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Federal Preemption in the Area of
Direct-to-Consumer (DTC) Advertising of Prescription Drugs

by

Carl J. Blicke (HLS '06)

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This paper is submitted in satisfaction of the course requirement.

Abstract:

FDA involvement in the policy space of direct-to-consumer (DTC) advertising of prescription drugs raises the question whether state-law based lawsuits based on such advertising are preempted. Congress and the Supreme Court have not provided helpful guidance. The FDA has recently taken an aggressive stance favoring preemption. The lower courts that have considered the issue in areas of (1) failure-to-warn claims, (2) fraud and false advertising claims, and (3) claims for specific relief. The lower courts have reached mixed results, though the majority seem to disfavor preemption. This paper argues that, for a variety of reasons, most state-law based claims founded on DTC advertising should be preempted under either “implied” preemption doctrine or as obstacles to the FDA’s program of encouraging optimal drug use.

1.

Introduction

Direct-to-consumer (DTC) advertising has become an important aspect of the prescription drug industry; in 2001, DTC advertising expenditures reached \$2.7 billion.¹ This has led to increased scrutiny of DTC advertising from many sources, including consumer advocacy groups, individual consumers, and academic commentators.² In addition, state courts and juries also have begun to scrutinize the practice as lawsuits asserting state law causes of action based upon DTC advertising have become more common. Since—and possibly in response to—this development, the Food and Drug Administration (FDA) has taken a more active role in addressing DTC advertising. The FDA’s higher visibility in this area raises an important question: does FDA’s posture or its recent related rulemaking activity preempt state-law causes of action based on DTC advertising? The lower courts have begun to rule on this question and have reached mixed results, although most cases hold that federal law administered by the FDA does not preempt state law

¹Carol Rados, *Truth in Advertising: Rx Drug Ads Come of Age*, FDA CONSUMER MAGAZINE at 1 (July-Aug. 2004).

²The transcripts of the FDA’s November 1 – 2, 2005, public meeting addressing the issue of DTC advertising contain an exhaustive amount of scrutiny of the practice. The transcripts from the November 1 and November 2 sessions are available at <http://www.fda.gov/cder/ddmac/dtc2005/transcript1.pdf> and <http://www.fda.gov/cder/ddmac/dtc2005/051102Transcript.pdf>, respectively.

causes of action. This paper argues that federal law should be interpreted to preempt most state law causes of action related to DTC advertising.

2.

The History and Regulation of DTC Advertising

a.

The Origins and Development of DTC Advertisements

DTC advertising of prescription drugs has its roots in the patient package insert (PPI) for prescription drugs, which first appeared in 1968.³ The purpose of the first PPI was to inform consumers about how to use the drug, but PPIs soon incorporated safety and efficacy information.⁴ Although the FDA originally mandated PPIs, this practice eventually met with resistance, and the FDA eventually transitioned to “a plan under which pharmaceutical companies would voluntarily make more information about their products available to consumers.”⁵ However, up until the late 1970s and early 1980s, drug companies were almost uniformly reluctant to *advertise* directly to consumers for fear of making doctors feel as though they were being left out of the treatment process.⁶

In the early 1980s, the tide turned and two manufacturers began using DTC advertising; this prompted FDA commissioner Arthur Hull Hayes, Jr., to address the topic at a speech before a drug industry organization.⁷

Hayes predicted “exponential growth” in DTC advertising; this was not intended as a show of FDA support,

³See Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 489 – 90 (1999). For a brief history of DTC advertising, see Daniel Richardson, *The Lost Child of Products Liability: New Thoughts About Advertising and the Learned Intermediary Doctrine*, 27 VT. L. REV. 1017, 1032 – 35 (2003).

⁴See Pines, *supra* note 3, at 490.

⁵See *id.*

⁶See *id.* at 491.

⁷See *id.* at 491 – 92.

but the industry interpreted it as such.⁸ In September 1982, the FDA called for a voluntary moratorium on DTC advertising, pending further study of its impact. In a notice published on September 9, 1985, the FDA finally ruled “that it had jurisdiction over DTC advertisements, and that all such advertisements must meet the same legal criteria as those directed at physicians.”⁹ According to Pines, this action was not intended as a full-scale foray into the regulation of DTC advertising—it was merely intended to establish FDA’s jurisdiction to regulate DTC advertising under “the existing rules and regulations that governed physician-directed advertising.”¹⁰ With the moratorium lifted, DTC advertising has escalated steadily to its present-day totals.¹¹

b.

The Regulation of DTC Advertising

Prescription drug advertisements were originally regulated by the Federal Trade Commission (FTC).¹² The 1938 Wheeler-Lea Act “expanded the FTC’s jurisdiction from policing ‘unfair methods of competition’ to include ‘unfair and deceptive acts or practices,’” which gave the FTC the power to protect consumers.¹³ Many states also enacted “little FTC Acts” to protect consumers against unfair trade practices.¹⁴ The Wheeler-Lea Act also gave the FTC jurisdiction over the advertising of prescription drugs.¹⁵ In 1971, pursuant to a Memorandum of Understanding between the two agencies, FTC transferred to FDA its responsibility for policing prescription drug advertising.¹⁶

⁸ See *id.* at 492.

⁹ See *id.* at 493.

¹⁰ See *id.*

¹¹ See *id.*

¹² See John Shaeffer, *Prescription Drug Advertising—Should States Regulate What is False and Misleading?*, 58 FOOD & DRUG L.J. 629, 630 (2003).

¹³ See *id.*

¹⁴ See *id.*

¹⁵ See *id.*

¹⁶ See *id.* at 631 – 32.

As mentioned above, in 1985, FDA formally asserted jurisdiction over DTC advertising and ruled “that all such advertisements must meet the same legal criteria as those directed at physicians.”¹⁷ FDA revisited the issue in 1995, when it held a public meeting “to help it evaluate what was happening in the marketplace and what further regulatory steps were needed.”¹⁸ After the 1997 departure of FDA Commissioner David A. Kessler—who one commentator characterizes as opposed to prescription drug advertising—FDA allowed drug companies to market specific products on television pursuant to a draft guidance statement.¹⁹ The final guidance document, published in August 1999, sets forth methods of fulfilling the requirement that firms using broadcast advertising make “adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation.”²⁰ Though the major focus of the guidance document was the “adequate provision” requirement, the document also indicates the other characteristics of permissible DTC advertising.²¹ Permissible DTC advertisements: (1) “[a]re not false or misleading in any respect,” (2) “[p]resent a fair balance of information about effectiveness and information about risk,” (3) “[i]nclude a thorough *major statement* conveying all of the product’s most important risk information in consumer-friendly language,” and (4) “[c]ommunicate all information relevant to the product’s indication (including limitations to use) in consumer-friendly language.”²²

The FDA’s program for evaluating DTC advertisements of prescription drugs conspicuously lacks any pre-clearance mechanism.²³ Companies can request FDA review of their draft advertisements, but this is not mandatory.²⁴ Though pre-clearance of advertisements is generally not mandatory, Congress has attempted

¹⁷See Pines, *supra* note 3, at 493.

