

Discovering the Boundaries: Federal Preemption of Prescription Drug Labeling Product Liability Actions

BY MARY J. DAVIS

Federally approved prescription drug labeling has not been considered conclusive on the reasonableness or adequacy of the label for assessing tort liability on the manufacturer because federal regulations in this field set a minimum standard rather than an optimal one. That fundamental statement of black-letter tort law is under attack. The Food and Drug Administration (FDA) has promulgated a regulation which revises the format for prescription drug labeling, and, in the process, has taken the position that the regulation displaces, or preempts, state products liability laws that seek to assess liability on the manufacturer for a label's warning adequacy. In the FDA's 100 year history, it has not taken the position that federal regulations preempt common law tort claims based on prescription drug labeling until now. This Article explains the applicability of preemption doctrine to prescription drug product liability actions, explores the importance of the change in FDA position on that doctrine, and provides direction to courts seeking to discover the boundaries of federal preemption in this critical area.

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I. INTRODUCTION

In late 2002, the FDA filed an amicus curiae brief in *Motus v. Pfizer, Inc.*,⁶ in which it

¹ *Stites & Harbison Professor of Law, University of Kentucky College of Law. B.A. University of Virginia, 1979; J.D. Wake Forest University School of Law, 1985. I would like to thank the participants at the Randall-Park Colloquium Speakers Series, University of Kentucky College of Law, for their observations on this subject. Thanks especially to Richard Ausness, Louise Graham, _____, for their helpful comments on earlier drafts, and to Tammy Howard, University of Kentucky College of Law, Class of 2006, for her fine research assistance.

²Witczak v. Pfizer, 377 F. Supp. 2d 726, 730 (D. Minn. 2005); Merrell Dow Pharm. v. Oxendine, 649 A.2d 825, 828 (D.C. 1994); Hill v. Searle Labs., 884 F.2d 1064, 1068 (8th Cir. 1989); Wells v. Ortho Pharm Corp., 788 F.2d 741, 746 (11th Cir. 1986). See also David G. Owen, M. Stuart Madden, and Mary J. Davis, Madden and Owen on Products Liability, § 28:6, at 910 (3d. Ed. 2000).

³21 U.S.C. § 393 (2006)(authorizes the creation of the Food and Drug Administration as the agency responsible for administering the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 - 397 (2006) (FDCA)).

⁴71 Fed. Reg. 3922, 3934-3936 (Jan. 24, 2006).

⁵For a discussion of the history of the FDA's position on preemption based on prescription drug labeling, see *infra* notes and accompanying text.

⁶Amicus Curiae Brief of United States, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004)(filed September 10, 2002), available at 2002 WL 32303084 (hereafter *Motus Amicus Brief of United States*). The Court of Appeals did not reach the preemption issue but affirmed the trial court's grant of summary judgment to defendant based on lack of proof of causation. *Motus*, 358 F.3d at 660-61.

asserted that a warning label it had approved for the anti-depressant drug Zoloft preempted the plaintiff's product liability action based on the inadequacy of the warning's risk of suicide from which the plaintiff died.⁷ Before *Motus*, the FDA's position was that "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."⁸ An FDA official has explained the more aggressive stance in favor of preemption: "Our willingness to invoke implied preemption can be traced to the growing propensity of bad scientific reasoning to seep into court cases involving FDA-regulated products."⁹ After the ensuing three years of debate regarding whether to strengthen the warning of suicide risk in the labeling of Zoloft and similar anti-depressants, the FDA ultimately required manufacturers to place a stronger warning, known as a "black box" warning, on the labeling, highlighting the potential association between the drugs and the risk of suicide.¹⁰

⁷358 F.3d at 660. Zoloft is in a category of anti-depressants known as selective serotonin reuptake inhibitors, or SSRIs. See *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1088 (C. D. Cal. 2000) (background information on Zoloft), rev'd on other grounds, 358 F. 3d 659 (9th Cir. 2004).

⁸Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 57 Food & Drug L. J. 7 (1997). Ms. Porter was FDA chief counsel at the time of the article. See also, James T. O'Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 Food & Drug L.J. 287, 287 (2003) ("Until DHHS [Department of Health & Human Services] asserted prescription drug preemption in [*Motus*], FDA had remained aloof from preemption arguments that often had been made by prescription drug manufacturers in defense of individual products liability lawsuits."). A few months before the *Motus* brief, the FDA took a similar preemption position in another products liability action which was ultimately decided on other grounds. See *Bernhardt v. Pfizer, Inc.*, 2002 U.S. Dist. LEXIS 16963 (S.D.N.Y. Nov. 16, 2002).

At the time of the *Motus* Amicus Brief, the FDA's General Counsel and architect of the changed preemption position, Daniel Troy, had formerly represented Pfizer, Inc. during his time in private practice. Gary Young, *FDA Strategy Would Pre-empt Tort Suits: Does it Close Off Vital Drug Data?*, THE NATIONAL LAW JOURNAL, vol 26, at p. ____, col 1. (March 1, 2004). Troy has been criticized for not disclosing his Pfizer ties. *House Cuts OC's Funds for Downplaying Troy's Drug Industry Ties*, FDA Week, § 29 (July 16, 2004). See also O'Reilly, *supra* note at 287 (discussing FDA change in position regarding preemption); Margaret Clune, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers*, Center for Progressive Regulation White Paper #403, at 2 - 4 (Oct. 2004) (describing new FDA position under Troy).

⁹Mary Ellen Egan, *Tort Turf*, Forbes, vol. 173, issue 9, at 48 (April 26, 2004).

¹⁰FDA Public Health Advisory, *Worsening Depression and Suicidality in Patients Being Treated With Antidepressant* (March 22, 2004)(recommending labeling for anti-depressants like Zoloft be modified to reflect potential suicide risks); FDA Press Release, *FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated With Antidepressant Medications* (October 14, 2004) (black box warning required on SSRIs).

The British equivalent of the FDA recommended a similar warning as early as 2002,

After 2002, the FDA continued to posit that approved prescription drug labeling preempts state tort laws,¹¹ culminating in the promulgation of a new labeling regulation in January 2006 formally taking that position.¹² The FDA first published a proposed new labeling regulation in December 2000 to begin the notice and comment period for revisions to make prescription drug labeling clearer, more concise, and rid of “legalese.”¹³ The proposed rule did not address nor seek comments on its possible preemptive effect on products liability actions.¹⁴ The proposed final regulation, to take effect on June 30, 2006, now takes the position that approved prescription drug labeling *does* preempt conflicting state product liability laws.¹⁵ Immediately upon the heels of publication of the final rule, Pfizer asked a federal district judge to vacate an order denying summary judgment on preemption grounds in another Zolofit case based on the new FDA preemption position.¹⁶

What has prompted the FDA’s change in position on preemption of state product liability laws and will that change in position have the preemptive effect it seeks? What does the Supreme Court’s preemption jurisprudence require in assessing the preemptive effect of a rule that will alter so significantly the balance between federal safety regulation and common law tort regulatory and compensation principles? Federal agency position on the preemptive effect of regulations has been given some level of deference in the Supreme Court’s modern preemption

before the FDA’s preemption position was made known in the amicus brief filed in *Motus*. See Amicus Curiae Brief of Public Citizen, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (filed April 21, 2003, available at 2003 WL 22716063). One commentator has suggested that “[m]aybe those juries aren’t so ignorant after all?” Egan, *supra* note at .

¹¹*Dusek v. Pfizer, Inc.*, 2004 WL 2191804, at * 1 (S.D. Tex. Feb. 20, 2004)(not reported in F. Supp. 2d) (summary judgment granted for manufacturer based on conflict preemption); *Needleman v. Pfizer, Inc.*, 2004 WL 1773697, at *2 (N. D. Tex., August 06, 2004)(not reported in F. Supp. 2d)(same). See also Clune, *supra* note at 2-3.

¹²71 Fed. Reg. 3922 (January 24, 2006).

¹³*Id.* at 3922.

¹⁴FDA Revises Labeling Format for Drugs, 34 Prod. Saf. & Liab. Rptr. (BNA) p. 52, 53 (January 23, 2006).

¹⁵21 Fed. Reg. at 3934. The preemption discussion appears in the introductory background, or preamble, and comments section of the final rule without having been subject to public comment. 34 Prod. Saf. & Liab. Rptr. (BNA) at 53.

For criticism of the FDA’s attempt to introduce the new preemption position in this manner, see Letter to Secretary Mike Leavitt, DHHS, from National Conference of State Legislatures, dated Jan. 13, 2006, noting in particular that the FDA specifically stated in its Dec. 22, 2000 Notice of Proposed Rule Making that the proposed rule did not preempt state law and that the proposed rule, therefore, did not implicate federalism concerns. See *id.* Letter available at <http://www.ncsl.org/programs/press/2006/060113Leavitt.html>.

¹⁶*McNellis v. Pfizer, Inc.*, 2005 WL 3752269 (No. 05-1286, D. N. J. January 30, 2006); see also 34 Prod. Saf. & Liab. Rptr. (BNA) at 220 (March 6, 2006) (discussing Pfizer’s motion to reconsider).

jurisprudence.¹⁷ The Supreme Court has not, however, answered the question of how agency position affects the operation of implied preemption doctrine under the federal Food, Drug, and Cosmetic Act,¹⁸ nor how the historic primacy of state regulation in the area of health and safety is to be considered in the balance. This Article provides the much needed factual background, doctrinal explanation, and policy insight to answer these questions.

This Article comprehensively explores the issue of preemption of product liability claims based on prescription drug labeling. Section II of the Article defines the general regulatory scheme under the federal Food, Drug and Cosmetic Act to place the preemption issue in context. It also explains the FDA's proposed new final regulation on prescription drug labeling and some of the cases which have been used to raise the preemption issue. Section III then describes general preemption doctrine and gives a detailed treatment of that doctrine in the area of food and drug regulation. Section IV explains the basis for the recent arguments for implied conflict preemption under the FDCA for prescription drug labeling cases, critiques those arguments, and analyzes implied preemption under the FDCA in a manner consistent with a deeper understanding of the Court's preemption doctrine.

Section V concludes that implied conflict preemption of pharmaceutical products liability claims is inconsistent with the Supreme Court's modern preemption jurisprudence. The FDA's current preemption position tries to paint with too broad a brush based on the proposed labeling regulation and significantly undervalues the historic primacy of state law in the field of public health and safety. There is ample room, according to implied conflict preemption doctrine, for both state product liability law and federal safety regulation to operate in a complementary fashion. Is traditional tort law soon to be a thing of the past as it applies to pharmaceutical products liability actions? This Article answers, "No." The boundary between state tort law and federal regulation of prescription drug labeling continues to be well-marked, preserving the traditional place for the operation of state tort law.

II. PHARMACEUTICAL LABELING REGULATIONS UNDER THE FEDERAL FOOD AND DRUG LAWS

In determining whether certain conduct is negligent, an applicable regulatory standard is often considered relevant and a jury may consider compliance with a regulation as support for a finding of no negligence, but it is not required to so find.¹⁹ The basic premise of this principle is that regulators, whether legislators or agency administrators, intend only to set minimum, not optimal, standards of care.²⁰ A corollary to that basic premise is that courts must be the arbiters

¹⁷See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). See also *infra* notes and accompanying text.

¹⁸21 U.S.C. §§ 301-397 (2006).

¹⁹Dan B. Dobbs, *The Law of Torts*, § 373, at p. 1033 (2000); David G. Owen, *Products Liability Law* § 14.3, at p. 888 (2005).

