-cholesterol, and erectile dysfunction drugs), an enormous amount of money is spent on advertising.[17]

13. Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 673 (2007).

14. *Id.* at 675–76. DTCA nonetheless constitutes a relatively small portion of money spent on drug promotion—roughly 15 percent of total promotional expenditures in 2005, as compared to the nearly 80 percent spent on direct promotion to health care professionals. *Id.* at 673. Over the last decade, spending on DTCA and promotional free samples to physicians has risen as a proportion of total promotional spending, whereas spending on visits to doctors' offices and advertising in professional journals has fallen as a proportional share. *Id.* at 675; *see also* GOVERNMENT ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 14 (GAO-03-177) (Oct. 2002) [hereinafter GAO 2002 REPORT] ("[H]alf of the 10 drugs with the highest DTC spending were also among the 10 drugs with the greatest volume of samples distributed to physicians in 2000."); GOVERNMENT ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS, IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 16 (GAO-07-54) (Nov. 2006) [hereinafter GAO 2006 REPORT] ("[S]tudies have found that advertising in medical journals and visits from drug sales representatives may influence physician prescribing to a greater degree than DTC advertising.").

15. Consider, for example, the claims made on behalf of "Lydia E. Pinkham's Vegetable Compound" in an 1881 print advertisement: "To cure entirely the worst form of female complaints, all ovarian troubles, inflammation and ulceration, falling and displacements. And the consequent spinal weakness, and it is particularly adapted to the change of life." Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 THE MILBANK Q. 659, 664 (2006) (quoting advertisement in an 1881 Salt Lake City newspaper).

From a comparative perspective, the United States is at one permissive pole when it comes to DTCA of prescription drugs. New Zealand is the only other country to allow direct-to-consumer advertising of pharmaceuticals (although bans in Canada and the European Union have recently been challenged). Donohue et al., *supra* note 13, at 680.

16. *See* J.E. Calfee, *An Assessment of Direct-to-Consumer Advertising of Prescription Drugs*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 357, 359 (2007) ("Most drugs remain unadvertised.").

17. For example, over half of industry spending in 2005 was used to promote twenty drugs. Donohue et al., *supra* note 13, at 676. Higher quality drugs (as measured by FDA's priority rating) are more likely to be advertised, particularly when the drug was first or second in its therapeutic class; and spending on advertising correlates with potential market size, rather than current treatment population size. *See* Ernst Berndt, *The United States' Experience with Direct-*

Typically, the campaigns for these heavily advertised drugs are targeted to run within one year of FDA approval of the drug.[18]

The proliferation of DTCA of prescription drugs has spawned a vibrant public policy debate. Staunch defenders of DTCA link the practice to the rise of consumer empowerment or patients' rights in health care, emphasizing that DTCA leads to better informed consumers, increased utilization of drugs, and increased quality of care.[19] Less obvious benefits touted by DTCA supporters are that

to-Consumer Advertising of Prescription Drugs: What Have We Learned?, *in* PHARMACEUTICAL INNOVATION 174, 181–84 (Frank A. Sloan & Chee Ruey Hsieh eds., 2007).

18. Donohue et al., *supra* note 13, at 676 ("Notably, nearly all (17 of 20) advertising campaigns for the most heavily advertised drugs began within a year after FDA approval of the drug."). In part, this is because relatively new drugs will have the longest prospective time under patent protection. *See* GAO 2002 REPORT, *supra* note 14, at 12–13.

19. *See, e.g.*, Alan F. Holmer, *Direct-to-Consumer Advertising—Strengthening Our Health Care System*, 346 NEW ENGL. J. MED. 526, 527 (2002) (advocating, as a PhRMA representative, that DTCA strengthens the doctor-patient relationship by encouraging patients to talk with their doctors about previously undiagnosed conditions) (citing a 1991 survey by *Prevention* magazine, which found that DTCA prompted twenty-four million Americans over a two-year period to initiate a conversation about previously unaddressed symptoms with their respective doctors); Andrew R. Robinson et al., *Direct-to-Consumer Pharmaceutical Advertising: Physician and Public Opinion and Potential Effects on the Physician-Patient Relationship*, 164 ARCH. INTERN. MED. 427, 428 (2004) (reporting results of a 2001 Kaiser Family Foundation survey that "found that 30 percent of adults have inquired about an advertised drug with their physician, and 44 percent of those actually reported receiving the requested prescription"). *But see* INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 159 (2007) (characterizing the impact of DTCA "as a communication or education tool" as "mixed," while acknowledging that "[t]here is evidence that advertisements have raised awareness about certain health conditions and led people to visit their health care provider and in some cases, receive needed diagnosis and treatment"); Sanjo Adeoye & Kevin J. Bozic, *Direct to Consumer Advertising in Healthcare: History, Benefits, and Concerns*, 457 CLINICAL ORTHOPEDICS & RELATED RES. 96, 98 (2007) ("DTCA cannot simultaneously fulfill goals of educating consumers and increasing pharmaceutical sales."); Sidney M. Wolfe, *Direct-to-Consumer Advertising—Education or Emotion Promotion?*, 346 NEW ENG. J. MED. 524, 526 (2002) ("The education of patients—or physicians—is too important to be left to the pharmaceutical industry, with its pseudoeducational campaigns designed, first and foremost, to promote drugs.").

Empirical studies have established a link between DTCA and drug utilization. *See, e.g.*, GAO 2006 REPORT, *supra* note 14, at 14 ("Studies we reviewed suggest that [DTCA] . . . increases prescription drug spending and utilization."). *But see* GAO 2002 REPORT, *supra* note 14, at 6 (suggesting, based upon comparative analysis of increased drug utilization in the United States, Canada, Germany, and the United Kingdom, that confounding factors—such as an aging population, new medications for previously untreatable conditions, and increased insurance coverage—may explain increased drug utilization). Making the link from increased drug utilization to increased (or decreased) quality of health care outcomes has proved much more difficult.

advertisements encourage compliance with treatment regimes[20] and spur new product development.[21]

Equally (or perhaps more) vociferous opponents, however, emphasize a host of downside risks and effects. First, physicians expend unnecessary time and energy responding to patients' requests for various prescription drugs that have piqued their interest on television.[22] Second, given the pressure of patient demand, physicians prescribe expensive and unnecessary medications, which can lead to heightened safety risks and health care costs.[23]

20. *See, e.g.*, Calfee, *supra* note 16, at 359 (reporting studies linking DTCA with modest improvements in compliance for particular classes of drugs, such as statins and anti-depressants); Holmer, *supra* note 19, at 527 (noting that 33 percent of individuals surveyed by *Prevention* magazine in 1999 "reported that such advertising had reminded them to fulfill a prescription"); *id.* (reporting results of a 2001 industry (Pfizer) study finding that patients who were prompted by an advertisement to fill their prescription were substantially more likely to continue treatment after six months than those who filled prescriptions absent such prompting).

21. *See* Calfee, *supra* note 16, at 357 (citing John E. Calfee, *The Role of Marketing in Pharmaceutical Research and Development*, 20 PHARMACOECONOMICS (Supp. 3) 77, 85 (2002) ("The prescription drug market offers exceptional opportunities for direct-to-consumer advertising to . . . motivate new-product development.")).