¹⁸See *id.* at 496.

¹⁹See *id.* This draft guidance document ultimately became U.S. FOOD & DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), <http://www.fda.gov/cder/guidance/1804fnl.pdf> (last visited Jan. 24, 2006).

²⁰U.S. FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 1 (1999), <http://www.fda.gov/cder/guidance/1804fnl.pdf>.

²¹See *id.* at 2.

²²*Id.*

²³See, e.g., 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, 167 (2005).

²⁴See, e.g., *id.* at 167; Shaeffer, *supra* note 12, at 632 & n.20 (citing 21 U.S.C. § 352(n)(3)(a)) (suggesting that the lack of a pre-clearance mechanism reflects congressional concern with running afoul of the First Amendment). FDA only requires

“motivate drug companies to submit all proposed advertisements to the [FDA] before release to the general public.”²⁵ To this effect, FDA enacted a “safe harbor” procedure whereby prescription drug advertisements which are submitted to FDA prior to their release, and which are deemed to comply with FDA regulations, will not be subject to later action without notice to the advertiser and a reasonable opportunity for correction.²⁶

Ten years after the 1995 meeting that resulted in the aforementioned guidance document, the FDA revisited the issue. On November 1 – 2, 2005, the FDA held a hearing to receive public comment on DTC advertising.²⁷ The agency received comments from a broad range of sources, from individual consumers to drug industry trade groups, and expressing a broad range of feelings about the desirability of DTC advertising, from some who condemn it to others who defend it as a constitutional right.²⁸ This paper will not discuss the views of all those who submitted comments but will proceed to the fundamental question raised by the FDA’s recent involvement in the policy space of DTC advertising: to what extent, if any, does FDA’s involvement in this area preempt state regulation (either legislative or through the working of state tort law)?

pre-clearance of promotional materials if the prescription drug was approved on an accelerated basis. *See, e.g.*, Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-To-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 429 (2002).

²⁵*See* Shaeffer, *supra* note 12, at 632.

²⁶*See id.* at 633. This “safe harbor” was enacted at the behest of Congress. *See id.* at 632 & n.21.

²⁷*See supra* note 2 for the location of the transcripts of the meeting.

²⁸The views of commentators who did *not* participate in the meeting are also divided. Many have called for stricter regulation of DTC advertisements. *See, e.g.*, Lenhardt, *supra* note 23, at 168 (calling for FDA pre-clearance of DTC advertisements); Palumbo & Mullins, *supra* note 24, at 434 – 46 (describing proposed legislation aimed at DTC advertising); *id.* at 438 – 39 (describing some doctors’ resistance to DTC advertising). Substantially fewer commentators have called for less-stringent regulation of DTC advertising. One such criticism comes from Evans and Friede, who lament that “requiring manufacturers to include an exhaustive list of a product’s risks as well as its benefits, not only dilutes the force and increases the cost of truthful, promotional messages that manufacturers wish to carry but also hampers drug manufacturers’ ability to respond truthfully to attacks on their products.” *See* George W. Evans & Arnold I. Friede, *The Food and Drug Administration’s Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 410 (2003). Evans and Friede also question the permissibility under the First Amendment of regulating DTC advertisements, *see id.* at 416, and criticize the FDA’s requirement of contemporaneous submission of DTC advertisements because although compliance is technically voluntary, “it functions in practice as a mandatory requirement.” *See id.* at 424 & n.373 (arguing that the FDA recognizes that the voluntary DTC submission policy is “perceived [as a] requirement for manufacturers to obtain prior clearance from the agency for all prescription drug and biological DTC promotion”).

3.

Preemption

Preemption doctrine comprises four analytical categories.²⁹ The first is express preemption, in which Congress writes preemptory language in the text of the statute.³⁰ Then, there are three types of implied preemption. The first type of implied preemption is “field preemption,” where the federal regulation “occupie[s] the entire field, leaving no scope of this topical issue for states to regulate.”³¹ Second is “conflict preemption,” where “a federal agency such as FDA may find a conflict between the state activity and the federal agency programs.”³² In the final category of implied preemption, “the overlap between federal and state norms may be troublesome, and a court may preempt because the state norms act as obstacles to completion of the federal program.”³³

In this Section, I will review the positions taken by the major players in the preemption debate—Congress, the Supreme Court, and the FDA—in areas under the purview of the FDA. Where these positions do not explicitly relate to DTC advertising of prescription drugs, I will offer my own analysis on how best to do so. The next Section will review how these positions are reflected in recent lower-court decisions on whether preemption applies in cases involving DTC advertising of prescription drugs.

a.

Congress’ insights on preemption in areas under FDA purview.

²⁹ See James T. O’Reilly, *A State of Extinction: Does Food and Drug Administration of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 289 (2003).

³⁰ See *id.*

³¹ See *id.*

³² See *id.*

³³ See *id.*

Congress has not explicitly addressed the issue of preemption in the prescription drug context, let alone in the context of DTC advertising thereof. However, Congress has explicitly addressed preemption in several other areas under the FDA’s purview. Congress first addressed the relative powers of the FDA and the states in the Fair Packaging and Labeling Act of 1966,³⁴ which “specifically provided that States could not enforce different or less stringent laws with respect to disclosures of quantity on the label of any food, drugs, or cosmetic.”³⁵ Next, in 1976, Congress enacted the Medical Device Amendments (MDA) to the FDCA, which contained a preemption provision that did not preempt state laws outright, but “precluded States from enforcing any requirements ‘which were different from, or in addition to, any requirement’ of the MDA.”³⁶ Because this language differs from that found in statutes where Congress preempted all state regulation in a given area, the Supreme Court in *Medtronic, Inc. v. Lohr* concluded that Congress did not intend to preclude all state tort law in the areas covered by the MDA.³⁷ Finally, when Congress enacted the Food and Drug Administration Modernization Act of 1998 (FDAMA), it included language intended to harmonize state and federal law related to OTC drug labeling and packaging.³⁸ However, FDAMA also “expressed a clear intent that this harmonization language not preempt state product liability claims or false advertising claims unrelated to product safety.”³⁹ FDAMA does not mention harmonization related to prescription drugs, which supports the conclusion that Congress did not intend to *expressly* preempt state laws regulating prescription drug packaging, labeling, and advertising.⁴⁰

With these examples of explicit congressional preemption in mind, what principle can be discerned? As mentioned above, the FDCA does not contain any express preemption language applicable to prescription

³⁴Pub. L. No. 89-755, 80 Stat. 1296 (1966) (codified at 15 U.S.C. §§ 1451 et seq.).

³⁵See Shaeffer, *supra* note 12, at 634 (citing 15 U.S.C. § 1461).

³⁶See *id.* at 634 & n.43 – 44 (quoting 21 U.S.C. § 360k(a)).