²⁰Restatement (Third) of Torts: Liability for Physical Harm § 16 cmt b (Proposed Final Draft)(May 17, 2005)(lawmaking process "insufficiently attentive" to interests of injured). See also Restatement (Second) of Torts § 288C (1965); Restatement (Third) of Torts: Products

of the content of civil standards of care in the absence of clear statutory or regulatory intent to the contrary.²¹

Recent critics of the operation of the tort system have encouraged state legislatures to provide that compliance with governmental regulations should be treated as more than simply some evidence of reasonable care; rather, it must be considered either conclusively or presumptively to establish due care.²² Such reform efforts have been particularly aggressive in the products liability area where tort litigation often challenges the design or warning of products that have received some measure of governmental approval.²³ It continues to be the “unusual situation,” however, when a court will rule that compliance with a regulatory standard is conclusive of a tort standard of care.²⁴

Against the backdrop of this effort to reform state tort laws, product manufacturers increasingly began in the 1990s to raise federal preemption doctrine as an additional defense to

Liability § 4(b) (1998). For a general discussion of the doctrine, see Symposium, *Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2049 (2000); Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 2120 (1996). See also, Teresa Moran Schwarz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J. L. REF. 431 (1997); Teresa Moran Schwarz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121 (1988).

²¹*Clinkscales v. Carver*, 136 P.2d 777, 779 (Cal. 1943) (“The decision as to what the civil standard should be still rests with the court, and the standard formulated by a legislative body in a police regulation . . . becomes the standard to determine civil liability only because the court accepts it.”).

²²See e.g., Colo. Rev. Stat. § 13-21-403 (1) (2005); Ind. Code § 34-20-5-1 (1998); Ky Rev. Stat. § 411.310 (1978). See generally Owen, *Products Liability Law* supra note 1 § 2.4, at p. 93.

²³See Owen, *Products Liability Law*, supra note at § 14.3 at p. 894 (“About a dozen states have enacted products liability reform statutes concerning the effect of a manufacturer’s compliance with a governmental safety standard.”).

See generally 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, 395 (1996) (“Fairness as well as public policy demand that compliance with the comprehensive federal regulation of prescription drugs be conclusive evidence that pharmaceutical manufacturers have discharged their duty to provide the public with reasonably safe and effective products and appropriate warnings.”); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 334-35 (1985) (“Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based. The courts are simply not qualified to second-guess such decisions; when they choose to do so they routinely make regressive risk choices.”).

²⁴Restatement (Third) of Torts; *Liability for Physical Harm*, § 16 cmt. e (Proposed Final Draft, May 17, 2005). But see Mich. Comp. Laws § 600.2946(5) (1995)(FDA approval is “conclusive on the issue of due care for drugs”).

tort liability.²⁵ Federal preemption doctrine rests on the principle that if Congress legislates in a field, its legislation is supreme and, therefore, displaces state regulation.²⁶ To determine whether federal legislation indeed operates to preempt state regulation, courts must search for congressional intent to preempt,²⁷ either through interpretation of an express preemption provision²⁸ or through the application of implied preemption principles.²⁹ Whether common law tort actions are preempted has proved to be an especially difficult task because of the typical lack of evidence of congressional intent to preempt, coupled with the historic primacy of state law in areas affecting the health and safety of the public.³⁰

Congress rarely expresses the scope of its preemptive intent clearly, especially as it affects common law tort actions.³¹ The Supreme Court historically has rejected the notion that Congress would entirely defeat the operation of traditional state tort laws that had long operated concurrently with federal regulation without clearly saying so.³² *A fortiori*, implied intent to

²⁵See *Cipollone v. The Liggett Group Inc.*, 505 U.S. 504 (1992)(tobacco companies raise preemption defense regarding warnings on cigarette packaging; limited preemption found based on express preemption provision); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000)(automobile manufacturer raises preemption defense regarding requirement for driver's side air bags; preemption found based on implied preemption doctrines).

²⁶The Supremacy Clause of the Constitution requires federal law supremacy. U.S. Const. art. VI, cl. 2 ("The Constitution, and laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land, . . .").

²⁷*Cipollone v. The Liggett Group, Inc.*, 505 U.S. 504, 517 (1992)(the intent of Congress is the 'ultimate touchstone' of preemption analysis, citing *Malone v. White Motor Co.*, 435 U.S. 497, 505 (1978)). See also Mary J. Davis, *On Preemption, Congressional Intent, and Conflict of Laws*, 66 U. Pitt. L. Rev. 181, 198 (2004)(hereafter Davis, *On Preemption*); Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Jurisprudence Since Cipollone*, 92 Ky. L. J. 913, 917-919 (2003-2004).

²⁸The FDCA does not contain a general express preemption provision. *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018 (S. D. Ill. 2001); *McCallister v. Purdue Pharms L.P.*, 164 F. Supp. 2d 783 (S.D. W. Va. 2001); *Eve v. Sandoz Pharm. Corp.*, 2002 WL 181972 at * 2 (S. D. Ind. Jan. 28, 2002)(portion of FDA dealing with pharmaceuticals does not contain preemption provision). See also, O' Reilly, *supra* note at 290; Geiger & Rosen, *supra* note at 400.

²⁹See *infra* notes and accompanying text.

³⁰See *infra* notes and accompanying text. See also Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. Rev. 967, 971 (2002) (history of preemption doctrine)(hereafter Davis, *Unmasking the Presumption*). See also, Davis, *On Preemption*, *supra* note at 200-202 (2004) (discussing implied preemption doctrine).

³¹Davis, *On Preemption*, *supra* note at 183-184, 198-202. See also Davis, *Unmasking the Presumption*, *supra* note at 990-997 (explaining Supreme Court's late twentieth century preemption cases involving common law tort actions); and Owen, *Products Liability*, *supra* note at § 14.4 at pp. 895 - 901 (general discussion of presumption against preemption of traditional state health and safety laws).

³²*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *English v. Gen. Elec. Co.*, 496 U.S. 72, 83 (1990).

preempt traditional state tort doctrines has rarely been found.³³

The Federal Food, Drug, and Cosmetic Act (FDCA)³⁴ does not have a general express preemption provision,³⁵ though Congress has on occasion written preemption provisions into the food and drug laws.³⁶ Implied preemption doctrine, therefore, will necessarily apply to the prescription drug labeling cases. Implied preemption is recognized in limited categories of cases: (1) when the broad sweep of the federal statute's scope suggests a total occupation of the regulatory field; and (2) when inconsistent state regulation would either make it impossible to comply with a federal mandate or would frustrate the purposes behind Congress' legislation.³⁷ State common law tort actions historically have not been considered either directly regulatory or inconsistent with Congress' purposes, and, therefore, typically not impliedly preempted under these doctrines.³⁸

Implied conflict preemption principles require an assessment of whether federal objectives are frustrated by actually conflicting state regulation. Consequently, an understanding of the regulatory scheme in issue and its objectives, both in general and as to the specific regulation in issue, is critical to an application of implied conflict preemption doctrine. The federal objectives must, therefore, be discerned; the source of those objectives explored, and the nature of the regulatory scheme understood.³⁹ The objectives of the FDCA in prescription drug

³³See, e.g., *Geier v. American Honda Motor Corp.*, 529 U.S. 861, (2000) (finding implied conflict preemption of state tort common law damages action). *Geier* is discussed in more detail *infra* notes and accompanying text. See also *Ausness*, *supra* note at 928 (“[I]n the years prior to *Cipollone* the Court generally refused to preempt state tort claims, even where there was an important federal regulatory interest at stake.”).

³⁴21 U.S.C. §§ 301-397 (2006).

³⁵See *supra* note 25.

³⁶Congress has enacted a number of specific preemption provisions in the food and drug laws, suggesting it is capable of doing so when it chooses, but none providing preemption for prescription drug labeling. For examples of specific preemption provisions, see, e.g., 21 U.S.C. § 379r (2006) (national uniformity for nonprescription drugs)(enacted 1997), and 21 U.S.C. § 379s (2006)(preemption for labeling or packaging of cosmetics)(enacted 1997). Both of these preemption provisions also contain a clause which saves the operation of product liability laws and states: “Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.” 21 U.S.C. § 379r(e); 21 U.S.C. § 379s(e).

³⁷See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230-231 (1947). See generally, *Davis*, *Unmasking the Presumption*, *supra* note at 969-971, 990-97; *Ausness*, *supra* note at 919.

³⁸*Davis*, *Unmasking the Presumption*, *supra* note at 990-993 (discussing the Supreme Court's important early cases on implied preemption of common law damages actions); *Ausness*, *supra* note at 922-924 (discussing implied conflict preemption in early preemption cases).

³⁹See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (discussing assessment of federal objectives in implied preemption inquiry.) See also *Davis*, *Unmasking the Presumption*, *supra* note at 979.

labeling and the nature of the regulatory scheme are the subject of the next subsection.

A. Regulation under Federal Food and Drug Laws

Federal regulation of food and drugs occurred in this country as early as the mid-nineteenth century but began in earnest in 1906 with enactment of the Pure Food and Drug Act.⁴⁰ The 1906 Act was prompted by concerns raised by state food and drug regulators over adulterated and misbranded food products moving in interstate commerce and contaminating the food and drug supply.⁴¹ State regulators encouraged, indeed implored,⁴² the national government to create a federal agency because of concerns over their inability to reach the interstate sale of fraudulent products and, thus, to protect consumers from them.⁴³ Until the federal legislation, the states had traditionally regulated the safety of food and drugs since the earliest days of our country's history.⁴⁴

The modern version of the federal food and drug regulatory scheme dates from the FDCA of 1938.⁴⁵ The 1938 Act was adopted to protect the public health by enforcing certain standards of purity and effectiveness as well as preventing the sale of misbranded or adulterated products.⁴⁶ The 1938 legislation extended control over more products and enlarged and stiffened the penalties for its disobedience.⁴⁷ A variety of amendments to the 1938 Act over the ensuing years⁴⁸ have added to the complexity of the regulatory scheme but its primary purpose has never

⁴⁰For a history of the early regulation of food and drugs in this country, see 1 James T. O'Reilly, *Food and Drug Admin.* §§ 3:1 - 3.4 (2d. ed. 2005)(hereafter O'Reilly, *Food and Drug Admin.* 2d).

⁴¹1 O'Reilly, *Food and Drug Admin.* 2d at § 3:2.

⁴²See Regler, *The Struggle for Federal Food and Drugs Legislation*, 1 *Law & Contemp. Probs.* 3 (1933). See also O'Reilly, *Food and Drug Admin* 2d at § 25:1. For additional discussion of the history of the FDCA, see the FDA's website, <http://www.fda.gov/oc/history>.

⁴³O'Reilly, *Food and Drug Admin.* 2d at § 25:1 (overview of relationship between the FDA and state governments).

⁴⁴*Id.* at § 25:1.

⁴⁵21 U.S.C. § 301, 331 (2006) (defining prohibited acts of adulteration and misbranding). See *United States v. Sullivan*, 332 U.S. 689 (1948) (discussing purposes of FDCA); *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914) (discussing similar purposes of predecessor Pure Food and Drug Act of 1906).

⁴⁶*United States v. Diapulse Corp. of America*, 457 F.2d 25 (2d Cir. 1972); *Pharmaceutical Mfrs. Ass'n v. Food and Drug Admin.*, 484 F. Supp. 1179 (D. Del. 1980).

⁴⁷*United States v. Dotterweich*, 320 U.S. 277 (1943); *Research Labs. v. United States* 167 F.2d 410 (9th Cir. 1948).