22. *See, e.g.*, Adeoye & Bozic, *supra* note 19, at 98; Joel S. Weissman et al., *Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising*, HEALTH AFFAIRS 219, 231 (2004), *available at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.219v1.pdf (reporting that physicians in focus groups "complained that DTCA caused them to waste time explaining to patients why they did not need a particular brand-name drug"); *id.* at 220 ("The American Medical Association (AMA) perceives that DTCA places a time burden on physicians but accepts the practice as long as there are efforts to ensure clear and balanced information.") (citing Council on Ethical and Judicial Affairs of the American Medical Association, *Direct-to-Consumer Advertising of Prescription Drugs*, 55 FOOD AND DRUG J. 119–124 (2000)); *see also* Robinson et al., *supra* note 19, at 427 (noting that physicians complain that "advertisements rarely provide enough information on cost (98.7%), alternative treatment options (94.9%), or adverse effects (54.8%)").

23. *See, e.g.*, GAO 2006 REPORT, *supra* note 14, at 20 ("Studies suggest that physicians are generally responsive to consumers' requests, and that decisions to prescribe a drug are influenced by a variety of factors in addition to a patient's medical condition."); INSTITUTE OF MEDICINE, *supra* note 19, at 158 ("DTC advertising may distort use patterns within classes of drugs, often driving use of more costly but not more effective therapies at the expense of older, cheaper options (e.g., generics)."); Robinson et al., *supra* note 19, at 428 (reporting survey results documenting that 71 percent of family physicians have prescribed a drug that they otherwise would not have prescribed, absent the patient's request for the drug); Weissman et al., *supra* note 22, at 229 (reporting results of a study in which physicians prescribed a drug requested by patients 39 percent of the time, and in 20 percent of those cases, physicians "thought that the DTCA drug would have no effect on their patient's overall health"); Wolfe, *supra* note 19, at 526 (arguing that physicians are often "duped gatekeepers" who too easily cede to patients' exhortations to write a prescription). *But see* Calfee, *supra* note 16, at 358 ("[T]here is considerable evidence that whether or not DTCA is involved, physicians tend to cater to patient preferences when they ask for prescriptions so long as the risks are minimal."); *id.* at 359 ("Some of the most heavily advertised drugs are in therapeutic classes (such as statins and antidepressants) that are underprescribed and that sometimes reduce total health-care costs.").

In recent years, there have been calls for a ban—either partial or total—on DTCA.[24] The Institute of Medicine called for the FDA to place limits on DTCA, especially for new drugs.[25] In 2006, Senators Edward Kennedy and Michael Enzi sponsored a bill that included a two-year moratorium on DTCA of new drugs.[26]

B. Litigation Surge?

One thing is sure: with the rise of DTCA, we can expect a burgeoning number of consumer fraud claims.

1. End Run Around Preempted Failure-to-Warn Claims?

The historical model for an end run around preemption of failure-to-warn claims is provided by the watershed case *Cipollone v. Liggett Group*,[27] which (as noted above) was the progenitor of the Court's products liability preemption jurisprudence.[28] *Cipollone* interpreted the Federal Cigarette Labeling and Advertising Act[29] as forging a distinction between health and safety specific failure-to-warn claims—which were expressly preempted under the statute—and general fraudulent misrepresentation claims—which were not preempted.[30] A plurality of the Court reasoned that unlike failure-to-warn claims, which were predicated upon "a duty 'based on smoking

24. Such calls were heightened in the wake of the Vioxx debacle, especially after the 2004 withdrawal of Vioxx from the market. Public opinion polls demonstrate the unpopularity of DTCA. For example, in a 2005 *Wall Street Journal* survey (conducted by Harris Interactive), 51 percent of respondents agreed that it would be beneficial to ban DTCA "for some period of time after [approval] so doctors have time to become familiar with the drug." INSTITUTE OF MEDICINE, *supra* note 19, at 162 (citing 2005 Harris Interactive Survey, *available at* http://www.harrisi.org/news/allnewsbydate.asp?NewsID=947).

25. *Id*. at 151–76.

26. *See* Enhancing Drug Safety and Innovation Act, S. 3807, 189th Cong. § 2 (2006). For Senators Kennedy's and Enzi's statements on the bill, see Press Release, Chairman Mike Enzi, S. Comm. on Health, Education, Labor and Pensions, *available at* http://help.senate.gov/Maj_press/2006_11_16.pdf. The bill also provided authorization for the FDA to require pre-approval of advertisements. S. 3807, 189th Cong. § 2 (2006).

27. 505 U.S. 504 (1992).

28. *See supra* notes 1–2 and accompanying text.

29. Pub. L. 89-92, 79 Stat. 282 (codified as amended at 15 U.S.C. § 1331 et seq. (1965)). The Act espouses two main goals: "(1) adequately informing the public that cigarette smoking may be hazardous to health, and (2) protecting the national economy from the burden imposed by diverse, non-uniform, and confusing cigarette labeling and advertising regulations." *Cipollone*, 505 U.S. at 514.

30. A plurality of the Court held that "fraudulent-misrepresentation claims that do arise with respect to advertising and promotions (most notably claims based on allegedly false statements of material fact made in advertisements) are not preempted." *Id.* at 528.

and health'" and thus preempted, fraudulent misrepresentation claims were based upon "a more general obligation—the duty not to deceive."[31] Moreover, the plurality continued, "[u]nlike state-law obligations concerning the warning necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity."[32]

In the wake of *Cipollone*, consumer fraud claims based upon the marketing of "light" and "lower tar and nicotine" cigarettes proliferated.[33] This Term, in *Altria Group, Inc. v. Good*, the Supreme Court jumped into the fray to resolve a circuit split on whether such consumer fraud and misrepresentation claims are preempted.[34] The key question was whether implied misrepresentation claims should be considered similar in kind to failure-to-warn claims or closer to fraud by intentional misrepresentation. The Fifth Circuit was partial to the view that the claims were failure-to-warn claims in disguise, and thus expressly preempted. The First Circuit, by contrast, rested its finding of no express preemption on the distinction between a "duty based on smoking and health" (which would be preempted) and a "duty not to deceive" (which would escape preemption).[35] The First Circuit, moreover, rejected the implied preemption argument (not addressed in *Cipollone*) based upon the Federal Trade Commission's (FTC) actions in regulating cigarette labeling.[36] The Supreme Court sided

31. *Id.* at 528–29.

32. *Id.* at 529.

33. *See* Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, in REGULATING TOBACCO 176, 184–85 (Robert L. Rabin ed., 2001) (contrasting the first two waves of tobacco litigation based on plaintiffs' claims of failure to warn with a "third wave" after *Cipollone* focused on industry deceit and misrepresentation, including class actions and suits by state governments, insurers, and union health care funds).

34. No. 07-562, 129 S. Ct. 538 (Dec. 15, 2008).

35. *Compare* Good v. Altria Group, Inc., 501 F.3d 29 (1st Cir. 2007), *with* Brown v. Brown & Williamson Tobacco Corp., 479 F.3d 383 (5th Cir. 2007).

36. 501 F.3d at 36. The FTC's regulation of light cigarettes over the past half century has taken some twists and turns. In 1959, the major cigarette companies agreed to remove all claims regarding tar and nicotine levels from cigarette labels and packaging. *Id.* at 30–32. In 1966, however, the FTC advised the companies that they could include a valid factual statement regarding lower tar and nicotine, so long as any statement was supported by adequate records of tastes. *Id.* In 1967, the FTC adopted the "Cambridge Filter Method" to test cigarettes' factual statements as to tar levels—the very method utilized by the cigarette companies, notwithstanding its inability to measure the amount of nicotine inhaled by a human smoker. *Id.* In 1970, the FTC proposed a rule to require all advertised cigarettes to include the levels of tar and nicotine as established by the FTC; the proposed rule was suspended when the manufacturers agreed to a

with the First Circuit, holding that plaintiff's state law fraud claim was neither expressly nor impliedly preempted.[37] *Altria*, decided by a five-to-four majority of the Court, thus shores up the *Cipollone* plurality ruling and breathes new life into efforts to structure state law fraud claims around federal preemption.