³⁷See *id.* at 634 – 35 & n.46.

³⁸See *id.* at 635.

³⁹See *id.* at 636.

⁴⁰See *id.*

drugs.⁴¹ This would seem to undermine the argument for preemption by the FDCA in the prescription drug context.⁴² Congress knows how to preempt state law when it wants to do so—or so the argument goes.

On the other hand, there are underlying reasons why Congress’ non-preemption in other areas might support preemption in the prescription drug context. For instance, in the medical device context, there are reasons to doubt the comprehensiveness of the FDA’s review process, making state law a beneficial supplement to FDA enforcement. As Hall points out, most medical devices reach market without FDA reviewing their safety (because they are claimed by the manufacturer to be substantially equivalent to a device already on the market).⁴³ Conversely, FDA reviews the safety and efficacy of all new prescription drugs—thus, it may seem more “reasonable to substitute the FDA scrutiny for state tort law regulation with respect to the drug’s safety.”⁴⁴

However, it would be problematic to simply conclude, based on this consideration, that preemption should apply. The FDA’s review of DTC advertising is not nearly as rigorous as its review of prescription drug safety and efficacy. In fact, most prescription drug advertisements reach the market the same way most medical devices do—without pre-clearance. Moreover, while many claims based on DTC advertising may be inextricably linked to a drug’s safety and efficacy (e.g., failure-to-warn and fraud claims), there may be claims where the connection is more tenuous.⁴⁵ Based on the above, it is this author’s opinion that a clear congressional stance on preemption of DTC advertising cannot be discerned. Of course, this does not rule out the possibility of implied preemption.⁴⁶

⁴¹ See, e.g., Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 256 (2004).

⁴² See *id.* at 256 – 57.

⁴³ See *id.* at 257.

⁴⁴ See *id.*

⁴⁵ For example, consider that one of the major objections to DTC advertising is not that it puts consumers in danger, but simply that it stimulates unnecessary demand for prescription drugs, particularly high-cost, brand-name drugs. See, e.g., Pines, *supra* note 3, at 511. This is a broader policy consideration that, at first blush, does not appear squarely within the FDA’s safety-and-efficacy review. On the other hand, the FDA has asserted that it believes drugs have an optimal level of use. See *infra* note 80 and accompanying text. If this is indeed true, then the FDA’s position toward a given drug may be influenced by what the agency considers to be the “optimal” demand for the drug.

⁴⁶ Cf. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 869, 120 S.Ct. 1913, 1919, 146 L.Ed.2d 914 (2000) (holding that, where an express preemption clause exists but does not cover state tort law, implied preemption still must be considered).

b.

The Supreme Court’s insights on preemption in areas under FDA purview.

The Supreme Court’s precedent on federal preemption in the areas of food and drug law also provides some insight on the preemption question in the DTC advertising context. The most important Supreme Court precedents on the question of whether the statutes administered by the FDA preempt state law are *Medtronic, Inc. v. Lohr*⁴⁷ and *Buckman Co. v. Plaintiffs’ Legal Committee*.⁴⁸

In *Medtronic*, the Court considered whether the Medical Device Amendments of 1976 preempted a common-law negligence action by a woman who was injured when her pacemaker failed.⁴⁹ The case addressed federal preemption under the MDA, not the FDCA,⁵⁰ so this summary will address only the considerations that would affect federal preemption of state laws related to prescription drugs.

The Court reasoned that its resolution of the preemption issue started with the text of the preemption provision but was “informed by two presumptions about the nature of pre-emption.”⁵¹ The first presumption is that “Congress does not cavalierly pre-empt state-law causes of action,” particularly in the areas of health and safety, given “the historic primacy of state regulation” in these areas.⁵² Second, the purpose of Congress—as discerned from the text of the statute, the statutory framework, the structure and purpose of the statute as a whole, and the intended effects of the statute on “business, consumers, and the law”—should guide the preemption inquiry.⁵³

⁴⁷518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

⁴⁸531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001).

⁴⁹See *Medtronic*, 518 U.S. at 474.

⁵⁰See *id.*

⁵¹See *id.* at 484 – 85.

⁵²See *id.* at 485. Coronato and Lanza date this presumption to *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 715, 718 (1985). See Wilfred P. Coronato & Stephen Lanza, *The Fracture That Will Not Heal: The Landscape of Federal Preemption in the Fields of Medical Devices, Prescription and Over-The-Counter Drugs Ten Years After Medtronic, Inc. v. Lohr*, ALI-ABA COURSE OF STUDY, PRODUCTS LIABILITY: PHARMACEUTICAL AND MEDICAL DEVICE ISSUES 365, 369 & n.19 (2005).

⁵³See *Medtronic*, 518 U.S. at 485 – 86.

The Court offered a number of indications of a congressional purpose not to preempt state law. First, the Court called it “implausible” that Congress intended to “bar[] most, if not all, relief for persons injured by defective medical devices” (because no private right of action was explicit or implied).⁵⁴ The Court found broad preemption implausible because the purpose of the MDA was to regulate more stringently an industry previously deficient in protecting health and safety.⁵⁵ Moreover, the Court found no indication in the legislative history that the MDA was intended to broadly preempt common-law actions; it found this absence significant, “particularly since Members of both Houses were acutely aware of ongoing product liability litigation.”⁵⁶ Finally, the Court opined that it could be sure it was effectuating Congress’ purpose by comparing the specificity of the relevant federal regulation to the specificity of the allegedly inconsistent state-law requirement.⁵⁷ Thus, specific state-law requirements that conflict with specific federal requirements are likely to be pre-empted.⁵⁸ On the other hand, “general obligations” under state law (such as a manufacturer’s general duty “to use due care to avoid foreseeable dangers in its products”) are unlikely to interfere with “generic concerns” expressed by the federal government in a given area.⁵⁹

Although it does not fall neatly into either of the two “presumptions” supposedly guiding the Court’s analysis, the Court also opined that its analysis was “substantially informed” by FDA regulations interpreting the scope of the preemption provision.⁶⁰

In *Buckman Co. v. Plaintiffs’ Legal Committee*, the Supreme Court revisited the question of when statutes

⁵⁴ See *id.* at 487.

⁵⁵ See *id.* at 487.

⁵⁶ See *id.* at 491.

⁵⁷ See *id.* at 500 – 501.

⁵⁸ See *id.* at 501.

⁵⁹ The Court contrasted these “generic concerns” with laws or regulations where the federal government “weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate.” See *id.* at 501.