⁴⁸See, e.g., *Food Allergen Labeling and Consumer Protection Act of 2004*, Pub.L. 108-282, Title II, § 201, 118 Stat. 905 (Aug. 2, 2004); *Best Pharmaceuticals for Children Act*, Pub. L. 107-09, § 1, 115 Stat. 1408 (2002); *Dietary Supplement Health and Education Act of 1994*, Pub. L. 103-417, § 1(a), 108 Stat. 4325 (1994); *Nutrition Labeling and education Act Amendments of 1993*, Pub. L. 103-80, § 1, 107 Stat. 773 (1993); and *Medical Device Amendments of 1976*, Pub. L. 94-295, § 1(a), 90 Stat. 539 (1976).

changed—protection of the public health.

The FDCA is administered by the Food and Drug Administration (FDA)⁴⁹ which regulates the safety of foods, drugs, medical devices, and cosmetics in a number of ways. The key protection against the marketing of ineffective or unsafe prescription pharmaceutical products comes from the New Drug Approval process that new drugs must complete before they can be marketed.⁵⁰ If a prescription drug fails to comply with any applicable regulation, that product may, as a result, be considered misbranded or adulterated under the Act.⁵¹ Penalties for selling an adulterated or misbranded drug or device may be assessed against the seller,⁵² non-compliant products may be seized,⁵³ and injunctive relief is available in federal district court.⁵⁴

To be misbranded, a regulated product’s labeling must be “false or misleading in any particular.”⁵⁵ Proper labeling includes certain identifying information, such as the name and place of business of the manufacturer, and prominent placement of information on the label to insure readability.⁵⁶ Proper labeling also includes the established name of the drug and information on the proportion of active ingredients and their established names, if any.⁵⁷

Most importantly, proper labeling includes “adequate directions for use” and “adequate

⁴⁹21 U.S.C. § 393 (2006).

⁵⁰*Id.* § 355 (new drug application requirements). See also 21 C.F.R. pt. 314 (regulations for new drug approval applications). Stories about the expense of the drug application process are legendary and are the backdrop to many calls for reform of the process. See, e.g., Clifton Leaf, How our National Obsession with Drug Safety is Killing People – And What We Can Do About It, *Fortune*, at 107 (February 20, 2006).

Similarly, the Medical Device Amendments to the FDCA contain a complex regulatory mechanism for the marketing of medical devices. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in 21 U.S.C. § 360). These amendments create a three-part classification of medical devices and regulate their marketing accordingly. 21 U.S.C. § 360(c). For a thorough discussion of the regulatory scheme of the MDA, see *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)(analyzing preemption under the MDA). See also Richard C. Ausness, “After You, My Dear Alphonse?”: Should the Courts Defer to the FDA’s New Interpretation of Section 360k(a) of the Medical Device Amendments?, *cite.* (discussing preemption under the Medical Device Amendments). For further discussion of *Medtronic*, see *infra* notes and accompanying text.

⁵¹21 U.S.C. § 351 (adulterated drugs and devices defined); § 352 (misbranded drugs and devices defined) (2006).

⁵²*Id.* at § 333.

⁵³*Id.* at § 334.

⁵⁴*Id.* at § 332.

⁵⁵*Id.* at § 352 (a).

⁵⁶*Id.* at § 352(b), (c).

⁵⁷*Id.* at § 352(e).

warnings against use . . . where its use may be dangerous to health, or against unsafe dosage.”⁵⁸ Tort liability for prescription drugs is based primarily on allegations of inadequate warnings of risk or improper use on the labeling such that the prescribing physician is ill-advised about the potential harms from use of the drug.⁵⁹ The physician acts as the “learned intermediary” between the manufacturer and the patient, for whom the information about risk and appropriate use is intended but who cannot understand its technicalities.⁶⁰ State common law tort actions predicated on negligence and strict products liability require the exercise of reasonable care by manufacturers in warning physicians of unreasonable risks of harm posed to their patients by the use of the drug.⁶¹ How the FDA defines what constitutes an “adequate” warning and how such warnings approved is treated in the next sub-section.

B. Pharmaceutical Labeling Regulations

Prescription drug labeling is intended to communicate information to the physician who then prescribes the product and communicates with her patient about its use.⁶² A number of sources are available for physicians to access information about the prescription drugs they may consider for treatment of their patients’ medical conditions.⁶³ “Labeling” is the set of documents

⁵⁸Id. at § 352 (f).

⁵⁹See Madden and Owen on Products Liability , supra note at §§ 22:9, 22:10. See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966)(one of earliest cases discussing manufacturer duty to warn physician, as learned intermediary).

Liability for the defective design, or formula, of a prescription drug is not the subject of this article. That topic is the subject of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998),and its predecessor, RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965). A number of cases and scholarly articles address design defect liability for pharmaceutical products. See, e.g., *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988); George Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L. J. 1087 (2000); and James Henderson and Aaron Twerski, *Drug Designs are Different*, 111 YALE L. J. 151 (2000).

⁶⁰Madden and Owen on Products Liability, supra note at § 22:11, p. 574-75.

⁶¹Madden and Owen on Products Liability, supra note at § 22:8, p. 564-65. Many academic commentators and some courts have criticized the learned intermediary doctrine as it applies to prescription drugs that are widely advertised to the consumer, otherwise known as the direct-to-consumer advertised product. See *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999) (rejecting learned intermediary doctrine in case of direct to consumer advertised contraceptive device); Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 92 (2002); Wiseman, *Another Factor in the “Decisional Calculus:” The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993 (2001).

⁶²*Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). See Madden and Owen on Products Liability, supra note at § 22:10, p. 568-69.

⁶³For example, the Physician’s Desk Reference, or PDR, is a compilation of the labeling inserts that accompany prescription drugs for easy physician access. “The PDR is an annual publication, a compendium of information about all ethical drugs, which reproduces the information from the

that accompany the drug to the prescriber and the end user.⁶⁴ The FDA must assure that the statutorily required information is adequately communicated to those users but it does not create the labeling. It approves the labeling provided to it by the manufacturer after review of the manufacturer's application pursuant to the New Drug Approval regulations.⁶⁵ A number of regulations have been adopted by the FDA to accomplish its task.

The FDA regulations include general requirements on the content and format of labeling for prescription drugs.⁶⁶ These regulations then refer to more specific requirements detailing what is to be included in the required labeling.⁶⁷ The specific requirements indicate the data that must be included, the order in which it must be included, and the indication and usage information that must be provided.⁶⁸ The labeling regulation states that "serious adverse reactions and potential safety hazards" must be described.⁶⁹ New drug applications are required to contain copies of the labeling proposed by the manufacturer⁷⁰ as well as a summary of the contents of that labeling.⁷¹

The FDA described this labeling formation process in its amicus brief in *Motus*: "FDA's decision as to appropriate labeling is based on the evidence submitted by the applicant, as well as on the agency's review of other relevant information. Commonly, a drug manufacturer and FDA will discuss in detail the proposed drug labeling, including the various warnings to be placed on the proposed drug labeling . . . Based on the known scientific evidence, appropriate warnings are drafted to express the known risks, while avoiding the statement of unsubstantiated risks that may unnecessarily deter use of the drug."⁷² The labeling formulation process is one of give-and-take with oversight by the FDA according to its implementing regulations with the burden on the manufacturer to submit information in support of its application.

Changes to approved labeling are permitted under certain circumstances. A manufacturer is permitted to make certain changes only after first obtaining prior FDA approval for the labeling change.⁷³ Manufacturers may make unilateral labeling changes without prior FDA approval "to include a warning as soon as there is reasonable evidence of an association of a

package inserts of all of them. The PDR is found in the offices of most United States physicians." MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note at § 22:11, at p. 575. See also <http://www.PDR.net> for the online version of the PDR.

⁶⁴O'Reilly, Food & Drug Admin 2d, *supra* note at § 15:9.

⁶⁵21 U.S.C. § 355 (2006)(defining application requirements for new drug approvals).

⁶⁶21 C.F.R. § 201.56 (2006).

⁶⁷*Id.* at § 201.57.

⁶⁸*Id.* at § 201.57(a), (b), (c), (d).

⁶⁹*Id.* at § 201.57(e), (f).

⁷⁰21 C.F.R. § 314.50(e)(2)(ii)(2006).

⁷¹*Id.* at § 314.50(c)(2)(i).

⁷²*Motus* Amicus Brief of United States, *supra* note at 5.

⁷³21 C.F.R. § 314.70(b) ("major changes" include changes in the qualitative or quantitative formulation of the drug or changes that may affect drug substance).

serious hazard with a drug; a causal relationship need not have been proved.”⁷⁴ The FDA need not approve the labeling before the manufacturer revises it under this section, but a supplemental application, a Supplemental Submission for Changes Being Effected, or SSCBE, to effect the change must be submitted.⁷⁵ Such a unilateral labeling change has been called a “safety valve” because it encourages manufacturer labeling changes to permit the addition of new warnings when severe risks become known that were not anticipated when the drug was originally approved.⁷⁶ The FDA must ultimately approve the labeling change,⁷⁷ but the regulation “was promulgated precisely to allow drug-makers to quickly strengthen label warnings when evidence of new side effects are discovered.”⁷⁸ Manufacturers initiate labeling changes but commonly do not implement them without FDA approval.⁷⁹

The FDA’s new proposed final labeling regulation takes the position that any labeling approved by the FDA acts to preempt state common law tort actions so that the manufacturer is not placed in the position of having to change labeling in response to possible tort liability, but may rest on prior FDA approval of labeling. The new regulation is discussed in the next subsection.

C. Proposed New Regulation on Labeling for Prescription Drugs

The proposed new final regulation alters the requirements for the labeling of prescription drugs and is intended to make that labeling clearer, more concise, and more usable for physicians and patients.⁸⁰ The new regulation has the following features: (1) introduces a “Highlights”

⁷⁴Id. at § 201.57(e). This section of the regulation also provides the FDA with authority to require a “prominently displayed box” with particularly important warning or risk information whose location is specified by the FDA. Id. This is the “black box warning” of which people speak.

⁷⁵Id. at §314.70(c)(6)(iii)(A). See also *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005) (discussing SSCBE process and its effect); *Dusek v. Pfizer, Inc.*, 2004 WL 3631155 (S. D. Tex., November 22, 2004) (same).

⁷⁶O’Reilly, *supra* note at 293-94 (“FDA’s regulations and policies encourage prompt action by the drug companies to improve their warnings when the data justifies such enhancements.”) See also *Werner v. Upjohn, Inc.*, 628 F.2d 848 (4th Cir. 1980).

⁷⁷21 C.F.R. at § 314.70(c)(6)(iii).

⁷⁸*Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 729 (D. Minn. 2005) (citing 30 Fed. Reg. 59290 (Jan. 30, 1965) and 44 Fed. Reg. 37447 (June 6, 1979)). See also *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 1033-1034 (S.D. Ill. 2001)(discussing manufacturer’s ability to supplement warnings under FDA regulations).

⁷⁹See 71 Fed. Reg. 3922, 3934 (January 24, 2006)(discussion of labeling procedures in comments to new proposed final labeling regulation); See also *Motus Amicus Brief of United States*, *supra* note at 17 (discussing ultimate FDA approval required for all labeling changes).