The post-*Cipollone* story is instructive, as it portends an analogous trajectory for drug advertising claims in the wake of potentially viable preemption defenses to failure-to-warn claims. Moreover, the state law claims for economic harms at issue in the cigarette cases are nearly identical to those asserted in the drug advertising context.

2. The Nature of Consumer Fraud Claims

Consumer fraud claims raise theories of economic harm. Consumer fraud statutes have their origin in common law fraud and the Federal Trade Commission Act ("FTC Act").[38] Common law fraud claims typically require an intentional misrepresentation of material facts, reliance by the recipient, causation, and damages.[39] Consumer protection statutes often relax one or more of the common law fraud elements, for example, by liberalizing standing requirements, or by relieving plaintiffs of the burden of demonstrating causation or injury.[40] Most consumer fraud statutes

voluntary program of like effect. *Id.* The FTC has not re-instituted any rulemaking proceedings; moreover, the tests were curtailed in 1987, though continued by the cigarette companies. *Id.*

The First Circuit based its rejection of implied preemption on the fact that the FTC did not use the formal rulemaking procedures; there is no established policy on the use of terms such as "low tar" and "light"; and implied preemption should be based upon the rationales for agency action, not agency action itself. *Id.* at 58–59.

37. *Altria Group, Inc.*, 129 S. Ct. at 545-46, 549-51. In rejecting implied preemption, the Court was swayed by the fact that the Government itself disavowed any longstanding policy of the FTC authorizing the use of "light" and "low tar" descriptors. *Id.* at 549. *Altria* then fits the empirical pattern of what I have described as Supreme Court deference to agency positions in preemption cases. *See* Sharkey, *Products Liability Preemption*, *supra* note 6, at 471 ("[F]rom *Cipollone* in 1992 to *Riegel* in 2008, the Supreme Court's position in every products liability preemption case (save one—*Bates*) aligned with the relevant underlying federal agency's take on preemption.").

38. *See* Alan S. Brown & Larry E. Hepler, *Comparison of Consumer Fraud Statutes Across the Fifty States*, 55 FED'N DEF. & CORP. COUNSEL Q. 263, 266–70 (2005). Brown and Hepler distinguish three categories of state consumer fraud statutes: 1) those based on the Uniform Deceptive Trade Practices Act or Uniform Consumer Sales Practices Act; 2) those based on "consumer fraud" acts; and 3) those based on the FTC Act.

39. *See* EPSTEIN, CASES AND MATERIALS ON TORTS 1195–96 (9th ed. 2008).

40. Brown & Hepler, *supra* note 38, at 264–65. Brown and Helper characterize the major differences among state consumer fraud statutes as follows:

also provide some version of a safe harbor for claims stemming from alleged violations of laws administered by the FTC[41] or another regulatory body.[42]

The misleading or false claims against the drug manufacturer could be directed either at the drug's risk profile (safety claims) or else the drug's performance (efficacy claims).[43] Drug advertising claims raise two related theories of damage: (1) the "price inflation" theory, which posits that consumers overpaid for a particular drug whose price was inflated as a result of misleading or false claims; and (2) the "product substitution" theory, which likewise claims that consumers overpaid for a particular drug, but in this instance because, absent the misleading or false claim, they would have purchased another (lower priced) drug that was equally (or more) efficacious. Each theory is based on the premise that the consumer paid more for the drug than was warranted on account of the drug manufacturer's false or misleading claims.[44]

Price inflation theories have thus far gained little traction in court.[45] Several commentators, moreover, argue against recovery in

> (a) whether the statutes permit a private cause of action; (b) whether causation or injury is a required element; (c) whether reliance is a required element; (d) whether and to what extent intent constitutes a required element; and (e) the remedies available and the standards for making such awards, including attorney's fees.

Id. at 270.

41. *See, e.g.*, Prohias v. Pfizer, Inc., 490 F. Supp. 2d 1228, 1233–34 (S.D. Fla. 2007).

42. *See, e.g.*, Bober v. Glaxo Wellcome PLC, 246 F.3d 934 (7th Cir. 2001).

43. *See, e.g.*, *Prohias*, 490 F. Supp. 2d at 1228 (raising allegations that drug manufacturer marketed Lipitor for conditions not yet approved by the FDA); Scott v. GlaxoSmithKline Consumer Healthcare, L.P., 2006 WL 952032 (N.D. Ill. 2006) (raising allegations that drug manufacturer overstated speed and efficacy of drug); New Jersey Citizen Action v. Schering-Plough Corp., 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003) (raising allegations that benefits of drug were overstated with promise of a "normal nearly symptom-free life").

44. Courts and commentators frequently invoke the analogy to the price inflation theory in the securities fraud context. The analogy is imperfect, however, to the extent that drug prices are fixed by drug companies based upon government-granted monopoly rights, whereas stock prices are set by the market and generally sensitive to changes in information. *See, e.g.*, Prohias v. Pfizer, Inc., 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) ("[Plaintiffs] depend on the faulty premise that the price of Lipitor fluctuates based on the public's knowledge of Lipitor's benefits, even though drug prices (unlike stock prices which are necessarily set by the price at which buyers are willing to buy, or sellers [are] willing to sell) are fixed by the product's manufacturer.").

45. *See, e.g.*, *id.* at 1336–37 ("[S]uch damages are too speculative to constitute an injury-in-fact under Article III." . . . [T]o show any damages under the 'price inflation' theory (assuming the price did incorporate information about Lipitor's benefits), would require evidence of the hypothetical price at which Lipitor would sell if not for the allegedly misleading advertisements."); *see also New Jersey Citizen Action*, 842 A.2d 174.

pure economic loss cases, so as to preserve damages "to compensate real victims, that is, consumers who have actually been harmed."[46]

Product substitution theories, by contrast, offer a glimmer of hope. Comparative safety and efficacy claims lend themselves to the product substitution theory of damages.[47] Courts have found this theory more promising, in part because "[t]o show injury, the parties need not speculate as to the price of the good at issue in a different world, but rather can simply look to the price of the substitute good."[48]

II. FDA'S REGULATORY REVIEW OF ADVERTISING

The FDA has the authority to regulate the realm of prescription drugs. So, what precisely, is the federal policy (if any) governing prescription drug advertising?

A. FDA Authority: Advertising Regulations and Guidelines

The FDA's authority to regulate advertising is related to its authority to approve prescription drugs for safety and efficacy. In the Federal Food, Drug, and Cosmetics Act ("FDCA"), Congress charged the United States Secretary of Health and Human Services ("HHS") with regulating drugs marketed in the United States, including the approval, labeling, and promotion of those drugs.[49] The Secretary has delegated that authority to the FDA.[50] Congress granted regulatory jurisdiction of prescription drug advertising to the FDA in 1962, displacing the FTC's prior jurisdiction.[51]

46. *See, e.g.*, Moin A. Yahya, *Can I Sue Without Being Injured?: Why the Benefit of the Bargain Theory for Product Liability Is Bad Law and Bad Economics*, 3 GEO. J.L. & PUB. POL'Y 83, 113–14 (2002) ("It can be argued, against the 'benefit of the bargain' plaintiff, that the difference between the value represented and the value received contains an insurance premium reserved for actual injuries and that this premium would be unjustly usurped by the no-injury plaintiff if his or her suit was successful.").