⁶⁰ See *id.* at 495.

administered by the FDA should preempt state law.⁶¹ The case involved state-law causes of action asserting that a medical device manufacturer “made fraudulent representations to the FDA as to the intended use of the [devices] and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs’ detriment.”⁶² The Court began its analysis by noting that “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied,’ such as to warrant a presumption against finding federal pre-emption of a state-law cause of action.”⁶³ The Court held that preemption applied so as not to upset the “balance of statutory objectives.”⁶⁴ The Court described the § 510(k) premarket notification scheme for medical devices substantially equivalent to a predicate device as “comprehensive,” even though it lacks the “rigor” of premarket approval, because it imposes “a variety of requirements” with “various provisions aimed at detecting, deterring, and punishing false statements made during this and related approval processes.”⁶⁵ The Court was concerned that facing fifty states’ tort regimes would unduly burden those going through the FDA premarket notification process and opined that “[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistent with the Administration’s judgment and objectives.”⁶⁶ Importantly, the Court held that preemption applied even though “Congress included an express preemption provision in the MDA.”⁶⁷ Referring to its opinion in *Geier v. American Honda Motor Co.*, the Court reiterated that “neither an express pre-emption provision nor a savings clause “bar[s] the ordinary working of conflict pre-emption principles.”⁶⁸

What general principle can be discerned from these two recent Supreme Court cases on preemption under the MDA? Perhaps none. Some commentators believed that *Buckman* “would herald the expansion of the

⁶¹ See 531 U.S. 341, 343, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001).

⁶² See *id.* at 347.

⁶³ *Id.* at 347 (internal citation omitted) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

⁶⁴ See *id.* at 348.

⁶⁵ See *id.* at 348 – 49.

⁶⁶ See *id.* at 350.

⁶⁷ See *id.* at 352.

⁶⁸ See *id.* (citing *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000)).

implied preemption doctrine.”⁶⁹ However, this has not proven to be true. The lack of guiding principles is perhaps reflected in the diversity of holdings in the lower courts, with some courts finding preemption while others essentially limit *Buckman* to its facts.⁷⁰ As a result, some have characterized the Supreme Court’s pronouncements on preemption in this area as confusing.⁷¹ The caselaw seems to reflect a patchwork of considerations rather than a guiding principle, even if congressional intent is ostensibly guiding the inquiry.

c.

The FDA’s stance on preemption

Of the three actors considered in this Section, the FDA currently has the clearest stance on preemption in the prescription-drug area. Before 2002, FDA “remained aloof from preemption arguments that often had been made by prescription drug manufacturers.”⁷² In recent years, however, FDA has started openly to espouse the view that the FDCA preempts state law in the area of prescription drug regulation. Some have argued that the George W. Bush administration is pushing for preemption of state tort-law suits related to prescription drugs and medical devices.⁷³ Whatever the impetus, the FDA’s preemption stance has been

⁶⁹ See Coronato & Lanza, *supra* note 52, at 380 (citing W. Kennedy Simpson, *Recent Developments in Products, General Liability, and Consumer Law*, 37 TORT & INS. L.J. 621, 644 (2002)).

⁷⁰ For example, these courts have held that, while *Buckman* preempts “fraud on the FDA” claims, it does not extend to claims of fraud on the general public, physicians, corporate healthcare providers, or others. See James M. Beck et al., *Recent Developments in Products, General Liability, and Consumer Law*, 39 TORT TRIAL & INS. PRAC. L.J. 629, 640 & n.104 (2004) (citing *Gilleon v. Medtronic USA, Inc.*, Nos. C01-20460 RMW, C01- 20497 RMW, C01-20693 RMW, 2002 WL 31300694, at *6 (N.D. Cal. Aug. 28, 2002); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802, 809-10 (W.D. Va. 2002); *Bryant v. Hoffmann-LaRoche, Inc.*, 585 S.E.2d 723, 725 (Ga. Ct. App. 2003)); see also William A. Dreier, *Direct-to-Consumer Advertising Liability Revisited*, ALI-ABA COURSE OF STUDY, PRODUCTS LIABILITY: PHARMACEUTICAL AND MEDICAL DEVICE ISSUES 25 (2005) (The version of this source available on the WestLaw database is, unfortunately, not paginated.). Dreier qualifies that the claim must not be “transparently an allegation of fraud on the FDA.” See *id.* (citing *Bouchard v. Am. Home Prods.*, 213 F.Supp.2d 802 (N.D. Ohio 2002)).

⁷¹ See Coronato & Lanza, *supra* note 52, at 380.

⁷² See O’Reilly, *supra* note 29, at 288 & n.12 (citing *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 139, 475 N.E.2d 65, 70 (1985)). *But cf.* Reni Gertner, *FDA Drug Rule Asserts Federal Preemption: Plaintiffs’ Lawyers Prepare for Battle*, LAWYERS WEEKLY USA, February 13, 2006, at 23 (stating that the January 24, 2006, prescription drug labeling rule itself “states that the agency has made similar preemption statements in rules since 1982, including those related to aspirin labeling, over-the-counter drug packaging and drug warnings about pregnancy and nursing”).

⁷³ See Hall, *supra* note 41, at 259 & n.325 (citing Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at 1); see also Gertner, *supra* note 72, at 23.

seen in two areas: (1) in *amicus curae* briefs in cases where drug manufacturers assert preemption arguments and (2) in regulations.

The first case where FDA submitted an *amicus curae* brief in support of preemption in the prescription drug area was in *Motus v. Pfizer Inc.*⁷⁴ In *Motus*, the wife of a man who committed suicide while taking Pfizer's prescription drug Zoloft sued for failure to warn her husband of the drug's side effects.⁷⁵ Pfizer defended that conflict preemption doctrine barred the claim because the FDA had "already considered and rejected the inclusion of such a warning in Zoloft's labeling."⁷⁶ The district court rejected the preemption defense.⁷⁷ On appeal, the FDA's *amicus* brief presented two reasons why preemption should apply. First, the FDA argued that preemption should apply when a manufacturer is faced with a choice "either to avoid tort liability or comply with the FDCA."⁷⁸ This would be the case, argued the FDA, if a state were to require a warning that had been considered and rejected by the agency.⁷⁹ Second, the FDA argued that preemption should apply to avoid "obstruct[ing] the purposes and objectives of federal law" by altering the balance struck by FDA regarding the "optimal use" of the drug; the additional warning that would have been required to comply with state tort law would have over-deterred use of the drug by imposing an artificially strong warning.⁸⁰

The FDA has also openly espoused the position that the FDA preempts state law causes of action in recent

⁷⁴ See O'Reilly, *supra* note 29, at 288 & n.11 – 12; *Amicus Brief for United States in Support of the Defendant-Appellee and Cross-Appellant, Motus v. Pfizer Inc.*, (2002) Nos. 02-55372, 02-55498, 2002 WL 32303084. It appears that the Ninth Circuit did not accept the preemption argument because the case was eventually decided on the merits. See *Motus v. Pfizer Inc.*, 196 F.Supp.2d 984 (C.D. Cal. 2001), *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004). The FDA also supported preemption on behalf of a drug manufacturer in *In re Paxil Litig.*, No. CV 01-07937 MRP, 2002 WL 31375497 (C.D. Cal. Oct. 18, 2002). See *infra* notes 127 – 130 and accompanying text.