⁸⁰71 Fed. Reg. 3922 (January 24, 2006). See also FDA Announces Final Rule on the Requirements for Prescribing Information for Drug and Biological Products, Press Release (Jan. 18, 2006). The labeling regulation change was prompted by “an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to

section to labeling which will provide immediate access to a drug's most commonly referenced material;⁸¹ (2) reorders and reorganizes the contents of labeling, introducing graphical requirements; and (3) makes warning and adverse reaction information more accessible.⁸² To assist manufacturers in complying with the new regulation, the FDA has produced four Guidance Documents in addition to the almost 200-page regulation with comments.⁸³

The regulation lists the general categories of information to be placed into the new "Highlights" section. Those categories include: a Boxed Warning, Recent Major Changes, Indications and Usage, Contraindications, and Warnings and Precautions.⁸⁴ Each manufacturer is required to choose the information that must be included within each of these sections, including the "Warning and Precautions" section of the new labeling.⁸⁵ "Judgment will continue to be necessary" in deciding which information must be emphasized.⁸⁶

Physicians and health care practitioners expressed "unequivocal enthusiasm" for the "Highlights" section while manufacturers were either opposed or "strongly" opposed to it.⁸⁷ Manufacturer opposition was based, in part, on the obligation to pick the important warning or other information to include while omitting other information which might cause the "Highlights" section to be misleading.⁸⁸ Similarly, several comments suggested more specific criteria were needed to enable manufacturers to choose consistently the appropriate information to be included in the now central "Highlights" section,⁸⁹ at least in part to prevent competitive disadvantage.⁹⁰ The FDA, acknowledging the concerns, suggested that it is "essential for FDA to review and approve most proposed changes to the information in Highlights" and consequently is

find specific information and to discern the most critical information." 71 Fed. Reg. at 3922.

⁸¹71 Fed. Reg. at 3923.

⁸²Id. The final regulation applies to new and recently approved drugs, approved after 2001, and the former labeling requirements will continue to apply to older approved drugs. Id. at 3923-3926.

⁸³Id. at 3929.

⁸⁴Id. at 3924.

⁸⁵Id. at 3930. FDA's guidance document on "Warnings and Precautions," intended to assist manufacturers with how to determine the content of the "Warnings and Precautions" section, states that it "does not establish legally enforceable responsibilities. Instead, Guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited." See Guidance for Industry, Warnings and Precautions, Contraindications, and Boxed Warnings Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format, at www.fda.gov/cder/guidance/indes.htm (January 18, 2006).

⁸⁶71 Fed. Reg. at 3932.

⁸⁷Id.

⁸⁸Id.

⁸⁹Id. at 3932.

⁹⁰Id..

revising its regulations on supplementing approvals.⁹¹

Consistent with the former regulation, the new regulation requires manufacturers to revise labeling to include warnings about “clinically significant hazards” as soon as there is reasonable evidence of a “causal association” with the drug.⁹² This language seems to require greater evidence of a connection between a drug and a risk about which a warning must be given unilaterally than its predecessor⁹³ though a causal relationship still is not required. Manufacturers continue to have “permission to add risk information to the Full Prescribing Information (FPI) without first obtaining FDA approval.”⁹⁴

Manufacturers maintain some discretion under the new regulation to choose what to say in their labeling and how to say, with considerable FDA oversight as before. Perhaps it is this necessary exercise of manufacturer discretion that prompted the FDA to include a section in the comments to the final regulation about the product liability implications of the proposed rule.⁹⁵

D. Proposed Preemptive Effect of the New Labeling Regulation

The FDA’s historical position has been that common law tort liability is an important component of the regulation of prescription drugs and that federal regulation is not intended to displace it.⁹⁶ The comments to the proposed final regulation argue, however, that product liability lawsuits have “directly threatened the agency’s ability to regulate manufacturer dissemination of risk information for prescription drugs.”⁹⁷ The FDA favored the concurrent operation of state tort law for almost the entire first century of its existence based on (1) its

⁹¹Id. at 3932. In particular, the FDA is revising 21 C.F.R. § 314.70(c)(6)(iii), the “safety valve” mentioned earlier at supra note , which permits a manufacturer to alter a label to introduce new and important safety information. Id.

⁹²Proposed Final Regulation, 21 C.F.R. § 201.57(a)(5), states: “In accordance with §§ 314.70 . . . the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established.” See 71 Fed. Reg. at 3990.

⁹³See supra note and accompanying text.

⁹⁴71 Fed. Reg. at 3934, 3969.

⁹⁵Id. at 3933.

⁹⁶See supra notes and accompanying text. See also Caraker v. Sandoz Pharms. Corp., 172 F. Supp. 2d 1018, 1036-1037 (S.D. Ill. 2001)(FDA historical position against preemption chronicled).

⁹⁷71 Fed. Reg. at 3933. The FDA cites three cases which arguably do not call for preemption alarm. Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1 (Cal. 2004), ultimately found that a FDA warning on nicotine replacement therapy drugs conflicted with, and thus preempted, a state warning, despite a savings clause in Food and Drug Administration Modernization Act of 1997 specifically protecting the requirement. Motus v. Pfizer, Inc. 358 F.3d 659 (9th Cir. 2004) was resolved in favor of the manufacturer on causation. In re Paxil Litigation, 296 F. Supp.2d 1374 (J.P.M.L. 2003), is in multi-district litigation consolidated proceedings.

inability to anticipate every way a consumer could be injured by the products it regulated, and (2) the lack of a federal remedy to provide redress for injured consumers.⁹⁸

The proposed final labeling regulation does not contain a specific section that addresses preemption but discusses the subject in the commentary. The FDA has formally regulated on preemption before, in its implementation of the Medical Device Amendments of 1976 to the FDCA.⁹⁹ In that statute, Congress included an express preemption provision which delegated to the FDA the authority to exempt state regulations from its preemptive effect and which permitted the FDA to assess the preemptive effect that the MDA and regulations promulgated pursuant to it would have on state laws.¹⁰⁰ As the Supreme Court said in *Medtronic, Inc. v. Lohr*,¹⁰¹ “FDA regulations implementing that grant of authority establish a process by which States or other individuals may request an advisory opinion from the FDA regarding whether a particular state requirement is pre-empted by the statute.”¹⁰²

Unlike the formally promulgated regulation under the MDA, the proposed new prescription drug labeling regulation does not contain a section on its preemptive effect but, rather, discusses product liability issues and preemption in the commentary.¹⁰³ That discussion reiterates the litigation positions taken in *Motus* and other product liability cases¹⁰⁴ which are

⁹⁸Motus Amicus Brief of Public Citizen, *supra* note 12 (“[W]hen Congress was considering legislation that ultimately was enacted as the Food, Drug, and Cosmetic Act of 1938, it made its intentions clear. Congress specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act on the ground that such a right of action already existed under state common law.” Citing Hearings Before Subcomm. of Comm. on Commerce on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933)). See also *Borden Co. v. Liddy*, 200 F. Supp. 221, 225 (S.D. Iowa 1961) (federal food labeling regulations provided a minimum level of safety which could be supplemented by more stringent state regulations); *Porter*, *supra* note 7 at .

⁹⁹21 U.S.C. § 360k (2006)(express preemption provision of Medical Device Amendments of 1976); 21 C.F.R. § 808.1 to 808.5 (2006) (regulations implementing preemption provision). For a discussion of preemption under the Medical Device Amendments, see *infra* notes and accompanying text.

¹⁰⁰21 U.S.C. § 360k(a)

¹⁰¹*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (interpreting express preemption provision of MDA; finding no preemption of common law damages claims).

¹⁰²*Id.* at 496.

¹⁰³71 Fed. Reg. at 3969. The National Conference on State Legislatures has expressed opposition “to the inclusion of language that would preempt state product liability laws” in the final regulation, and to the process by which the preemption language was included. See Letter to Secretary Mike Leavitt, Secretary, Department of Health and Human Services, from National Conference of State Legislatures, Re: Food and Drug Administration Final Rule on the Requirements on Content and Format of Labeling for Human Prescription Drugs, dated January 13, 2006.

¹⁰⁴71 Fed. Reg. at 3934: “In order to more fully address the comments expressing concern about the product liability implications of revising the labeling for prescription drugs, we believe it

inconsistent with the historical FDA position. To more fully understand the proposed preemption position taken in the labeling regulation, a deeper appreciation of the *Motus* case is necessary.

The amicus brief filed by the United States in *Motus v. Pfizer, Inc.* takes the position that state common law tort actions based on a prescription drug's warning inadequacies are preempted because any such claim would require a warning that the FDA has concluded is not required, thereby rendering the drug misbranded under the FDCA.¹⁰⁵ In *Motus*, plaintiff alleged that the warnings on the anti-depressant Zoloft were inadequate under state product liability laws because they did not emphasize sufficiently the association between use of the drug and an increased risk of suicide.¹⁰⁶ Prior to and in the course of approving Zoloft in 1991, the FDA explored the potential associations between the use of SSRI's and suicide that had been raised regarding other SSRI's, particularly Prozac.¹⁰⁷ Those concerns caused the FDA to convene a committee of experts, the Psycho-pharmacological Drugs Advisory Committee ("PDAC")¹⁰⁸ to consider the issue. In 1991, the PDAC unanimously found that "[o]n the question whether 'there is credible evidence to support a conclusion the antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors,'" there was no such evidence.¹⁰⁹ The FDA subsequently made suggestions to Pfizer regarding warning language it should incorporate in Zoloft labeling, asking Pfizer to "[p]lease use proposed text verbatim" which it did.¹¹⁰

Pfizer moved for summary judgment in *Motus* on the basis of implied conflict preemption.¹¹¹ The trial court denied the motion finding that the federal regulation which permits a manufacturer to alter a warning without prior FDA approval defeated any conflict with state product liability laws.¹¹² The trial court was persuaded as well by the FDA Commissioner's statement, in support of that regulation, that supported the role of unilateral manufacturer

would be useful to set forth in some detail the arguments made in those amicus briefs." The regulation suggests that preemption of state tort law is the FDA's "longstanding view" on preemption, *id.*, but that description is inconsistent with prior statements of the FDA.

¹⁰⁵Motus Brief of United States, *supra* note at 3.

¹⁰⁶*Motus v. Pfizer, Inc.*, 127 F. Supp.2d 1085, 1087 (C.D. Cal. 2001)(denial of summary judgment on issue of preemption), *rev'd* on other grounds, 358 F.3d 659 (9th Cir. 2004). The District Court's opinion contains a lengthy discussion of the regulatory history of Zoloft and other SSRIs.

¹⁰⁷127 F.Supp.2d at 1090.

¹⁰⁸*Id.* at 1088, 1090.

¹⁰⁹*Id.* at 1090. During the PDAC proceedings, the Director of the Division stated concern that an unintended side effect of modifying the labeling to raise an increased concern over suicidality "might be a reduction in the use of antidepressants in the treatment of depression, and that the result might cause overall injury to the public health." *Id.*

¹¹⁰*Id.* at 1088. Plaintiff contended that Pfizer drafted the ultimately approved labeling language, not the FDA. *Id.*

¹¹¹*Id.* at 1093. Pfizer also argued for implied conflict preemption based on the impossibility of being able to comply with both the federal and state requirements. *Id.* at 1092.

¹¹²*Id.* at 1094 (referring to 21 C.F.R. § 314.70(c)).

labeling changes to increase information provided to health care providers and enhance public safety.¹¹³ In addition, the trial court noted that while the FDA concluded that no labeling change was required based on its review of the scientific evidence, the “FDA never stated that it would be impermissible to include additional warnings.”¹¹⁴

In support of Pfizer’s appeal of the denial of summary judgment, the United States argued that while FDA regulations permit a drug’s manufacturer to alter or strengthen a warning, “ultimately, however, FDA, not each state court system applying its own standards, must approve the warning.”¹¹⁵ The United States disagreed with the suggestion that to constitute an actual conflict for preemption the FDA must reject a proposed warning change formally because “*all* imaginable warnings that could reasonably have been read as describing or alluding to [the association with suicidality] would have been false or misleading for lack of scientific support and therefore in conflict with federal law.”¹¹⁶ The brief concludes that any state common law damages action that resulted in requiring that a warning be given that was not approved would have misbranded the drug *per se*, thereby subjecting the manufacturer to penalties under the FDCA.¹¹⁷

The FDA’s position assumes that misbranding liability would be automatic. However, as a number of courts have recognized, the FDA must make a determination that a drug is misbranded and then seek injunctive relief from the federal district court before a final determination on the issue is reached and penalties ensue.¹¹⁸ The manufacturer is entitled to a jury trial on the issue, establishing that the ultimate decision on misbranding is not the FDA’s to make.¹¹⁹

The proposed final labeling regulation furthers the preemption position by generally

¹¹³Id. at 1094. The FDA Commissioner had stated, in support of the then current regulation:

The commissioner also advises that these labeling requirements do not prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling . . . of additional warnings . . . is not prohibited by these regulations . . . In the case of an approved NDA, 314.8(d) [now §314.70(c)(2)(i)] permits the addition to the drug's labeling . . . of information about a hazard without advance approval by the FDA.