47. *See, e.g.*, *In re* Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230 (E.D.N.Y. 2007) (denying drug manufacturer's motion for summary judgment in a case where plaintiffs alleged that Eli Lilly marketed Zyprexa as safer and more efficacious than other available drugs, finding that the economic analysis required to determine damages might be sophisticated, but such challenges did not preclude recovery).

48. *Prohias*, 485 F. Supp.2d at 1338 n.3.

49. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–321 (2006).

50. 21 C.F.R. § 5.10(a)(1) (1999).

51. Food, Drug and Cosmetic Act Amendments of 1962, § 502, 21 U.S.C. § 352(n) (2006). Subsection (n) reads:

> [N]o advertisement of a prescription drug, published after the effective date of

Under the FDCA's regulatory regime, drugs are "misbranded" if pharmaceutical companies do not comply with the Act's advertising requirements.[52] Section 502(n) of the FDCA sets forth three required components for all prescription drug advertisements: (1) the established (organic) drug name;[53] (2) the formula showing each ingredient;[54] and (3) a "brief summary relating to side effects, contraindications, and effectiveness."[55] A 1969 FDA regulation required advertisements to present a "fair balance" between information regarding side effects and information regarding the effectiveness of the drug.[56] The FDCA's advertising requirements apply to promotional materials that identify prescription drugs by name published in journals, magazines, newspapers, other periodicals, and the Internet or broadcast via radio, television, or telephone.[57]

In the 1980s, the FDA examined the desirability of DTCA.[58] The FDA proposed a voluntary moratorium in 1983 but in 1985 concluded that the regulations "provide[d] 'sufficient safeguards to protect consumers.'"[59] A 1985 directive required advertisements to

> regulations issued under [the] paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections [12 through 17 of the Federal Trade Commission Act].

Id. (citing 15 U.S.C. §§ 52–57 (2006)). The 1962 Amendments (Kefauver-Harris) expanded the FDA's authority over prescription drugs to ensure that drugs are not only "safe" but also "effective" prior to marketing. The FTC has had jurisdiction over drug advertisements since 1938, under the Wheeler Lea Act. The FTC retains jurisdiction over advertisements promoting over-the-counter drugs, as well as "help seeking" advertisements that publicize the symptoms of a disease or condition but do not identify drugs by name. *See* GAO 2006 REPORT, *supra* note 14, at 2 n.4.

52. 21 U.S.C. § 352(a), (n) (2006). Specific regulations spell out what constitutes a false or misleading advertisement. 21 C.F.R. § 202.1(e)(6) (2007). Misbranded drugs are subject to seizure in enforcement proceedings. *See* 21 U.S.C. §§ 332, 334, 337. There is no private right of action under the FDCA. *Id.* § 337(a).

53. *Id.* § 352(n)(1).

54. *Id*. § 352(n)(2).

55. *Id.* § 352(n)(3). Subsequent FDA regulations further explicate the "brief summary" requirement, which differs across advertising media. *See* 21 C.F.R. § 202.1(e)(1)(2007).

56. 21 C.F.R. § 202.1(e)(5)(ii). In addition, drug manufacturers are prohibited from making unsupported comparison claims and presenting information that has been invalidated by subsequent studies. *Id.*

57. *Id.* § 202.1(l)(1).

58. *See e.g.*, INSTITUTE OF MEDICINE, *supra* note 19, at 160.

59. How DTC Evolved, http://www.fda.gov/cder/ddmac/Presentations/SocietyforWomensHealth/societyforwomenshealth2005novideo_files/frame.htm#slide0280.htm.

meet the same legal requirements as those directed to physicians.[60] The effect of these regulations was to preclude television advertising, as it was all but impossible to present a "fair balance" of side effects information within a sound bite television commercial.[61]

The unleashing of television advertisements was prompted in 1997 by the issuance of draft guidelines for broadcast activity.[62] Most significantly, the guidelines stated that the requirement to provide summary information on "side effects, contraindications, and effectiveness" could be met by directing consumers to one of four sources for additional information: a doctor, a toll-free number, a print advertisement, or a website.[63]

B. FDA Activity: Review and Enforcement

Drug manufacturers must submit prescription drug advertisements to the FDA concurrently with first publication or broadcast to the public.[64] FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") reviews advertisements for compliance with the FDCA and for possible enforcement action.[65] In 2002, DDMAC created a Direct to Consumer Review Group, which handles oversight of all DTCA.[66] FDA review is designed to make sure that information communicated to consumers is neither false nor misleading, presents a fair balance of the risks and benefits, reveals material facts, and discloses major side effects.[67]

Pre-publication review of advertisements is conducted on a limited basis.[68] Drug manufacturers may submit advertisements to

60. 56 Fed. Reg. 36,677 (Sept. 9, 1985).

61. The advertisements that did air were "help seeking" advertisements in which the companies described a condition and prompted viewers to visit their doctors and "reminder" advertisements, in which companies gave the name of the drug but did not explain its indication.

62. The final guidelines were issued in 1999. FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), *available at* http://www.fda.gov/cder/guidance/1804fnl.pdf.

63. *Id.*

64. 21 C.F.R. § 314.81(b)(3) (2007).

65. DDMAC is housed within FDA's Center for Drug Evaluation and Research. As of 2006, DDMAC had forty-one full time employees responsible for reviewing advertising directed both to consumers and to health care professionals. *See* GAO 2006 REPORT, *supra* note 14, at 10.

66. *See* GAO 2008 REPORT, *supra* note 12, at 5.

67. *See* GAO 2006 REPORT, *supra* note 14, at 9.

68. 21 C.F.R. creates a safe harbor in the limited circumstances when FDA requires drug manufacturers to submit advertisements prior to dissemination. 21 C.F.R. § 202.1(j)(4).

the DDMAC on a voluntary basis prior to release.[69] The FDA is committed to review proposed prescription drug advertisements when requested to do so by pharmaceutical companies.[70] The DDMAC may provide advisory comments for the drug manufacturer's consideration prior to dissemination of the advertisement.[71] The FDCA, however, prohibits the FDA from requiring pre-approval of advertisements, except in "extraordinary circumstances."[72]

The FDA issues regulatory letters to drug manufacturers, giving notice of violations.[73] Regulatory letters come in two varieties: (1) "warning letters," which carry the potential for subsequent enforcement action should the drug manufacturer not address the violation; and (2) "untitled letters," which do not have the accompanying enforcement sting.[74] The typical infractions noted in the letters include minimizing risks, exaggerating effectiveness, or both.[75] The DDMAC can request that a drug manufacturer cease using an offending advertisement; it can also request that the manufacturer issue a remedial advertisement to correct any misstatement.[76] Should a drug manufacturer fail to withdraw or correct an offending advertisement, the Department of Justice's Office of Consumer Litigation may, at the behest of the FDA, seize

69. *See id.* ("Any advertisement may be submitted to the [FDA] prior to publication for comment."). Industry group Pharmaceutical Research and Manufacturers of America (PhRMA) encourages member companies to submit television advertisements to the FDA prior to broadcast in order "to give the FDA the opportunity to comment, consistent with its priorities and resources." PHMRA, PHRMA GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES 8 (2005), *available at* http://www.phrma.org/files/DTCGuidingprinciples.pdf.

70. 21 C.F.R. § 202.1(j)(4).