⁷⁵ See *Motus*, 127 F.Supp.2d at 1086 – 87.

⁷⁶ See *id.* at 1087.

⁷⁷ See *id.* at 1096 (no conflict preemption), 1099 (no frustration of congressional purpose).

⁷⁸ *Amicus Brief for United States in Support of the Defendant-Appellee and Cross-Appellant, Motus v. Pfizer Inc.*, 2002 WL at *12.

⁷⁹ See *id.* at *12 – *13.

⁸⁰ See *id.* at *14 – *15; see also *id.* at *23 ("Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects.").

regulations. On January 18, 2006, the agency announced a final rule regarding the format of the physician package insert for prescription drugs.⁸¹ The new rule introduces new Highlights and Table of Contents sections aimed at improving consumer understanding of drug benefits and risks.⁸²

The new format appears to give the manufacturer some discretion in the presentation of risk-and-benefit information; this aspect had troubled many of the parties who submitted comments on the proposed rule because of its implications for product liability litigation. Thus, some comments on the proposed rule expressed concern that manufacturers who highlighted some information to the exclusion of other information would be “more vulnerable to product liability claims.”⁸³ In a similar vein, other comments “requested that the agency state in the final rule that FDA approval of labeling, whether it be in the old or new format, preempts conflicting or contrary State law, regulations, or decisions of a court of law for purposes of product liability litigation.”⁸⁴ The FDA responded that it “believes” that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.”⁸⁵ The agency elaborated that it considers this “the government’s long standing views on preemption.”⁸⁶

Further elaborating its stance on preemption, the agency criticized some state courts for holding “that FDA labeling requirements represent a minimum safety standard” above which states are free to require additional information.⁸⁷ The FDA corrected that it “interprets the act to establish both a ‘floor’ and a ‘ceiling’ . . .”

⁸¹See U.S. FOOD AND DRUG ADMINISTRATION, FDA ANNOUNCES NEW PRESCRIPTION DRUG INFORMATION FORMAT TO IMPROVE PATIENT SAFETY, <http://www.fda.gov/bbs/topics/news/2005/NEW01272.html> (last visited Jan. 24, 2006). The new rule was published in the Federal Register on January 24, 2006. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

⁸²See U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 81.

⁸³See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3933 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

⁸⁴See *id.* at 3933 – 34

⁸⁵See *id.* at 3934.

⁸⁶See *id.* But see *supra* note 72.

⁸⁷See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

because “additional disclosures of risk information” could render labeling false and misleading as well.⁸⁸ The agency believes that “[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.”⁸⁹ The agency also noted the litigation briefs submitted by the Justice Department supporting implied federal preemption of state law causes of action in areas within the purview of FDA.⁹⁰ The agency then set forth a non-exhaustive list of the claims it believed would be preempted.⁹¹ Most relevant to the current discussion on DTC advertising are

claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug’s sponsor has used Highlights consistently with FDA draft guidance regarding the ‘brief summary’ in direct-to-consumer advertising. . . . claims 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 FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn). . . . [and] claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising.⁹²

To some, this represents a stronger stance than ever before; it may be telling that this rule immediately attracted the attention of the mainstream press.⁹³ Moreover, former FDA attorneys have expressed a belief that this stance would “provide broader protections to drug makers.”⁹⁴

The importance of the FDA’s stance is a nuanced issue. On the one hand, the Supreme Court’s decision in

⁸⁸ See *id.* at 3935.

⁸⁹ *Id.* at 3935.

⁹⁰ See *id.* at 3934, 3935 & n.8. The agency points out that the lack of an express preemption provision “does not bar the operation of ordinary principles of implied preemption.” *Id.* at 3935 n.8 (citing *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000)).

⁹¹ See *id.* at 3935 – 36.

⁹³ Both the New York Times and the Wall Street Journal carried articles mentioning the preemption language soon after announcement of the final rule. See Gardiner Harris, *New Drug Label Rule Is Intended to Reduce Medical Errors*, N.Y. TIMES, Jan. 19, 2006, at A14; Heather Won Tesoriero & Anna Wilde Mathews, *Decision on Pre-Emption May Change Plaintiff Lawyers’ Tactics*, WALL ST. J., Jan. 19, 2006, at D3.

⁹⁴ See Harris, *supra* note 93, at A14. Providing broader protection to drug makers is presumably why “[t]rial lawyers reacted angrily” to the preemption language as well. See *id.*

Medtronic seem to give deference to the agency’s stance on preemption.⁹⁵ On the other hand, the Supreme Court’s decision in *Sprietsma v. Mercury Marine* declines to give deference to the agency’s well-considered stance on preemption in situations where the agency has declined to regulate. Specifically, in *Sprietsma*, the Court held that “the Coast Guard’s decision not to adopt a regulation requiring propeller guards on motorboats” did not preempt, either expressly or impliedly, state-law claims based on the manufacturer’s failure to provide a propeller guard.⁹⁶ *Sprietsma* has led one commentator to conclude that, from now on, “there will be little if any implied preemption in situations where a regulatory agency has made a decision not to regulate, even if that decision was deliberate and was the product of intense prior study.”⁹⁷ Another commentator agrees: “When an agency with power to make rules does much less—[such as] simply submitting one appellate amicus brief [in support of preemption]—it has eschewed the platform from which deference can be asserted, and from which past FDA actions have won deference.”⁹⁸ However, if it chose to do more than merely submitting *amicus curiae* briefs, the FDA would risk running afoul of the First Amendment by unduly insinuating itself into DTC advertising. It is uncontroversial that FDA regulation or restriction of DTC prescription-drug advertising would be subject to First Amendment scrutiny.⁹⁹ Moreover, Congress has expressed concern about allowing restriction of DTC and thus rejected pre-clearance.¹⁰⁰ Thus,

⁹⁵ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 116 S.Ct. 2240, 2255, 135 L.Ed.2d 700 (1996) (“The FDA regulations interpreting the scope of [21 U.S.C.] § 360k’s pre-emptive effect support the Lohrs’ view, and our interpretation of the pre-emption statute is substantially informed by those regulations.”); see also *Coronato & Lanza*, *supra* note 52, at 384 – 85 & n.184 (citing *Hillsborough County*, 471 U.S. at 722); cf. also *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883, 120 S.Ct. 1913, 1926 (giving “some weight” to the Department of Transportation’s conclusion that conflict preemption should apply in the context of a statute implemented and administered by the agency).

⁹⁶ See *Sprietsma v. Mercury Marine*, 537 U.S. 51, 55 – 56, 123 S.Ct. 518, 527 – 28 (2002), cited in Beck et al., *supra* note 70, at 639.

⁹⁷ See Beck et al., *supra* note 70, at 640.

⁹⁸ O’Reilly, *supra* note 29, at 290 – 91 (internal citations omitted).