Id. at 1094 (citing 21 Fed. Reg. 37447 (1979)).

¹¹⁴127 F. Supp. 2d at 1095.

¹¹⁵Id. at 13.

¹¹⁶Id. at 14.

¹¹⁷Id. at 16-17.

¹¹⁸*Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005). See also Amicus Brief of Public Citizen, *supra* note at 16 (filed April 21, 2003) (threat of enforcement action not enough to create a conflict; filing of enforcement does not guarantee that the FDA will prevail).

¹¹⁹21 U.S.C. § 332-334 (2006) (jury trial available on issue regarding injunctions, criminal penalties, and seizures).

arguing that state law actions frustrate the agency's implementation of federal objectives.¹²⁰ The FDA disagrees with the assertion widely made that its labeling requirements are "minimum safety standards" and charges that characterization as a "misunderstanding of the Act."¹²¹ The FDA takes the position that its regulations can establish both a floor and a ceiling.¹²² When additional labeling requirements may not be more protective of patients, "they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug."¹²³ The overwarning concern is supported in the regulation's commentary by a case in which a state court found federal preemption of an inconsistent state regulation, not a product liability action.¹²⁴ The FDA has expressed the overwarning concern in recent medical device cases seeking greater preemptive effect of its regulations.¹²⁵

After articulating the arguments in favor of preemption, the FDA identifies those claims which would be impliedly preempted by its proposed labeling regulation.¹²⁶ It protects manufacturers for choices they make about what to include in the new "Highlights" section of the regulation.¹²⁷ It also seeks to codify its position in *Motus* that if a label was proposed to the FDA and ultimately not required by the time plaintiff claims it should have been, the plaintiff's claim based on a failure to warn is preempted.¹²⁸

The FDA notes that its position on preemption in the final regulation is, in essence, a litigation position¹²⁹ which may change depending on the factual circumstances presented. The FDA acknowledges that some state common law damages actions will not be preempted¹³⁰ but it never speaks directly to the potential complementary way in which common law damages actions operate with FDA regulations by permitting compensation for injury and thereby creating an additional incentive to public safety.

The FDA claims that existing preemption principles undergird its preemption analysis. The proposed new regulation affects new and recently approved drugs, but the former regulation continues to apply to older drugs.¹³¹ Consequently, the FDA is attempting to alter its historical position against preemption and apply its new position retroactively to all drugs approved and

¹²⁰71 Fed. Reg. 3922, 3934.

¹²¹*Id.* at 3934-35.

¹²²*Id.* at 3935.

¹²³*Id.* This concern of overwarning was raised in the Zolof cases in support of preemption, but ultimately the FDA required a stronger warning of the heightened risk of suicidality which it had earlier rejected. See *supra* notes and accompanying text.

¹²⁴71 Fed. Reg. at 3935.

¹²⁵*Horn v. Thoratec Corp.*, 376 F.3d 163, 171 (3d Cir. 2004).

¹²⁶*Id.* at 3935-36.

¹²⁷*Id.* at 3936.

¹²⁸*Id.*

¹²⁹*Id.*

¹³⁰*Id.* at 3936 (those based on parallel federal and state requirements).

¹³¹See *supra* note and accompanying text.

regulated under the former regulation. Because of the FDA's attempt to distance itself from its historical position against preemption and, at the same time, rely on existing preemption principles, those principles must be fully explored. The next Section provides that exploration.

III. PREEMPTION UNDER THE FEDERAL FOOD AND DRUG LAWS

The Supreme Court has addressed the scope of federal preemption since the earliest days of the regulatory state. While this Article will emphasize preemption analysis under the food and drug laws, the Court's preemption doctrine generally has been the subject of much academic interest¹³² and that scholarship informs the following discussion.

A. *Preemption Doctrine Under the Pure Food and Drug Act of 1906*¹³³

Shortly after enactment of the first federal food and drug law, questions arose regarding how much state authority it displaced. In *Savage v. Jones*,¹³⁴ the Court was asked to determine whether the federal legislation affected an effort by the State of Indiana to require the inspection and additional labeling of an animal feed additive that federal regulators had concluded was not a food and, therefore, not subject to the federal Act's requirements.¹³⁵ The seller of the food additive claimed that it was marketed as an herbal treatment for animals, not as feed, and consequently escaped federal regulations.¹³⁶ Further, because Congress had regulated in the field, the seller argued that the states were entirely foreclosed from regulating.¹³⁷

The Court, after rejecting the argument that the Indiana statute was unconstitutional because of its interference with interstate commerce,¹³⁸ noted that Congress did not expressly declare its intention to prevent the States from regulating within the subject of food and drugs.¹³⁹ The Court then described the applicable implied preemption inquiry:

¹³²Symposium, *Federal Preemption of State Tort Law: The Problem of Medical Drugs and Devices*, 33 *Pepp. L. Rev.* 1 (2005); Davis, *On Preemption*, supra note ; Davis, *Unmasking the Presumption*, supra note ; Ausness, supra note ; Alexander Haas, *Chipping Away at State Tort Remedies Through Preemption: Geier v. American Honda Motor Co.*, 89 *Cal. L. Rev.* 1927 (2001); Susan Raeker-Jordan, *A Study in Judicial Sleight of Hand: Did Geier v. American Honda Motor Co. Eradicate the Presumption Against Preemption*, 17 *BYU J. PUB. L.* 1 (2002); Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 *WASH. & LEE U. L. REV.* 475, 503-510 (2002); Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 *U.C. DAVIS L. REV.* 1, 28-29 (2001); Caleb Nelson, *Preemption*, 86 *VA. L. REV.* 225, 290-91 (2000); Viet D. Dinh, *Reassessing the Law of Preemption*, 88 *GEO. L.J.* 2085 (2000).

¹³³34 Stat. at L. 768, U.S.Comp. Stat. Supp. 1911, p. 1354.

¹³⁴225 U.S. 501 (1912).

¹³⁵*Id.* at 509.

¹³⁶*Id.* at 511.

¹³⁷*Id.* at 512.

¹³⁸*Id.* at 528.

¹³⁹*Id.* at 533.

For when the question is whether a Federal act overrides a state law, the entire scheme of the statute must, of course, be considered, and that which needs must be implied is of no less force than that which is expressed. If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.

But the intent to supersede the exercise by the state of its police power as to matters not covered by the Federal legislation is not to be inferred from the mere fact the Congress has seen fit to circumscribe its regulation and to occupy a limited field. In other words, such intent is not to be implied unless the act of Congress, fairly interpreted, is in *actual conflict* with the law of the state.¹⁴⁰

The Indiana statute was not impliedly preempted because of two corollary principles the Court articulated: (1) Congress' implied purpose to preempt must be clearly manifested, and (2) the repugnance or conflict between the congressional purpose and the state regulation must be "direct and positive," so that the two acts could not be reconciled.¹⁴¹ The Indiana statute was found not to be in actual conflict with the federal regulation because it did not impose conflicting standards nor did it oppose federal authority—it rather added consistent, but more rigorous, regulation.¹⁴²

Savage v. Jones was decided decades before the onslaught of post-Depression era economic regulation and post-World War II civil rights and public interest regulatory. Preemption doctrine was in its infancy. Nevertheless, *Savage* is an important foundational case because it articulated implied conflict preemption doctrine in an early food and drug regulation matter. The Court continues to refer to *Savage's* articulation of implied conflict preemption analysis, suggesting its continuing influence.¹⁴³

Building on its discussion of implied preemption in *Savage*, the Court in 1913 decided

¹⁴⁰Id. (citations omitted) (emphasis added).

¹⁴¹Id. at 537. The Court relied for support on a case holding that a state statutory action for civil damages for transporting diseased cattle was not preempted by a federal statute regulating the animal industry because there was no obstruction of the purposes of Congress by permitting the states to impose civil damages. The Court stated, "May not these statutory provisions stand without obstructing or embarrassing the execution of the act of Congress? This question must, of course, be determined with reference to the settled rule that a statute enacted in execution of a reserved power of the state is not to be regarded as inconsistent with an act of Congress . . . unless the repugnance or conflict is so direct and positive that the two acts cannot be reconciled or stand together." *Id.* at 535. (citing *Missouri, K. & T. Rd. Co. v Haber*, 169 U.S. 613, 624 (date)).

¹⁴²*Savage*, 225 U.S. at 539.

¹⁴³*Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (explaining that Massachusetts' Burma law was impliedly preempted by foreign affairs power and congressional Burma Act). See also Davis, *Unmasking the Presumption*, supra note at 1012 (discussing re-emergence of *Savage* in Court's modern preemption cases).

McDermott v. Wisconsin.¹⁴⁴ In *McDermott*, Wisconsin had enacted a food labeling provision which appeared to be in direct conflict with a federal regulation. The Secretary of Agriculture, in charge of enforcing the food and drug laws, had concluded that the defendant's corn syrup label was in compliance with the federal statute's misbranding provision.¹⁴⁵ The Wisconsin statute required that, before sale, the complying federal label had to be removed and replaced with an alternate label.¹⁴⁶ To comply with the Wisconsin statute, therefore, the seller had to remove the federal label and, possibly, suffer penalties as a result of misbranding.¹⁴⁷ This is the first case in which the federal government, through the Secretary of Agriculture, took the position that a federal food or drug regulation preempted a state regulation.

The Court concluded that the state's attempt to regulate exclusively was an improper interference with Congress' authority.¹⁴⁸ The Court explained:

Conceding to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs, we think to permit such regulation as is embodied in this statute is to permit a state to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statute which have accrued both to the government and the shipper, and to impair the effect of a Federal law. . . .¹⁴⁹

The problem with the Wisconsin statute was its attempt at exclusivity: the regulated seller could not comply with both labeling requirements. Such "impossibility" of dual compliance has since become a category of implied conflict preemption which the Court identifies but rarely applies.¹⁵⁰

B. Early Preemption Doctrine under the Food, Drug and Cosmetic Act (FDCA) of 1938

Like its predecessor, the FDCA of 1938 does not have a generally applicable express preemption provision.¹⁵¹ Therefore, preemption under the FDCA, whether of state and local regulations or common law tort actions, must proceed under implied preemption doctrine.

Preemption doctrine during the years between the early twentieth century and the mid-twentieth century is generally marked by a more generous attitude toward state regulation.¹⁵²

¹⁴⁴228 U.S. 115 (1913).

¹⁴⁵*Id.* at 127.

¹⁴⁶*Id.* at 133.

¹⁴⁷*Id.*

¹⁴⁸*Id.* at 134.

¹⁴⁹*Id.*

¹⁵⁰See, e.g., *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963) (discussing implied preemption involving impossibility). See also Davis, *Unmasking the Presumption*, *supra* note at 984-85.

¹⁵¹See *supra* notes and accompanying text.

¹⁵²Davis, *Unmasking the Presumption*, *supra* note at 978.