71. *See* GAO 2006 REPORT, *supra* note 14, at 10.

72. 21 U.S.C. § 352(n)(A) (2006) ("[E]xcept in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement. . . ."). Qualifying "extraordinary circumstances" include potentially fatal drugs whose risks have not been widely disseminated in the medical literature, *see* 21 C.F.R. § 202.1(j), life-saving drugs approved under the FDA's accelerated approval process, *see id.* § 314.550; and drugs approved based on animal studies alone (where human efficacy studies are not feasible), *see id.* § 314.640.

73. *See* GAO 2008 REPORT, *supra* note 12, at 5.

74. *Id.*; *see also id.* at 5–6 ("Both types of letters cite the type of violation identified in the company's advertising material, request that the company submit a written response to FDA within 14 days, and request that the company take specific actions.").

75. The FDA posts letters on www.fda.gov/cder/ddmac/lawsregs.htm.

76. *See* GAO 2008 REPORT, *supra* note 12, at 6.

the "misbranded" drugs on account of their false or misleading advertising or issue an injunction against the manufacturer.[77] While there is no private right of action for individuals to enforce the FDCA,[78] private citizens (including consumers, competitors, etc.) may submit complaints or requests for investigations to the DDMAC.[79]

The FDA's capacity to police advertising regulations has weakened in recent years. First, the number of letters sent by the FDA to drug manufacturers regarding violations of drug advertisements decreased from 142 in 1997 to 21 in 2006.[80] Part of this precipitous decline has been attributed to the Secretary of HHS's decision in 2002 to require the FDA's Office of Chief Counsel to oversee all regulatory letters.[81] Second, the number of staff members dedicated to reviewing advertisements has not kept pace with the rising tide of spending on drug advertising.[82]

The FDA's seemingly lax regulation of prescription drug advertisements has come under sharp criticism. The Government Accountability Office has faulted the FDA for inadequate review of advertisements as well as for the low level and slow speed of its enforcement actions.[83] Calls for reform have reached the national

77. 21 U.S.C. §§ 332–34 (2006).

78. *Id.* § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this [Act] shall be by and in the name of the United States.").

79. *See* GAO 2006 REPORT, *supra* note 14, at 10–12.

80. Donohue et al., *supra* note 13, at 676.

81. A GAO Report found that this oversight contributed to a decline in the number of letters written—from 68 in 2001 to 28 in 2002. *See* GAO 2006 REPORT, *supra* note 14, at 12; *see also* GAO 2008 REPORT, *supra* note 12, at 3 ("After the policy change, FDA issued about half as many regulatory letters that cited violative DTC advertisements per year—between 8 and 11 letters annually from 2002 through 2005, compared with 15 to 25 letters annually from 1997 through 2001. FDA issued 4 such letters in 2006 and 2 in 2007.").

82. In 2002, the DDMAC created the "DTC Review Group" to oversee advertising materials directed to consumers. *See supra* text accompanying note 66. But staffing has not kept pace with the surge in DTCA. For example, during the time period from 2002–2004, spending on advertisements increased by 45 percent, whereas the number of FDA staff members dedicated to reviewing advertisements increased only from 3 to 4. *See* Julie Schmit, *Drug Ads to Get More FDA Scrutiny*, USA TODAY, Feb. 25, 2008 at 1B, *available at* http://www.usatoday.com/money/industries/health/drugs/2008-02-24-drug-ads_N.htm.

As of May 2008, the DTC Review Group consisted of two group leaders, seven reviewers and two social scientists dedicated to policing DTCA. *See* 2008 GAO REPORT, *supra* note 12, at 5. In 2007, the FDA received 12,616 advertisements to review. *See* Schmit, *supra*, at 1B.

83. Only a "small portion" of drug advertisements are reviewed. GAO 2008 REPORT, *supra* note 12, at 6. Moreover, the GAO noted that the FDA often did not weigh in on the misleading

agenda. In his proposed 2009 budget, President Bush called for $14 million from fees to fund twenty-seven FDA positions devoted to the consumer-advertisement review program.[84]

III. PREEMPTION ANALYSIS

Before analyzing the case for preemption of consumer fraud claims based upon false or misleading drug advertisements, it is worth situating this issue within the broader context of federal preemption of state tort claims involving FDA-approved medical devices and pharmaceutical drugs. At the outset, it is worth highlighting that there is a salient difference between preemption in the realms of medical devices and pharmaceuticals. The Medical Devices Amendment to the FDCA contains an express preemption clause,[85] whereas the provisions governing pharmaceuticals do not. In fact, the drug provisions include a qualified "savings" clause.[86]

nature of the advertisement until the advertisement campaign had already run its course. *See* GAO 2006 REPORT, *supra* note 14, at 27 (finding that more than half of the advertising materials cited in regulatory letters were no longer in circulation by the time DDMAC's letters were issued). In other instances, even after receiving the FDA's regulatory letter, drug manufacturers continued to disseminate violative advertisements. *See* GAO 2008 REPORT, *supra* note 12, at 14 ("From 1997 through 2005, FDA issued regulatory letters for violative DTC materials used to promote 89 different drugs. Of these 89 drugs, 25 had DTC materials that FDA cited in more than one regulatory letter, and one drug had DTC materials cited in eight regulatory letters.").

84. U.S. Dept. of Health & Human Services, Budget In Brief: Fiscal Year 2009, 16 (2008), *available at* http://www.hhs.gov/budget/docbudget.htm.

Funding the program with user fees, as opposed to direct congressional appropriations, is a controversial feature. The user fee program was established by the FDA Amendments Act in September 2007, but was not implemented within the statute's required timeline. *See* FDA Budget Summary, FY 2009 Congressional Justifications, Other Legislative Items (Jan. 30, 2008), *available at* http://www.fda.gov/oc/oms/ofm/budget/2009/Execsum/9_Other_Leg_Items.pdf.

User fees were vociferously opposed by Representative Rosa DeLauro (D-Conn), who chairs a subcommittee overseeing FDA funds: "I believe Congress should provide a direct appropriation in order to minimize industry influence in the FDA." Schmit, *supra* note 82, at 1B (quoting Representative DeLauro); *see also* Press Release, *Restoring the Gold Standard at the FDA* (expressing desire for "a strong funding proposal for the FDA"), *available at* http://www.house.gov/delauro/press/2008/January/Gold_FDA_1_29_08.html.

Congress ultimately refused to authorize the base funding required to launch the program in the Consolidated Appropriations Act of 2008. 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) (withdrawing notice set forth in 72 Fed. Reg. 70334 establishing user fee rates for program for FY 2008).

85. *See* 21 U.S.C. § 360k(a)(1) (2006).