⁹⁹ See, e.g., Evans & Friede, *supra* note 28, at 366; cf. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002) (holding that truthful advertising of compounded drugs constitutes protected “commercial speech” under the First Amendment).

¹⁰⁰ See *supra* note 24 and sources cited therein. The policy of allowing manufacturers a voice in the debate seems sound because the speech of the other actors in the prescription drug market—even interested actors—is unregulated by the FDA. See Evans & Friede, *supra* note 28, at 427 (“[M]any unregulated messages reach the intended audience for DTC advertisements.”). As Evans and Friede point out, “Health Maintenance Organizations, Pharmacy Benefits Managers and even state Medicaid administrators pursue their own economic interests in affecting prescribing behavior. . . . Even the government has added its voice to the public health debate, launching a year-long DTC advertising campaign extolling the virtues of generic drugs.” See *id.* at 368.

one must recognize that any action taken by FDA will be taken in the shadow of invalidation under the First Amendment. For this reason, the FDA should be able to “win deference” in the eyes of the Court, without formally regulating the activity where it believes preemption applies (as was required by the Court in *Sprietsma*).¹⁰¹

4.

The Lower Courts’ Treatment of Preemption in the Prescription Drug and DTC Advertising
Context Since *Medtronic* and *Buckman*.

I will now examine cases that have addressed the question of whether preemption applies to certain claims based on DTC advertising. The lower courts have addressed (or inevitably will address) preemption in three distinct types of claims.

a.

Failure to Warn Claim Not Preempted: *Perez v. Wyeth Laboratories Inc.*

In *Perez v. Wyeth Laboratories Inc.*, the Supreme Court of New Jersey addressed plaintiffs’ claims that Wyeth had engaged in a “massive advertising campaign” for the contraceptive Norplant, “which it directed at women rather than at their doctors.”¹⁰² According to the plaintiffs, this advertising failed to adequately warn them of Norplant’s dangers.¹⁰³ The Supreme Court of New Jersey crafted an exception to the “learned intermediary doctrine”—which would normally insulate the manufacturer from liability where the prescribing physician was adequately warned of the dangers of the drug—in instances where the manufacturer marketed

¹⁰¹ See *Sprietsma*, 537 U.S. at 55 – 56.

¹⁰² 161 N.J. 1, 6, 734 A.2d 1245, 1248 (1999).

¹⁰³ See *id.*

directly to consumers.¹⁰⁴ Although the Court seemed to intimate that federal preemption might apply in this area,¹⁰⁵ it concluded that plaintiffs should be permitted to rebut the presumption that manufacturers complying with federal law have satisfied whatever duty to warn may arise from the fact that they advertise directly to consumers.¹⁰⁶ In sum, under *Perez*, failure-to-warn claims based on DTC advertising are not barred by federal preemption. Despite the potential significance of this holding, one commentator has noted that “[s]tate courts have by and large ignored DTC advertising and its effects when deciding cases involving the [learned intermediary doctrine].”¹⁰⁷ Nonetheless, it is important to consider claims of this type for two reasons.

First, failure-to-warn cases based on prescription drug *labeling* are relatively common.¹⁰⁸ Since labeling and advertising are close cousins (in terms of containing statements or omissions that could generate litigation), one might reasonably expect an increase in failure-to-warn claim based on DTC advertising. Second, failure-to-warn claims based on DTC advertising are specifically targeted by the FDA’s recent rulemaking; the final rule asserts preemption of failure-to-warn cases beyond the labeling context and into the advertising context.¹⁰⁹

Although failure-to-warn claims based on DTC advertising might seem like a brier patch for plaintiffs because of the FDA’s recent rulemaking, it may not be extraordinary to encounter such claims in the near future.

First, the courts have not yet decided whether the FDA’s assertion of preemption in its recent rulemaking

¹⁰⁴See *id.* at 21.

¹⁰⁵See *id.* at 21 – 22 (“In reaching the conclusion that the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers, we must necessarily consider that when prescription drugs are marketed and labeled in accordance with FDA specifications, the pharmaceutical manufacturers should not have to confront ‘state tort liability premised on theories of design defect or warning inadequacy.’” (quoting Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 773 (1990))).

¹⁰⁶See *id.* at 24.

¹⁰⁷See Daniel Richardson, *The Lost Child of Products Liability: New Thoughts About Advertising and the Learned Intermediary Doctrine*, 27 VT. L. REV. 1017, 1020 (1999).

¹⁰⁸See, e.g., *Motus v. Pfizer Inc.*, 127 F.Supp.2d 1085 (C.D. Cal. 2000).

¹⁰⁹See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3935 – 36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

is legally valid.¹¹⁰ Although valid federal regulations are entitled to preemptive effect,¹¹¹ some have argued that, because of its placement *in the preamble* to the rule, the preemption language means that it “has no force [or] effect of law.”¹¹² Second, plaintiffs in some jurisdictions may be forced to channel their claims into the DTC advertising arena to avoid more-settled preemption in other areas—for example, in jurisdictions that have found consumer fraud claims preempted.¹¹³ Such a shift seems eminently plausible since prescription drug litigation has *already* witnessed one wave of claim transmogrification in order to avoid preemption: Drier writes that “[i]nstead of (or in addition to) asserting defect or warranty claims,” plaintiffs now place the claims within a traditionally state-based area,¹¹⁴ such as under state consumer fraud laws, to avoid preemption.¹¹⁵ Thus, plaintiffs may shift their claims into the failure-to-warn rubric if other claims have already been deemed preempted in that jurisdiction.

b.

Fraud and False Advertising Claims

Claims for fraud and/or false advertising have been the most frequently litigated of those claims that could involve DTC advertising of prescription drugs. The lower courts are split on whether federal preemption applies to state-law fraud and false advertising claims.

i.

¹¹⁰See Gertner, *supra* note 72, at 23; Tesoriero & Mathews, *supra* note 93, at D3.

¹¹¹See, e.g., Shaeffer, *supra* note 12, at 637 & n.66 (quoting *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982)).

¹¹²See Gertner, *supra* note 72, at 1, 23. *But see id.* at 1 (quoting Daniel Troy, former chief counsel of the FDA, for the proposition that, “[i]f any court applies sound administrative law principles, it should find [that the FDA’s position embodied in the rule] is entitled to deference”).

¹¹³See *infra* notes 123 – 126 and accompanying text.

¹¹⁴See Dreier, *supra* note 70.