During this time, the Supreme Court defined implied preemption doctrine more clearly and rarely found it. During the period from the 1940s to the 1980s, implied preemption doctrine coalesced into the now-standard categories of occupation of the field preemption and conflict preemption.¹⁵³

Occupation of the field preemption occurs where Congress' legislation is so comprehensive that it occupies the entire field, displacing all state law.¹⁵⁴ An important early example of such field preemption is *Hines v. Davidowitz*.¹⁵⁵ *Hines* found that a federal alien registration statute preempted all state regulation because of the national interest, based on the presence of foreign affairs concerns, in a uniform registration mechanism.¹⁵⁶ The Court found implied congressional intent to legislate fully and exclusively because of the core national interest at stake.¹⁵⁷

Conflict preemption occurs most frequently when the state law "stands as an obstacle" to the accomplishment of federal objectives and, therefore, must yield.¹⁵⁸ Preemption issues under the FDCA have typically involved state or local regulation which allegedly impacted the federal regulatory scheme. For example, in *Cloverleaf Butter v. Patterson*,¹⁵⁹ Alabama officials seized substantial quantities of packing stock butter, used by Cloverleaf Butter Company in the manufacture of processed butter sold in interstate commerce, because of concerns over its quality under state food and drug regulation.¹⁶⁰ The federal Department of Agriculture regulated the use of the packing stock butter¹⁶¹ and was not authorized to seize the product until after it was manufactured and moved in interstate commerce, when it might be considered adulterated.¹⁶² Consequently, the state law required seizure at a time which the federal law did not permit. The Company sought an injunction against the Alabama officials prohibiting them from seizing the packing stock butter.¹⁶³

The Supreme Court, relying on *Savage* and *McDermott*, concluded that the Alabama law was preempted.¹⁶⁴ The Court stated, "When the prohibition of state action is not specific but inferable from the scope and purpose of the federal legislation, it must be clear that the federal

¹⁵³Id. at 988.

¹⁵⁴*Hines v. Davidowitz*, 312 U.S. 52 (1941) (Alien Registration Act of 1940 occupied field, foreign affairs and national treatment of aliens intended to be exclusive).

¹⁵⁵*Hines v. Davidowitz*, 312 U.S. 52 (1941).

¹⁵⁶Id. at 72-74.

¹⁵⁷See Davis, Unmasking the Presumption, supra note at 978-79, 988-89.

¹⁵⁸See *Hillsborough County, Florida v. Automated Medical Labs., Inc.*, 471 U.S. 707, 712-713 (1985); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Hines v. Davidowitz*, 312 U.S. 52, 61 (1941).

¹⁵⁹*Cloverleaf Butter Co. v. Patterson*, 315 U.S. 786 (1942).

¹⁶⁰Id. at 165.

¹⁶¹Id. at 150. The Internal Revenue Service was also involved in regulating the product. Id.

¹⁶²Id. at 166.

¹⁶³Id. at 151.

¹⁶⁴Id. at 158-59.

provisions are inconsistent with those of the state to justify thwarting the state regulation.”¹⁶⁵ Recognizing that the line distinguishing cases of inconsistency is narrow, the Court found the case to be more like *McDermott* in which the state law prohibited what the federal law permitted.¹⁶⁶ The Court distinguished *Savage* because the state law in issue in that case required additional disclosures that the federal law neither required nor prohibited.¹⁶⁷ In *Savage*, federal law was agnostic on the value of the state regulation; in *McDermott* and *Cloverleaf Butter*, federal law appeared to be affirmatively against the state’s regulatory choice.

The majority’s finding of implied conflict preemption in *Cloverleaf Butter* was based on a minimal conflict¹⁶⁸ and reflects a broad definition of actual conflict in which the Court rejects the State’s argument that the two regulatory schemes could operate harmoniously.¹⁶⁹ The Court’s broad definition of the boundaries of federal authority was intended to minimize clashes between the regulating authorities and free the regulated industry from inconsistencies.¹⁷⁰ By contrast, the dissenting opinion emphasized “due regard for the maintenance of our dual system of government” which “demands that the courts do not diminish state power by extravagant inferences regarding what Congress might have intended if it had considered the matter, or by reference to their own conceptions of a policy which Congress has not expressed and is not plainly to be inferred from the legislation which it has enacted.”¹⁷¹ Sixty years after *Cloverleaf Butter Company* was decided, such arguments continue to be made on both sides of the preemption debate.

The Court did not address another FDCA preemption case until 1985 in *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*¹⁷² In the intervening years, the Court decided a number of implied preemption cases. Importantly, in *San Diego Building Trades Council v. Garmon*,¹⁷³ the Court was faced with an application of implied preemption doctrine to state common law damages actions.¹⁷⁴ *San Diego Building Trades Council* involved whether the National Labor Relations Act (NLRA) preempted state tort actions for damages by employers allegedly injured in the course of peaceful picketing by labor activists.¹⁷⁵ The Court spoke of the difficulty of ascertaining congressional intent when the enacting Congress, writing twenty-five years earlier, could not have foreseen the conflicts that would eventually arise.¹⁷⁶ In finding

¹⁶⁵Id. at 156.

¹⁶⁶Id. at 158-59.

¹⁶⁷Id. at 158.

¹⁶⁸See 315 U.S. 148, 172-73 (Stone, C.J., dissenting)(“complete want of conflict between the two statutes;” state statute “aids and supplements the federal regulation and policy”).

¹⁶⁹*Cloverleaf Butter Co.*, 315 U.S. at 169.

¹⁷⁰Id.

¹⁷¹315 U.S. 148, 177 (Stone, C.J., dissenting).

¹⁷²*Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

¹⁷³*San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959).

¹⁷⁴Id. at 237-39.

¹⁷⁵Id. at 241-46 (describing NLRA, as amended by the Labor Management Relations Act, 29 U.S.C. §§ 157, 158).

¹⁷⁶Id. at 240.

implied preemption based on a conflict with federal legislative objectives, the Court relied on two considerations: (1) the case involved national labor policy about which Congress had legislated “with broad strokes,”¹⁷⁷ and (2) state regulation can be exerted through common law damages actions as effectively as through more direct regulatory means.¹⁷⁸ These two features of implied preemption analysis, how to define the federal objectives with which state law arguably conflicts and the regulatory nature of common law damages actions, will be central to implied preemption analysis under the FDCA.

In the 1980s, the Court refined its approach regarding the effect of common law damages actions within implied preemption analysis. In *Silkwood v. Kerr-McGee Corp.*,¹⁷⁹ the Court was called upon to determine whether the Atomic Energy Act (AEA),¹⁸⁰ which regulated the nuclear energy industry, permitted state common law damages actions as a means of concurrent state regulation. Karen Silkwood alleged contamination with plutonium through irregularities at the Kerr-McGee Corp. nuclear power plant where she worked and sought personal injury and punitive damages under negligence and strict liability doctrines.¹⁸¹

The AEA was enacted in 1954 to free the nuclear energy industry from total federal control and to provide for private involvement.¹⁸² Some limited regulatory authority was given to the states which had never before had any authority over nuclear power.¹⁸³ The states were precluded, however, from regulating the safety aspects of nuclear material.¹⁸⁴ Thus, the preemption provision of the AEA carved out of federal dominion some small state regulatory authority.

The Supreme Court concluded unanimously that the AEA did not preempt Silkwood’s compensatory damages action.¹⁸⁵ The Court, after reviewing the Act’s legislative history and other congressional actions regarding the AEA,¹⁸⁶ stated, “It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal

¹⁷⁷Id.

¹⁷⁸Id. at 246-47. For a more complete discussion of the importance of San Diego Building Trades Council, see Davis, *Unmasking the Presumption*, supra note at 982-983.

¹⁷⁹*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).

¹⁸⁰42 U.S.C. §§ 2011 et seq (date). The AEA is administered by the Nuclear Regulatory Commission, formerly the Atomic Energy Commission. See id. § 2073 (defining NRC authority).

¹⁸¹*Silkwood*, 464 U.S. at 243.

¹⁸²The Atomic Energy Act of 1954, 68 Stat. 919, 42 U.S.C. §§ 2011-2284.

¹⁸³*Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm’n*, 461 U.S. 190 (1983).

¹⁸⁴42 U.S.C. § 2021(c)(4).

¹⁸⁵*Silkwood*, 464 U.S. at 246. A majority of the Court held that the AEA similarly did not preempt Silkwood’s punitive damages claim. Id.

¹⁸⁶Id. at 249.

conduct.”¹⁸⁷ The regulatory effect of common law damages actions was recognized but considered consistent with federal objectives in the absence of clear congressional intent to prohibit them.

One year later, the Court addressed a preemption challenge under the FDCA, though not one involving the regulatory effect of common law damages actions. In *Hillsborough County Florida v. Automated Medical Laboratories, Inc.*,¹⁸⁸ a Florida county sought to regulate the collection of blood plasma from paid donors by requiring additional limitations to those required under federal regulations.¹⁸⁹ The defendant blood plasma center argued for preemption under both implied occupation of the field and conflict preemption.¹⁹⁰ The Supreme Court disagreed and reversed an appellate court finding of preemption.¹⁹¹

The Court, after describing the basic implied preemption doctrines applicable,¹⁹² noted that the defendant “faces an uphill battle” in arguing for implied preemption. The hurdles to preemption fell into two categories: (1) prior agency position against preemption;¹⁹³ and (2) the presumption that state or local regulation of matters related to health and safety can constitutionally coexist with federal regulation.¹⁹⁴

The Court rejected occupation of the field preemption even though the regulations were comprehensive,¹⁹⁵ noting that “merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field.”¹⁹⁶ The Court was “even more reluctant” to infer field preemption from regulations than from statutes, saying, “To 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.”¹⁹⁷ The Court found persuasive that the FDCA had neither altered its position on preemption since the regulations were originally enacted a decade earlier, nor had the agency otherwise made its intentions clear regarding preemption.¹⁹⁸ The

¹⁸⁷Id. at 251 (“Indeed, there is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress’ failure to provide any federal remedy for persons injured by such conduct.”).

¹⁸⁸*Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

¹⁸⁹Id. at 710.

¹⁹⁰Id. at 714.

¹⁹¹Id. at 712.

¹⁹²Id. at 713. Preliminarily, the Court confirmed that preemption of local ordinances is analyzed in the same way as the preemption of statewide laws. Id.

¹⁹³Id. at 714.

¹⁹⁴Id. at 715.

¹⁹⁵Id. at 716.

¹⁹⁶Id. at 717.

¹⁹⁷Id.

¹⁹⁸Id. at 718.

federal interest was not so dominant to justify occupying the field given the historic primacy of state regulation in matters of health and safety.¹⁹⁹

Similarly, the Court rejected the implied conflict preemption argument.²⁰⁰ The Court found the purported conflict to be speculative: the increased cost to plasma collection operators and an increased burden on donors imposed under the local regulation did not necessarily interfere with the federal goal of maintaining an adequate plasma supply.²⁰¹ According to the Court, neither Congress nor the FDA had struck a particular balance between safety and quantity; rather, “the regulations which contemplated additional state and local requirements merely establish minimum safety standards.”²⁰² Finally, the Court noted that the FDA could promulgate preemption regulations “with relative ease” but it had not done so.²⁰³ The Court attached significance to the absence of either a FDA position or formal regulation on preemption.

Hillsborough County is a strong pro-state regulation preemption decision under the FDCA. The Court had found preemption under the FDCA only in narrow cases involving impossibility²⁰⁴ and those cases rested on shaky ground after the increasingly narrow definition of actual conflict the Court began to use subsequent years.²⁰⁵ It appears that common law damages actions would survive the preemption hurdles defined by the Court. If the local regulations at issue in *Hillsborough County* did not create the kind of obstacle to federal objectives required to preempt, the more indirect regulation of common law damages actions would surely not be sufficient, particularly given the long tradition of permitting such actions.