86. Harris-Kefauver Act § 202, 76 Stat. 780, 793 (1962) ("Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a *direct and positive conflict* between such amendments and such provision of State law." (emphasis added)). Despite the existence of the savings clause, federal law may still preempt state law claims when the federal requirements "conflict" with state

Arguments in favor of preemption in the pharmaceutical context, then, must be based on *implied* as opposed to express preemption. In deciding implied preemption, courts look beyond statutory provisions specifically addressing preemption to consider the entire statutory scheme, including its regulatory purposes.[87] Implied preemption comes in two varieties. "Field preemption" occurs where the federal government has regulated an area so comprehensively that the federal interest occupies, and thus dominates, an entire subject matter, leaving no room for competing state regulation. "Conflict preemption" occurs where the federal interest conflicts with underlying state law, either in the narrow sense that an actor would find it impossible to comply with both commands, or, in the broader sense, that compliance with the state law command would pose an obstacle to, or frustrate, federal regulatory purposes and objectives.[88]

A. Field Preemption

I have argued elsewhere that implied field preemption arguments should be taken off the table in the context of failure-to-warn claims stemming from drug labeling.[89] As an initial matter, the field preemption argument may be a nonstarter in light of the statutory provisions—namely, the inclusion of a qualified savings clause, which would seem to require narrower conflict preemption.[90] Moreover, in enacting the drug provisions, Congress's full attention was devoted to specifying regulatory requirements; in the 1962 amendments, Congress neither provided a federal private right of action nor addressed remedies for consumers injured by dangerous drugs with inadequate warnings.[91] Although the existence of such a complete "remedial void" should not lead inevitably to an anti-preemption position, it should nonetheless take arguments for implied *field* preemption off the table. And in the drug labeling

requirements. In other words, implied conflict preemption—arguably including both the narrower "impossibility" variety as well as the broader "obstacle" or "frustration of purposes" variety—retains its vitality in the realm of pharmaceuticals. *See infra* text accompanying notes 88, 110–11.

87. *See* Sharkey, *Products Liability Preemption*, *supra* note 6, at 455.

88. *See id.* at 456 n.21.

89. *See id.* at 503–504.

90. *See supra* note 86.

91. *See* Sharkey, *Products Liability Preemption*, *supra* note 6, at 503.

context, field preemption arguments are few and far between.[92] Therefore, it is all the more surprising to see these arguments surface—let alone succeed—in the drug advertising context.

For example, the United States, on behalf of the FDA, intervened at the California federal district court's request in *In re Paxil Litigation*,[93] a case involving consumer fraud claims stemming from the alleged misleading advertisements of Paxil, one of a class of pharmaceuticals known as SSRIs (selective serotonin re-uptake inhibitors). In a somewhat remarkable amicus brief, the government argued that the FDA's administration of the comprehensive statutory and regulatory scheme governing prescription drug advertising in essence preempted the field, displacing state-law consumer fraud claims.[94] In the alternative, the government urged that "given the intent of Congress to centralize prescription drug advertisement regulation in the FDA, [the] Court should defer to the agency's primary jurisdiction."[95] In making its claims, the government painted a picture of a highly concentrated and highly regulated drug advertising review process:

> Congress clearly intended the FDA to regulate prescription drug marketing. The law gives FDA the authority to review

92. Several academic commentators, nonetheless, continue to clamor for field preemption, arguing its desirability "[b]y virtue of the specificity and comprehensiveness of the [FDCA's] regulation of prescription drugs." David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 414–16 (1996); *see also* Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. COLLOQUY 54 (2008), *available at* http://www.law.northwestern.edu/lawreview/colloquy/2008/29.

93. No. CV 01-07937, 2002 WL 31375497, at *1 (C.D. Cal. 2002).

94. Brief of the United States of America at 10, *In re* Paxil Litig., No. CV 01-07937 MRP, 218 F.R.D. 242, 2001 WL 34883537 (C.D. Cal. 2001). The facts in *In re Paxil* supported a much narrower implied conflict argument. At the time the FDA approved the new drug application for Paxil, the agency found no clinical evidence that it was habit-forming. *Id.* at 4. The FDA reviewed Paxil advertisements on five separate occasions between 2001 and 2002; four versions of these advertisements contained the statement: Paxil is "non-habit forming." The FDA found none of these advertisements to be misleading. *Id.* The government's brief also raised implied conflict preemption: "In the present case, FDA reviewed the particular advertisement at issue and made suggestions as to the precise issue that is the subject of plaintiff's request for relief. Based on its scientific and medical expertise with this drug and other similar drugs, FDA decided that the advertisements are acceptable." *Id.* at 6. But clearly the government wanted to use the favorable fact scenario to press for a wider field preemption position.

95. *Id.* at 2; *see id.* at 7 ("If Plaintiffs are found to state a valid claim despite preemption analysis, the Court should exercise its discretion under the doctrine of primary jurisdiction and allow FDA to consider further, in light of Plaintiffs' arguments, whether the Paxil advertisement is misleading.").

> all published prescription drug advertisements and to bring enforcement actions against those who would attempt to mislead the public in any way. The FDCA and its implementing regulations set specific criteria by which the FDA is to judge such advertisements. . . . [T]he FDCA subjects the drug industry to a *comprehensive national regulatory scheme* in which FDA stands at the center.[96]

According to the government, the FDA is "responsible for answering scientific and policy questions in the national arena of prescription drug advertisements."[97] And, echoing its argument with respect to the need for uniformity in drug labeling, the government reasoned that

> [w]ere the courts of various jurisdictions to mandate what may and may not appear in prescription drug advertisements pursuant to state law, the public undoubtedly would receive inconsistent information from region to region; furthermore, court-imposed advertising content or restrictions would lack the benefit of FDA's scientific expertise and consideration of relevant policy issues.[98]

The federal district court was fairly harsh in rejecting the FDA's (and the manufacturer's) preemption claim, saying the "position contravenes common sense."[99]

The government's entrée (at the court's behest) into the drug advertising preemption row was also its finale. Given the steady stream of government intervention in drug labeling cases beginning in 2000 (and continuing to the present),[100] one might consider dismissing the government's view as aberrant or idiosyncratic. In fact, its amicus brief in *In re Paxil* had gone largely unnoticed (again, unlike its interventions in the drug labeling cases)—that is, until the

96. *Id.* at 8 (emphasis added).

97. *Id.* at 10.

98. *Id.* at 5.

99. *In re* Paxil Litig., No. CV 01-07937, 2002 WL 31375497, at *1 (C.D. Cal. 2002) ("FDA and [the drug manufacturer] invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state claims.").

100. *See* Sharkey, *Federalism in Action*, *supra* note 6, at 1037–38 (describing numerous instances in which the government filed amicus briefs in drug cases since 2000).

Court of Appeals for the Third Circuit heartily endorsed it in a recent decision.

In *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*,[101] the Third Circuit staked out a field preemption position that went well beyond what the defendant drug manufacturer had requested (and was unnecessary to resolve the case). In holding that a claim of false advertising, based upon an alleged unsupported comparison to another brand name drug, was preempted,[102] the court reasoned:

> Implied conflict preemption of state consumer fraud laws is required . . . because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. . . . The high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising.[103]

Note the affinity with the government's foundational premise in its *In re Paxil* briefing that the advertising regulations comprise a "comprehensive national regulatory scheme."[104] This view, moreover, has been echoed by some commentators.[105]

But the field preemption position is wholly misguided in the realm of drug advertising. To begin, the Supreme Court has been emphatic that:

> [t]o infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance

101. 499 F.3d 239 (3d Cir. 2007).

102. In *Zeneca*, the court affirmed the district court's decision to dismiss plaintiff's claims that the drug manufacturer engaged in false advertising of Nexium by making an unsupported comparison to Prilosec. *Id.* at 242.

103. *Id.* at 251–52 (citing 21 U.S.C. § 352(n) (2006); 21 C.F.R. § 314.81(b)(3) (2007)).

104. Brief of the United States of America at 8, *In re Paxil* Litig., No. CV 01-07937 MRP, 218 F.R.D. 242, 2001 WL 34883537 (C.D. Cal. 2001).