¹¹⁵See *id.*

In *Solvay Pharmaceuticals, Inc. v. Ethex Corp.*, both plaintiff and defendant marketed “competing prescription pancreatic enzyme supplements used in the treatment of cystic fibrosis.”¹¹⁶ The plaintiff alleged that the defendant’s marketing of its product as “equivalent,” “comparable,” and “generic” compared to the plaintiff’s product violated Section 43(a) of the Lanham Act, as well as the Minnesota Unfair Trade Practices Act, the Minnesota Uniform Deceptive Trade Practices Act, the Minnesota False Advertising Act, and the Minnesota Consumer Fraud Act.¹¹⁷ To avoid the defendant’s contention that it was impermissibly attempting to privately enforce the FDCA, the plaintiff phrased its argument as simply that the defendant’s comparisons were false in fact.¹¹⁸ The court held that, despite the “overlap”—and “potential conflict”—between the Lanham Act and the FDCA, “the FDA’s enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims.”¹¹⁹ Thus, “false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA,”¹²⁰ as long as the statements can be proven false without reference to FDA standards.¹²¹ The court then extended its analysis on the Lanham Act claim to the state law claims as well and held that preemption did not apply.¹²²

ii.

¹¹⁶ See No. Civ. 03-2836 JRTFLN, 2004 WL 742033, at *1 (D. Minn. March 30, 2004).

¹¹⁷ See *id.*

¹¹⁸ See *id.* at *1 – *2.

¹¹⁹ See *id.* at *3.

¹²⁰ See *id.* (quoting *Summit Technology, Inc. v. High-Line Medical Instruments*, 933 F.Supp. 918, 933 (C.D. Cal. 1996)). The limitation of the Lanham Act claim is that it may not be enforceable by consumers (or those acting on their behalf), but only by competitors. See Lenhardt, *supra* note 23, at 170 – 71 & n.27.

¹²¹ See *Solvay Pharmaceuticals*, 2004 WL at *3.

¹²² See *id.* at *4.

Fund

In *Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, the plaintiff class sued the drug manufacturer for falsely implying in advertising materials that its drug Nexium was superior to its other drug Prilosec once the latter went generic.¹²³ This behavior allegedly violated the Delaware Consumer Fraud Act, as well as the consumer protection statutes of all other states.¹²⁴ The court concluded that claims based on statements consistent with FDA-approved labeling would be preempted by federal law because the FDA approval “reflects a determination by the FDA that the information is not ‘false or misleading.’”¹²⁵ The court also concluded that preemption would apply even if a particular state consumer protection statute did not have a provision exempting statements from liability if they complied with relevant FTC regulations.¹²⁶

c.

Specific Relief Claim Not Preempted: *In re Paxil Litigation*

In *In re Paxil Litigation*, the plaintiffs sought to prevent Glaxo Smithkline Beecham from airing television commercials claiming that its prescription drug, Paxil, is “not habit forming.”¹²⁷ Both the FDA and Glaxo Smithkline Beecham argued that preemption should apply to state common-law claims based on direct-to-consumer advertising.¹²⁸ The court remarked that that “the parties reveal no case holding that the FDCA preempts state law either expressly or impliedly” and that preemption would “run contrary to the grain of other decisions.”¹²⁹ In the court’s view, it defied common sense that Congress would simultaneously decline

¹²³ See No. Civ. 05-075-SLR, 2005 WL 2993937, at *1 (D. Del. Nov. 8, 2005).

¹²⁴ See *id.*

¹²⁵ See *id.* (citing 21 C.F.R. § 314.125(b)(6)).

¹²⁶ See *id.* at *2 – *3.

¹²⁷ See No. CV 01-07937 MRP, 2002 WL 31375497 at *1 (C.D. Cal. Oct. 18, 2002).

¹²⁸ See *id.*

¹²⁹ See *id.*

to authorize a private cause of action and also preempt state common-law claims.¹³⁰

5.

Analysis—When Should Preemption Apply?

As a preliminary matter, there are certain considerations that apply across-the-board to the analysis of the preemption issue. First, one must recognize that prescription drug labeling and DTC advertising of prescription drugs are closely linked. Much of the information that appears in (or is omitted from) prescription drug labels is also used in (or omitted from) DTC advertisements of prescription drugs. Although the FDA’s review of DTC advertisements is more sporadic, it is not necessarily less searching—DTC advertisements, like prescription drug labels, must not be “false or misleading.” Moreover, there is no compelling reason why plaintiffs should be able to maintain claims alleging the same acts or omissions under a “DTC advertising” rubric that would more clearly be preempted if based on the drug’s labeling.

Second, “conflict” preemption should apply in a substantial number of concrete cases as a result of the FDA’s “safe harbor” for DTC advertisements submitted for pre-release review.¹³¹ The case is strong for preemption of state-law suits based on any DTC advertisement that had undergone such review. For states to impose tort liability without giving the manufacturer a reasonable opportunity to correct any defects in the advertisement would be plainly inconsistent with the “safe harbor” that Congress intended.¹³²

This also hints at another reason for extending preemption to all actions based on DTC advertising: if drug manufacturers knew that pre-release review would insulate them from state-law suits based on DTC advertising, there would be a massive increase in the number of advertisements submitted for review. It is

¹³⁰ *See id.*

¹³¹ *See supra* note 26 and accompanying text.

¹³² *See id.*

not clear that the FDA is staffed and funded at a level sufficient for it to pre-clear all DTC advertisements. If resources were kept at current levels and a backlog in the pre-clearance process resulted, it would put more pressure on the First Amendment concerns that argue against pre-clearance of DTC advertisement in the first place.¹³³

With these two points in mind, I will consider whether there remains any appropriate place for state tort law in the three types of actions discussed above.

a.

Failure-To-Warn Claims

State-law failure-to-warn claims based on DTC advertising should generally be preempted under implied preemption doctrine as an “obstacle” to the FDA’s program of prescription drug labeling, which encompasses the notion of optimal drug use.¹³⁴ When the FDA approves prescription drug labeling, it does so only after thorough, considered evaluation of the drug’s risks and benefits.¹³⁵ Failure-to-warn claims based on DTC advertising may assert positions inconsistent with the FDA’s judgment as to a drug’s optimal use, accounting for its risks and benefits, as embodied in its labeling. To the extent that manufacturers make statements in DTC advertising that are not essentially founded in their drugs’ labeling, there remains a place for failure-to-warn claims. The FDA’s January 24, 2006, rulemaking recognizes this—it only asserts preemption as to actions based on statements “the substance of which appears anywhere in the labeling.”¹³⁶ Given the

¹³³See *supra* note 24.

¹³⁴See *supra* note 33.

¹³⁵See, e.g., Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (“[T]he agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product’s risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling.”).

¹³⁶See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3935 – 36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

deference that the Supreme Court shows to agency decisions embodied in rulemaking,¹³⁷ particularly when expressed as specifically as the FDA has done for failure-to-warn claims,¹³⁸ most state-law failure to warn claims should be preempted.

b.

Consumer Fraud Claims

Consumer fraud claims are potentially the most interesting area because, as some have noted, the FDA's recent rulemaking activity does not explicitly reach consumer fraud claims and may not reach them at all.¹³⁹ However, implied preemption should also apply to state-law consumer fraud claims as an "obstacle" to the FDA's program of "optimal use" of prescription drugs.