C. *The Rise of Express Preemption Doctrine and the FDCA: Of Cipollone and Medtronic*

A short seven years after *Silkwood*, the Court would re-evaluate preemption doctrine as it applied to common law damages actions. In *Cipollone v. Liggett Group, Inc.*,²⁰⁶ the Court, applying preemption doctrine in a products liability action for the first time, concluded that where Congress has included an express preemption provision, and that provision provides a “reliable indicium of congressional intent,” the provision controls and an implied preemption analysis is unnecessary.²⁰⁷ In such a case, the Court’s task was only to determine the scope of the provision.²⁰⁸ Rarely had the Court given exclusive control to an express preemption provision,

¹⁹⁹Id. at 719. Prior field preemption cases had involved a “special feature” supporting preemption--the foreign affairs power. Id. (citing *Hines v. Davidowitz*, 312 U.S. 52 (1941)).

²⁰⁰Id. at 720.

²⁰¹Id.

²⁰²Id. at 721.

²⁰³Id.

²⁰⁴See supra notes ____ and accompanying text (discussing *McDermott and Cloverleaf Butter*).

²⁰⁵See supra notes ____ and accompanying text (discussing *Silkwood*); see also Davis, *Unmasking the Presumption*, supra note at 983-986, 989 (discussing narrowing of implied preemption doctrine during 1960s and 1970s).

²⁰⁶*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

²⁰⁷Id. at 517.

²⁰⁸Id. at 518, 523.

particularly as it applied to common law damages actions.²⁰⁹ *Cipollone*'s focus on defining the scope of congressional intent narrowly out of respect for the presumption against preemption of traditional state health and safety regulations and its discussion of the regulatory effect of common law damages actions are important in the implied preemption context.

Cipollone involved the preemptive effect of the federal cigarette labeling and advertising laws on products liability actions.²¹⁰ The Court mentioned the presumption against federal preemption of matters historically within the states' police powers, and emphasized the prominence of discerning congressional intent.²¹¹ The plurality opinion, written by Justice Stevens, used the text of the provisions, which referred to state "requirements or prohibitions" as forbidden, and the legislative history to preempt some, but not all, common law damages actions.²¹² The plurality acknowledged that common law damages actions can have an indirect regulatory effect²¹³ but the dissenting justices recognized that the Court's preemption cases "have declined on several recent occasions to find the regulatory effects of state tort law direct or substantial enough to warrant preemption."²¹⁴

In its next products liability preemption cases, the Court adhered to its *Cipollone* analysis and exclusively analyzed the express preemption provisions of the National Traffic and Motor Vehicle Safety Act (NTMVSA)²¹⁵ and the Federal Railroad Safety Act.²¹⁶ In both cases the express preemption provisions were found not to preempt the damages actions in issue²¹⁷ but the Court left room for the operation of implied preemption principles in the event that Congress' intent could not be clearly established from the express provision.²¹⁸

²⁰⁹See Davis, Unmasking the Presumption, supra note __, at 1001.

²¹⁰Federal Cigarette Labeling Act of 1965, 15 U.S.C. §§ 1331-1341 (2000); Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331-1341 (2000)(as amended).

²¹¹*Cipollone*, 505 U.S. at 516.

²¹²505 U.S. at 521-524. The 1965 cigarette labeling act's preemption provision stated that "No statement relating to smoking and health" shall be required on cigarette packages or in advertising." 15 U.S.C. § 1335. The 1969 act changed the preemption provision slightly to state that "No requirement or prohibition based on smoking and health shall be imposed under State law" regarding cigarette labeling or advertising. *Id.* The use of the phrase "requirement or prohibition" was critical to the Court's analysis of whether common law damages actions were prohibited. *Cipollone*, 505 U.S. at 522-524.

²¹³*Id.* at 524.

²¹⁴*Id.* at 537 (Blackmun, J., dissenting)(referencing *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988); *English v. General Electric Co.*, 496 U.S. 72 (1990), and *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984)).

²¹⁵15 U.S.C. § 1392(d) (codified as amended at 49 U.S.C. § 30103(b)(1)), analyzed in *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995)(no preemption because federal agency had not promulgated regulation addressing product feature in issue).

²¹⁶*CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 662 (1993)(the FRSA did not preempt state common law damages actions; preemption provision specifically exempts concurring, non-conflicting, state regulations from its operation).

²¹⁷*Freightliner Corp.*, 514 U.S. at 284; *CSX Transp., Inc.*, 507 U.S. at 662.

²¹⁸*Freightliner Corp.*, 514 U.S. at 284.

The Court's next preemption opinion, *Medtronic, Inc. v. Lohr*,²¹⁹ involved preemption under the Medical Device Amendments of 1976 (MDA) to the FDCA.²²⁰ The MDA directs the FDA to regulate the safety and effectiveness of medical devices depending on the marketing approval method and type of medical device involved.²²¹ Congress included an express preemption provision in the MDA which provides that states may not establish "any requirement" which is "different from or in addition to" any FDA imposed requirement regarding a device's safety or effectiveness.²²² In *Medtronic*, defendant sought preemption of plaintiff's design and manufacturing defect claims regarding its pacemaker because the device had been approved through a pre-market notification process under the MDA.²²³ The Court was divided on whether the MDA preempted the plaintiffs claims, but all justices agreed that the express preemption provision controlled the analysis.²²⁴

The Court reiterated the historic primacy of state regulation "to protect the health and safety of their citizens" which supports the "great latitude" states have had to govern in this area.²²⁵ Consequently, the majority opinion precisely considered the language of the express preemption provision.²²⁶ The pre-market notification process, under which the pacemaker had been approved, did not include specific requirements.²²⁷ The plurality opinion concluded that common law damages actions based on design or labeling defects were not "requirements" for purposes of the statute, stating that "we have long presumed that Congress does not cavalierly preempt state law causes of action. . . That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety."²²⁸

A majority of the justices, four in dissent and Justice Breyer in concurrence, thought that common law damages actions generally do impose requirements, and, therefore, may be preempted under the statute if they differ from a federal requirement.²²⁹ Justice Breyer, whose

²¹⁹*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

²²⁰21 U.S.C. § 360k (2000).

²²¹See *Medtronic*, 518 U.S. at 475-80 (detailing history of MDA and its regulatory scheme).

²²²21 U.S.C. § 360k(a) (2000).

²²³518 U.S. at 477.

²²⁴*Id.* at 484-85, 503 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring and dissenting). Justice Stevens' plurality opinion suggested that actual conflict implied preemption analysis may be appropriate in certain circumstances even when an express preemption provision was in issue, and cited *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995). *Id.* at 503.

²²⁵*Medtronic*, 518 U.S. at 475 (citing *Hillsborough County*, 471 U.S. 707, 719 (1985)).

²²⁶*Id.* at 487-88.

²²⁷This pre-market notification requirement, also known as the 510k notification process, permits marketing of devices that are substantially equivalent to a device already on the market and is not as rigorous as the pre-market approval process required of entirely new devices. See *Medtronic*, 518 U.S. at 476-80 for a description of the processes and their differences. See also, S. Foote, *Managing the Medical Arms Race: Innovation and Public Policy in the Medical Device Industry* (1992).

²²⁸*Medtronic*, 518 U.S. at 493-94.

²²⁹*Id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

opinion provided the final vote against preemption, complained of the “highly ambiguous” nature of the preemption provision in issue which required that courts look elsewhere for help as to “just which federal requirements preempt just which state requirements, as well as just how they might do so.”²³⁰ Justice Breyer stated that express preemption provisions should be interpreted based on their “clear congressional command,” if one exists. If none, courts may infer that the “relevant administrative agency possess a degree of leeway” to proscribe the preemptive effect of its regulations.²³¹

All three *Medtronic* opinions explored the importance of agency position and interpretation of agency regulations in determining the scope of preemption.²³² The justices disagreed on the extent to which they should rely on an agency’s position on preemption, though in earlier cases the Court had noted that agency regulations could be informative on defining the scope of preemption where consistent with statutory language.²³³ The FDA had adopted a regulation explaining its position on the scope of MDA preemption²³⁴ consistent with the authority granted to it by Congress to do so.²³⁵ The plurality opinion’s interpretation of the scope of the preemption provision was “substantially informed” by the agency’s regulations²³⁶ because of the “unique role”²³⁷ given to it by Congress to implement provisions of the Act.²³⁸ The plurality, after comparing the state common law requirements to the “entirely generic concerns” of the federal regulations, concluded that “these general [common law] obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force.”²³⁹

²³⁰Id. at 505.

²³¹Id.

²³²Id. at 495-96 (“The FDA regulations interpreting the scope of § 360k’s pre-emptive effect support the Lohrs’ view, and our interpretation of the pre-emption statute is substantially informed by those regulations.”); id. at 505-06 (Breyer, J., concurring); id. at 511-12 (O’Connor, J., dissenting).

²³³*CSX Transp. Inc. v Easterwood*, 507 U.S. 658, 670 (1993) (involving preemption of common law damages actions under the Federal Railroad Safety Act); *Norfolk & Southern Railway Co. v. Shanklin*, 529 U.S. 344, 355 (2000) (same; agency position on preemption not persuasive when inconsistent with prior agency position and with statutory scheme). See Davis, On Preemption, *supra* note at 208 (discussing *CSX Transp. v. Easterwood* and *Norfolk & Southern Ry v. Shanklin*).

²³⁴21 C.F.R. § 808.1(d) (2000) (no preemption of state or local requirements that are “equal to, or substantially identical to, requirements” imposed under the MDA); id. at § 808.1(d)(1) (no preemption of “State or local requirements of general applicability”). See *Medtronic*, 518 U.S. at 496-97.

²³⁵21 U.S.C. § 360k(b)(2000).

²³⁶518 U.S. at 495.

²³⁷Id. at 496.

²³⁸Id. (citing 21 U.S.C. § 371(a)). The plurality also noted that the FDA is uniquely qualified to determine whether a particular form of state law “stands as an obstacle” to the fulfillment of federal objectives. Id. (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

²³⁹518 U.S. at 501-02.

Justice Breyer concurred, agreeing that “the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.”²⁴⁰ In particular, the FDA has a “special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives . . . The FDA can translate these understandings into particularized pre-emptive intentions accompanying its various rules and regulations.”²⁴¹ Justice Breyer concluded that the express preemption provision did not fully answer the preemption question.²⁴² Consequently, he considered implied preemption principles applicable, in conjunction with the FDA’s own regulatory understanding of preemption, to conclude that there was no actual conflict between the federal requirements and the common law “liability-creating premises” of state tort law.²⁴³

D. Implied Conflict Preemption and the FDCA: Of Geier and Buckman Co.

Justice Breyer authored the Court’s next opinion on the preemption of common law damages actions, *Geier v. American Honda Motor Company*,²⁴⁴ which firmly reinstated implied conflict preemption doctrine as central to preemption analysis. In *Geier*, the Court was asked to analyze the effect of the express preemption provision in the National Traffic and Motor Vehicle Safety Act (“NTMVSA”) on a lawsuit alleging that a 1987 Honda was defective in design because it did not have a driver’s side air bag.²⁴⁵ The NTMVSA contains a preemption provision which states that whenever a federal motor vehicle safety standard, “FMVSS,”²⁴⁶ is in effect, states may not establish or continue in effect any “safety standard applicable to the same aspect of performance” which is not identical to the federal standard.²⁴⁷ The statute also contains a “savings clause:” “Compliance with any Federal motor vehicle safety standard issued under this sub-chapter does not exempt any person from any liability under common law.”²⁴⁸

The Department of Transportation issued FMVSS 208 regarding Occupant Crash Protection in 1967.²⁴⁹ After several revisions, the 1984 version, in issue in *Geier*, permitted

²⁴⁰Id. at 505-06 (citing *Hillsborough County*, 471 U.S. 707, 721 (1985)).