105. *See, e.g.*, William Dreier, *Liability for Drug Advertising, Warning, and Frauds*, 58 RUTGERS L. REV. 615, 629 (2006) ("The field of consumer prescription drug advertising has been substantially occupied by the FDA, and thus a claim of a separate state standard can be disposed of by a finding of federal preemption.").

embodied in our Supremacy Clause jurisprudence.[106]

It is also far-fetched to proclaim that the FDA administers a "comprehensive" regulatory scheme for prescription drug advertisements. The limited nature of the FDA's regulatory review of advertisements is detailed above in Part II.B. This more modest view, moreover, is shared by those within the agency. Thomas Abrams, director of the FDA's DDMAC, says the biggest misconception is that the DDMAC screens and approves all promotional items before they are released to the public.[107] While the FDA does provide comment on certain materials, most advertisements are launched without the agency reviewing them first.[108]

B. Conflict Preemption

Even where broader arguments for clearing the field—foreclosing state law causes of action simply because they arise in an area that is the domain of comprehensive federal regulatory law—fail, narrower claims for conflict preemption may hold forth. Implied conflict preemption remains controversial; indeed, the very definition elicits sharply divided opinion.[109] In its narrowest incarnation, an implied conflict arises when it would be "impossible" for a manufacturer (or other defendant) to abide by both the federal and state standards or regulations.[110] Moving out in concentric circles from this narrow core are "obstacle" preemption—whereby enforcement of the state law would obstruct the federal regulatory

106. Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 717–18 (1985).

107. Abrams elaborated as follows: "We get complaints from consumers and physicians who call us up and say, 'Tom, how can you allow that TV ad to be on?' . . . They're flabbergasted when we say, 'We didn't approve it before it went on TV.' Often, we're seeing it at the same time as the American public. DDMAC has limited resources and we use our limited resources as effectively as we can to do our job." Grant Winter, Inside DDMAC: A Conversation with Thomas Abrams, Dec. 1, 2005, http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=256550&pageID=1.

108. *Id.*; *see also* Robert A. Bell et al., *Direct-to-Consumer Prescription Drug Advertising and the Public*, 14 J. GEN. INTERN. MED. 651, 654 (1999) (finding that 50 percent of the public believed that the FDA required prior approval of all prescription drug advertisements).

109. *See, e.g.*, Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767 (1994); Ernest A. Young, *The Rehnquist Court's Two Federalisms*, 83 TEX. L. REV. 1 (2004).

110. *See, e.g.*, Geier v. American Honda Motor Co., Inc., 529 U.S. 861, 873 (2000) (describing one prong of the implied conflict preemption inquiry as looking at the entire statutory and regulatory framework to determine whether state laws "make it 'impossible' for private parties to comply with both state and federal law").

scheme—and the even more protean concept where the state law would "frustrate" the purposes of the federal regime.[111]

Once again, a close comparison with implied conflict arguments in the drug labeling context is warranted. First, there is a basic conceptual distinction between the realms of failure-to-warn claims relating to drug labeling and consumer fraud claims relating to drug advertising. The rationale for a failure-to-warn claim is ensuring safety. Typically, in order to prevail on such a claim, one must prove that a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced by the provision of reasonable instructions or warnings by the seller . . . and the omission of the instruction or warnings renders the product not reasonably safe."[112] The FDA's charge under the FDCA to determine whether prescription drugs are safe and efficacious overlaps (at least to a significant degree) with the rationale for failure-to-warn claims. Whereas the main purpose of drug labels is to ensure safety, drug advertising, by contrast, is aimed at promotion of the drug and increasing its market size.[113] While the FDA is charged with protecting against false and misleading advertisements, its purview is more limited than that of consumer fraud claims.

With this background distinction in mind, we can turn to a more concrete implied preemption analysis. In prior work, I have proposed disaggregating the FDA's "regulatory action" sphere from its "interpretive" sphere.[114] Applying this framework, we can profitably contrast the FDA's action and interpretation in the context of drug advertising from that in the drug labeling realm.

111. *See, e.g.*, Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (inquiring whether state laws "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). The U.S. Supreme Court, however, has resisted forging a "legal wedge-[as opposed to] only a terminological one-between 'conflicts' that prevent or frustrate the accomplishment of a federal objective and 'conflicts' that make it 'impossible' for private parties to comply with both state and federal law." *Geier*, 529 U.S. at 873.

112. RICHARD A. EPSTEIN, TORTS § 16.12.2 at 418 (1999).

113. Research shows a direct correlation between drug companies' expenditures on advertising and increased sales. *See, e.g.*, GAO 2006 REPORT, *supra* note 14, at 14 ("Studies have found that, for many drugs, DTC advertising increases sales of the drug itself, though the amount varies substantially.").

114. *See* Sharkey, *Products Liability Preemption*, *supra* note 6, at 478; Sharkey, *What* Riegel *Portends*, *supra* note 6, at 419–23.

1. Regulatory Action

Notwithstanding the rigor of the FDA's process for premarket approval of drugs and accompanying labeling,[115] preemption of failure-to-warn claims remains controversial. The courts are roughly evenly split on the question, and await guidance from the United States Supreme Court.[116] My own position—which I have elaborated upon elsewhere—is that the FDA's initial approval of a drug's labeling should not bestow a blanket immunity upon the manufacturer for any and all failure-to-warn claims stemming from risks associated with the approved drug.[117] Instead, a narrower class of claims should be preempted. This class should be comprised of those claims arising from the precise risks that were weighed by the FDA, either at the time of initial approval, or more typically in the case where a new risk has come to light after initial approval, and upon the FDA's considered inquiry into a weighing of the new attendant risks. Such claims, in essence, call for courts (and juries) to conduct a "redo" of a determination already made by the FDA. This framework could profitably be applied in the context of FDA review of advertising.

There is, however, a salient difference between the failure-to-warn claims and drug advertisements, given the generally more lax system of regulatory review pertaining to advertisements. In terms of regulatory action with respect to drug labeling, the FDA necessarily must make a definitive determination—at the very least, at the time the drug is approved—that the information on the drug label comports with safety and effectiveness.[118] By contrast, the FDA may choose not to take any action whatsoever with respect to a print advertisement submitted for the agency's review.[119] Advertisements, unlike drug labels, can run before any review is

115. For a detailed description of the FDA drug approval process, see Lars Noah, *Premarket Approval and Postmarket Surveillance*, *Pharmaceutical Products*, *in* LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 221–54 (2d ed. 2007).

116. *See* Wyeth v. Levine, 128 S. Ct. 1118 (No. 06-1249) (argued Nov. 3, 2008) (considering "[w]hether the prescription drug labeling judgments imposed on manufacturers by the [FDA] pursuant to FDA's comprehensive safety and efficacy authority under the [FDCA] preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use"), *available at* http://origin.www.supremecourtus.gov/qp/06-01249qp.pdf(link).

117. Sharkey, *Products Liability Preemption*, *supra* note 6, at 513–14.

118. *See* 21 U.S.C. § 355(d) (2006).