As a preliminary matter, one should consider the disruption that would follow from subjecting manufacturers to the consumer fraud or false advertising regimes of fifty states. The risk of undermining the uniform legal treatment of goods marketed nationwide should be obvious,¹⁴⁰ and the Supreme Court has suggested that it will take into account the interests of businesses and consumers when deciding whether preemption applies. Both businesses and consumers would be ill-served by the uncertainty that would be created if drug manufacturers were forced to comply with fifty states' consumer fraud and false advertising regimes.¹⁴¹

One the other hand, one might initially think that the presumption against preemption applies with particular

¹³⁷See *supra* note 95 and sources cited therein.

¹³⁸See *supra* notes 57 – 59 and accompanying text.

¹³⁹Victor Schwartz, general counsel for the American Tort Reform Association, acknowledges that the new regulation "doesn't protect a company against fraud" or breach of warranty claims. See Gertner, *supra* note 72, at 23. *But see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3935 – 36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (opining that the list of preempted state-law causes of action was not exhaustive); Tesoriero & Mathews, *supra* note 93, at D3 (noting that the preemption language may have a broader reach than simply failure-to-warn claims).

¹⁴⁰The importance of uniform treatment in a national marketplace exposes the faulty logic of the court in *Solvay Pharmaceuticals*. Even if a cause of action under the Lanham Act is not preempted, the Lanham Act is a single body of law that will be applied in a manner that is more substantively uniform than would be the application of fifty states' consumer fraud or false advertising regimes (whether common-law or statutory).

¹⁴¹See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 – 86, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

force in this area since policing “fraud” is an area traditionally and primarily regulated by the states. However, this is too simplistic a conclusion—it depends on the level of specificity at which one describes the activity being policed. Surely, policing “fraud” dates back as far as the common law itself. Policing “fraud” in the context of prescription drugs, on the other hand, was within the purview of the FTC before states even enacted their “little FTC acts.”¹⁴²

In the final analysis, preemption should apply because (contrary to what the *Solvay Pharmaceuticals* court seemed to assume¹⁴³), the FDA has always policed the economic harm that consumer fraud claims attempt to redress. The FDA ensures that prescription drugs are both safe and not “economically adulterated.”¹⁴⁴ The FDA’s concept of “optimal use” in the context of drug safety also surely extends to cost-effectiveness. That is to say, if a drug that posed no health hazard at all, but were advertised in a manner that clearly overstated its benefits, the FDA would surely take action against it. For this reason, consumer fraud claims are analogous to failure-to-warn claims in the sense that they attempt to substitute a jury’s judgment about a drug’s optimal use for that of the FDA. Therefore, these claims should also be preempted as obstacles to the FDA’s program of optimal drug use.

c.

Specific Relief Claims

Claims for specific relief, such as those involved in *In re Paxil Litigation*, should be preempted either as an “obstacle” to the FDA’s program of promoting optimal drug use or, in many cases, as in “conflict” with specific FDA requirements.

¹⁴² See *supra* notes 12 – 14 and accompanying text.

¹⁴³ See *Solvay Pharms., Inc. v. Ethex Corp.*, No. Civ. 03-2836 JRTFLN, 2004 WL 742033, at *3 (D. Minn. March 30, 2004) (“[T]he FDA’s enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims”).

¹⁴⁴ See, e.g., PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 88 – 96.

The one case to find that preemption does not apply to a claim for specific relief, *In re Paxil Litigation*,¹⁴⁵ should not be followed. One should evaluate that case against the background of *Medtronic*, where the Court reserved judgment on whether a common-law duty could be a state-law “requirement” within the meaning of the MDA preemption provision (and thus, whether a common-law duty could be preempted if inconsistent with the MDA).¹⁴⁶ The Court declined to address the argument in part because it predicted that “[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has ‘the effect of establishing a substantive requirement for a specific device.’”¹⁴⁷ The Paxil litigation is close to being such a “rare” case: the plaintiffs pressed common-law causes of action to affirmatively prevent the manufacturer from making the specific claim that Paxil is “not habit forming.”¹⁴⁸ What makes the Paxil case unworthy of being followed is that, far from recognizing that it was nearing the edge of the scope of the Court’s holding in *Medtronic*, the court in the Paxil litigation blithely cited *Medtronic* for its conclusion that preemption does not apply.¹⁴⁹

In addition to there being no strong precedent in favor of denying preemption, if plaintiffs were permitted to dictate the contents of prescription drug advertising in different jurisdictions, it would derogate from the ideal of uniform legal treatment of a product sold nationwide. This would have a disruptive effect on business and consumers alike, a result the *Medtronic* Court suggested it would seek to avoid in performing its preemption analysis.¹⁵⁰ But more fundamentally, it would often contradict the FDA’s decision as to the optimal use of a drug, as embodied in the drug’s labeling. In determining what manufacturers may claim in drug labeling, the FDA sets standards to encourage optimal use of a drug, given its risks and benefits.¹⁵¹ To

¹⁴⁵No. CV 01-07937 MRP, 2002 WL 31375497 at *1 (C.D. Cal. Oct. 18, 2002).

¹⁴⁶*Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

¹⁴⁷*See id.* at 502 – 03.

¹⁴⁸*See In re Paxil Litig.*, 2002 WL at *1.

¹⁴⁹*See id.* (citing *Medtronic*, 518 U.S. at 487).

¹⁵⁰*See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 – 86, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

¹⁵¹*See, e.g.*, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (“Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.”); *Amicus Brief for United States in Support of the Defendant-Appellee and Cross-Appellant, Motus v. Pfizer Inc.*, (2002) Nos. 02-55372, 02-55498, 2002 WL 32303084, at *23

allow plaintiffs to require manufacturers to meet more stringent standards before being able to make certain claims without incurring liability, plaintiffs would be deviating from the ideal of optimal drug use.

6.

Conclusion

The FDA's recent activity in the area of direct-to-consumer advertising raises serious questions about whether federal law preempts state tort actions based upon such advertising. The lower courts have begun to address such claims and have reached mixed results, though non-preemption has been the norm. However, all of the cases discussed herein predate the FDA's recent rulemaking activity in which the agency asserted broad preemption of state law tort law in the prescription drug advertising context. This analysis concludes that the FDA's rulemaking (formalizing a position taken earlier in amicus curiae briefs), has the effect of preempting almost all state tort actions related to DTC advertising. If the manufacturer makes use of the pre-clearance "safe harbor" for an advertisement, any state-law action based on that advertisement should be preempted under "conflict" preemption principles. Apart from this, claims based on statements or omissions that are intertwined with a prescription drug's labeling should be preempted as an "obstacle" to the FDA's labeling program, which encompasses a notion of optimal drug use. The FDA's position is now embodied in a final rule, which should give it preclusive effect. Those who still doubt the clarity of the FDA's position must recognize that the FDA acts in the shadow of the First Amendment when it regulates DTC advertising. Given this, the FDA's position is as clear as can be expected. The courts should therefore (generally) reverse course and accord the FDA's position the deference it is due.

("Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects.").