119. *See supra* Part II.B.

conducted; whereas drug labels are put through the rigorous premarket approval process. The bottom line is that in sharp contrast to the premarket approval process for drugs and labeling, which culminates in a finding that the drug is "safe for use under the conditions . . . suggested in the proposed labeling,"[120] the DDMAC does not acknowledge or even track advertisements that do not result in regulatory letters.[121]

For this reason, even in a case where failure-to-warn claims present a strong case for preemption, consumer fraud claims stemming from advertising may pale in comparison. In this regard, the analysis of the California federal district court in *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation* is spot on.[122] The court preempted the labeling claims, while refusing to preempt advertising claims.[123] The drug manufacturer (Pfizer) had submitted its challenged advertisements to the DDMAC; and, on the whole, the DDMAC did not object to them.[124] On this basis, Pfizer argued that the FDA "'necessarily determined'" that the unobjected-to advertisements are accurate and strike a fair balance between the benefits and risks of Celebrex; therefore, "any claim that such advertisements were deceptive conflicts with the FDA's determination to the contrary and are impliedly preempted."[125]

The court, however, rightly resisted reading the FDA's silence in this context as a determinative regulatory action.[126] The court was emphatic that "there is nothing in the record from which the Court could conclude that the FDA has actually reviewed all of the submitted advertisements, let alone conclude that the FDA's review

120. 21 U.S.C. § 355(d).

121. *See* GAO 2006 REPORT, *supra* note 14, at 20 ("[B]ecause FDA does not track information on its reviews, the agency cannot determine whether a particular material has been reviewed."); *id.* at 26 ("[B]ecause FDA does not document decisions made at the various stages of its review process about whether to pursue a violation, officials were unable to provide us with an estimate of the number of materials about which concerns were raised but the agency did not issue a letter.").

122. No. M:05-1699 CRB, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006).

123. *Id.* at *1.

124. *Id.* at *11.

125. *Id.*

126. *Id.* ("Pfizer cites no authority for its assertion that the FDA's silence as to a particular advertisement means that the FDA 'necessarily determined' that the advertisement was not deceptive . . . .").

means that it has definitively determined that the advertisement was not misleading."[127]

Therefore, the FDA's silence in the face of submitted advertisements cannot be read as a definitive regulatory action sufficient to preempt state law claims. There is no basis, in other words, for an argument that the state law claims would conflict with the federal regulatory scheme.[128]

It is a closer call where the record demonstrates that the FDA made some definitive determination. There may be a class of cases in which the consumer fraud claim attempts a redo of the FDA's regulatory review, and preemption might appropriately succeed in those circumstances. In that case, however, the court must scrutinize the precise regulatory determination by the FDA and then proceed to solicit the agency's interpretation of its regulatory process.

2. Interpretive Sphere

Reliance upon federal agencies in the interpretive sphere (as distinct from on the basis of their regulatory actions) is a largely uncharted area in terms of preemption doctrine. In deciding products liability preemption issues, the Supreme Court has been influenced by agency positions, but has not always been upfront about the degree to which the agency's view is dispositive.[129] Reliance upon federal agency interpretation at successive levels—issuance of regulations regarding preemptive scope, contemporaneous views interpreting regulatory action, and expressions of views in amicus briefs before courts—is contentious (and increasingly so, with the FDA's move away from official regulations toward less formal interpretive positions).[130]

Beginning in the early 2000s, the FDA has taken a fairly aggressive stance on preemption in the context of failure-to-warn

127. *Id.*

128. Consider in this regard the dissent's position in *Zeneca*. *See* Pennsylvania. Employees Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 258 (3d Cir. 2007) (Cowen, J., dissenting) ("Given that there are limitations to the FDA's oversight over prescription drug advertisements—both congressionally-imposed limitations, such as the lack of authority to require preapproval, and practical limitations attendant to the sheer volume of drug advertisements in the media—the supplementation of state-law remedies would seem to aid the FDCA's objectives and purposes, not frustrate them.") (citations omitted).

129. *See* Sharkey, *Products Liability Preemption*, *supra* note 6, at 471–72.

130. *Id.* at 479.

claims, by strategically intervening as amicus in cases in order to persuade courts to rule in favor of preemption.[131] In 2006, in order to consolidate and formalize its position, the FDA issued a preamble to a rule that specified the format and content of prescription drug labels.[132] In that preamble, the FDA made a controversial assertion that FDA approval of drugs should lead to preemption of some state law claims.[133] The preamble's focus is, by and large, on failure-to-warn claims. It alludes to advertising in passing and only when either omissions or inclusions in advertisements would be used to support a warnings claim.[134] For example, the preamble calls for preemption of a state law claim

> that a drug sponsor *breached an obligation to warn* by failing to include a statement in labeling *or in advertising*, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by the FDA at the time plaintiff claims the sponsor had an obligation to warn.[135]

In a similar vein, the FDA takes the position that print advertisements in compliance with draft guidelines for the DTCA should foreclose suits based upon allegations that the advertisement itself does not contain a warning arguably required by state law, so long as a suitable warning is contained in the brief summary.[136]

131. *Id.* at 504–05.

132. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006); *see also* Sharkey, *Preemption by Preamble*, *supra* note 6.

133. *See* 71 Fed. Reg. at 3934.

134. Each of the FDA's examples that reference advertisements refer to failure to warn claims that should be preempted: (i) a plaintiff claims failure to warn because a label or advertisement lacks a statement, but the statement is prohibited by FDA's labeling rules; (ii) a plaintiff claims failure to warn because a label or advertisement lacks a statement of contraindications or warnings which is not supported by the evidence according to standards of the labeling rule; (iii) a plaintiff claims failure to warn because a label or advertisement lacks a statement, but when the drug company proposed the statement to the FDA for inclusion, the FDA did not require it; (iv) a plaintiff claims failure to warn because an advertisement lacks information that appears in the drug label, but the drug sponsor has followed the FDA's draft guidance regarding direct-to-consumer print advertisements. *Id.* at 3936 (examples 5, 3, 4, 2). Example 6 further asserts preemption of claims alleging that drug sponsors "breached an obligation to plaintiff by making statements" the FDA has approved for use on product labeling. *Id*.

135. *Id.* at 3934.

136. *Id.* at 3936; *see also* FDA, *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (Feb. 2004), *available at* http://www.fda.gov/cder/guidance/5669dft.pdf.

In recent drug advertising cases raising consumer fraud allegations, the FDA has remained curiously silent. Courts thus far have read the silence as attesting to the FDA's lack of commitment to preempt consumer fraud claims: "The FDA has been silent with respect to the preemption of lawsuits challenging false claims in prescription drug advertisements. This silence suggests that the FDA does not intend its review of promotional materials to preempt false advertising claims."[137] The FDA's silence, though, is only one piece of the evidence of lack of conflict between state law consumer fraud claims and the federal scheme regulating drug advertising.

CONCLUSION

As preemption's frontier pushes out beyond state law products liability claims alleging dangerous and defective FDA-approved medical devices and drugs into the realm of consumer fraud claims based upon false or misleading drug advertisements, it is worth pausing to ask whether this move is an inevitable, logical extension. Does it further underlying rationales privileging the FDA's domain over the common law or does it represent a progression with surface appeal only, which cannot withstand probing scrutiny?

The crux of the preemption debate centers on whether the decision-maker adjudges the FDA's regulation a floor (or minimal) or ceiling (or optimal) standard—the former permitting complementary state actions; the latter foreclosing them as meddlesome substitutes. The FDA's advertisement review process appears to provide a (rather weak) floor rather than an optimal regulatory standard. On the whole, the FDA does not appear to be engaged in an exercise of optimization, weighing the costs and benefits of the DTCA. For this reason, it would be rare for pursuit of the state law tort action to be characterized as a "redo" of what the FDA has already determined. And thus, consumer fraud claims arising from drug advertisements should withstand preemption challenges.

137. *In re* Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. M: 05-1699 CRB, 2006 WL 2374742, at *11 (N.D. Cal. Aug. 16, 2006). The court concluded that "[w]hile this silence is not dispositive of conflict preemption, it is additional evidence of no actual conflict." *Id.*