²⁴¹Id. at 506.

²⁴²Id. at 505.

²⁴³Id. at 508.

²⁴⁴*Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

²⁴⁵Id. at 865. The National Traffic and Motor Vehicle Safety Act of 1966, 80 Stat. 718, 15 U.S.C. § 1381 et. seq. (1988 ed.). The statute was re-codified in 1994 at 49 U.S.C. §§ 30101-30169 (1994 & Supp. 1999).

²⁴⁶15 U.S.C. § 1391(2): safety standard is a “minimum standard for motor vehicle performance, or motor vehicle equipment performance.”

²⁴⁷Id. § 1392(d) (codified at 49 U.S.C. 30103(b)(1)).

²⁴⁸Id. § 1397(k).

²⁴⁹See *Pub. Citizen v. Steed*, 851 F.2d 444, 445 (D.C. Cir. 1988) (“Passive restraint regulation (Standard 208) has advanced over the years along a protracted, winding, sometimes perilous course.”). See also *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 34-38 (1983) (history of Standard 208).

manufacturers to choose, with some restrictions, between air bags and seat belt systems.²⁵⁰ Ms. Geier’s 1987 Honda did not have a driver’s side air bag. She was injured as a result and sued the manufacturer based on the vehicle’s defective design.²⁵¹

Justice Breyer, writing the majority opinion, mirrored his analysis from *Medtronic*, concluding that the express preemption provision did not preempt plaintiff’s common law actions because that provision, read together with the savings clause, did not disclose congressional intent to defeat product liability claims in the face of only a federal minimum standard of safety.²⁵² The Court then asked whether the savings clause also prevented the operation of “ordinary pre-emption principles insofar as those principles instruct us to read statutes as preempting state laws (including common law rules) that *actually conflict* with the statute or federal standards promulgated thereunder?”²⁵³ The Court concluded it did not, reasoning that it would be impermissible “to take from those who would enforce a federal law the very ability to achieve the law’s congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect.”²⁵⁴

The Court found that an “actual conflict”²⁵⁵ existed and thus plaintiff’s common law actions were preempted.²⁵⁶ A number of factors were important in making that determination. First, the Court rejected as conclusive the statutory definition of federal standards as “minimum” standards of care.²⁵⁷ Instead, the Court reviewed carefully the objectives of the regulation itself. In doing so, the views of the Secretary of Transportation were very influential.²⁵⁸ The Court relied on comments to the standard and the current Secretary’s position, “through the Solicitor General, [that] the 1984 version of FMVSS 208 ‘embodies the Secretary’s policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car.’”²⁵⁹ The Court’s review of the regulation

²⁵⁰Geier, 529 U.S. at 865. See 49 C.F.R. § 571.208; 49 Fed. Reg. 28999 (1984) (Standard 208). For a full discussion of the administrative history of FMVSS 208, see Geier, 529 U.S. at 875-877; *id.* at 889-892 (Stevens, J., dissenting). See also Ralph Nader and Joseph Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 *Geo. Wash. L. Rev.* 415 (1996).

²⁵¹Geier, 529 U.S. at 865.

²⁵²*Id.* at 868.

²⁵³*Id.* at 869.

²⁵⁴*Id.* at 872. The Court had shown concern for “careful regulatory scheme[s] established by federal law” in its prior implied conflict preemption cases and the regulatory scheme in Geier deserved such concern. *Id.* at 870 (quoting *United States v. Locke*, 529 U.S. 89, 106-07 (2000)).

²⁵⁵By relying on “actual conflict” preemption, the Court rejected a categorization of its implied preemption doctrine, noting it “sees no grounds . . . for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.” *Id.* at 874.

²⁵⁶*Id.* at 883.

²⁵⁷49 U.S.C. § 30102(a)(9).

²⁵⁸Geier, 529 U.S. at 875-880 (relying on Secretary’s comments in DOT rule-making in 1984).

²⁵⁹*Id.* at 881.

identified the Secretary's efforts to balance a variety of concerns which impacted its primary objective of consumer safety, including obstacles to consumer acceptance of restraint devices, industry reluctance to adopt restraint devices, and Congress' responses to a variety of public pressures regarding the restraints.²⁶⁰

Second, in defining the federal objectives in issue, the Court relied to a significant extent on the National Highway Transportation Safety Administration's (NHTSA's) position on the matter.²⁶¹ The Court justified its reliance on the agency's position based on 1) the technical subject matter; 2) the complex and extensive nature of the relevant history and background; and 3) the agency's "uniquely qualified" position to comprehend the likely impact of state requirements.²⁶² The consistency of the Secretary of Transportation's position on preemption over time was also influential in permitting the considerable deference the Court showed to it.²⁶³

The Court weighed the stated federal objectives against the general interest that the states have in promoting the health and welfare of citizens by compensating for personal injuries suffered as a result of defective products. The Court did not mention the presumption against preemption²⁶⁴ but it discussed the state's general interest in the health and welfare of its citizens.²⁶⁵ The Court was sympathetic to this important concern.²⁶⁶ Nevertheless, the Court was of the strong opinion that the state and federal objectives could not be reconciled: "Such a state law--i.e. a rule of state tort law imposing such a duty--by its terms would have required manufacturers of all similar cars to install air bags rather than other passive restraint systems, . . . It thereby would have presented an obstacle to the variety and mix of objectives that the federal regulators sought."²⁶⁷

Finally, the plaintiff argued that a jury finding of defectiveness based on the lack of an air bag did not conflict with the federal objectives; indeed, state law promoted those objectives.²⁶⁸ While acknowledging that Congress intended some nonuniformity in the regulatory system it created, the Court concluded that jury-assessed standards would lead to unpredictability and uncertainty in the standard of due care.²⁶⁹ While acknowledging that "tort law may be somewhat different, and that related considerations--for example, the ability to pay damages instead of modifying one's behavior--may be relevant for pre-emption purposes,"²⁷⁰ the Court found those

²⁶⁰Id.

²⁶¹Id. at 878.

²⁶²Id.

²⁶³For a proposal that would consider agency determinations of preemption only if they were part of the rule-making process when the regulation was formulated, see Ausness, *supra* note 4, at 50.

²⁶⁴See *id.* at 894 (Stevens, J., dissenting). See also Davis, *Unmasking the Presumption*, *supra* note ____, at 1008; Raeker-Jordan, *supra* note ____, at 8-9.

²⁶⁵529 U.S. at 880.

²⁶⁶Id. at 881.

²⁶⁷Id..

²⁶⁸Id. at 882.

²⁶⁹Id..

²⁷⁰Id.

considerations not to be persuasive in this instance.

The Court's next preemption case again involved the Medical Device Amendments of the FDCA. In *Buckman Company v. Plaintiff's Legal Committee*,²⁷¹ the Court was called upon to determine whether the MDA preempted the plaintiff's fraud claim based on the defendant's misrepresentations to the FDA to obtain approval of its orthopedic bone screws.²⁷² The Court used implied conflict preemption principles without engaging in an express preemption analysis, stating that the express preemption provision did not cover the matter so implied conflict preemption must operate.²⁷³ Because policing fraud on a federal agency was not a subject which states had traditionally governed, no presumption against preemption would operate unlike cases involving the historic primacy of state regulation over other health and safety matters.²⁷⁴

The Court began by identifying federal objectives: the federal regulatory scheme empowers the FDA to protect itself from and to deter fraud.²⁷⁵ The Court emphasized the need for flexibility in enforcing that regulatory scheme given its other "difficult (and often competing) objectives," including generally protecting medical care practitioners from unnecessary interference with the practice of medicine.²⁷⁶ The Court did not mention the FDA's position on the preemption issue, central to *Medtronic* and *Geier*, but the concurring opinion noted that the FDA had waffled on the preemptive effect of its regulatory objectives on state fraud-on-the-FDA claims.²⁷⁷

The Court then evaluated the state law interest at stake to determine whether an actual conflict existed. The tort law deterrent effect could increase burdens on the medical device industry, potentially discouraging the request for approval of devices that might have beneficial off-label uses, in contravention of the stated goal of non-interference with medical practice.²⁷⁸ Similarly, the cost that recognizing state law fraud claims would impose on the industry could

²⁷¹*Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001)

²⁷²*Id.* at 344. For a complete description of the fraud allegations, see Ausness, *supra* note at ; and Owen, *supra* note at 427-28.

²⁷³*Buckman Co.*, 531 U.S. at 347-348, n. 2 ("we express no view on whether these claims are subject to express preemption"). The Court also swiftly concluded there was no presumption against preemption where the interests at stake are uniquely federal. *Id.* at 347.

²⁷⁴*Id.* at 347-48.

²⁷⁵*Id.* at 348-349.

²⁷⁶*Id.* at 349-350.

²⁷⁷*Id.* at 354, n. 2 (Stevens, J., concurring: "Though the United States in this case appears to take the position that fraud-on-the-FDA claims conflict with the federal enforcement scheme even when the FDA has publicly concluded that it was defrauded and taken all the necessary steps to remove a device from the market, that has not always been its position. As recently as 1994, the United States took the position that state tort law suits alleging fraud in FDA applications for medical devices do not conflict with federal law where the FDA has 'subsequently concluded' that the device in question never met the appropriate federal requirements and 'initiated enforcement actions' against those responsible.").

²⁷⁸*Id.* at 350.

create approval delays of valuable devices, agency administrative inefficiency, and delay in the provision of health care.²⁷⁹ The Court saw no corresponding benefit to the application of state law because it was not based on a common law duty of care, but rather on a federal regulation.²⁸⁰ The Court noted, however, that a traditional state tort action might survive.²⁸¹

E. Last Words on Implied Preemption Doctrine: Of Sprietsma and Bates

The Court's next two preemption opinions, *Sprietsma v. Mercury Marine*²⁸² and *Bates v. Dow Agrosciences LLC*²⁸³ provide additional insight into the Court's implied conflict preemption analysis though both involve express preemption provisions. Both cases address the importance of agency position on preemption and the value of common law damages actions in regulating conduct.

Sprietsma involved allegations of design defect against manufacturers of recreational boats that did not have propeller guards.²⁸⁴ The Federal Boat Safety Act of 1971 ("FBSA")²⁸⁵ gave the Secretary of Transportation authority, delegated to the Coast Guard, to establish "a coordinated national boating safety program" including authority to promulgate safety standards for boating equipment to establish uniform safety regulations.²⁸⁶ The Coast Guard, after gathering data and holding public hearings over a several year period, decided *not* to require such guards for reasons of safety, feasibility and economics.²⁸⁷ Neither did the Coast Guard forbid the use of such guards.²⁸⁸ In defense of *Sprietsma*'s claim of design defect, the manufacturer argued that the Coast Guard's decision not to require a propeller guard preempted plaintiff's claim.²⁸⁹ The FBSA contains both an express preemption provision and a savings clause.²⁹⁰

The Court, consistent with *Geier*, found no express preemption and engaged in an

²⁷⁹*Id.* at 351.

²⁸⁰*Id.* at 352-53 (plaintiff not relying on traditional state tort law; existence of federal enactment is critical element of claim, contrasting *Silkwood* and *Medtronic*).

²⁸¹*Id.* ("In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question.").

²⁸²*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

²⁸³*Bates v. Dow Agrosciences LLC*, 125 S.Ct. 1788 (2005).

²⁸⁴*Id.* at 55. Plaintiff's wife had been thrown from a boat and was killed when struck by the propeller blades. *Id.*

²⁸⁵46 U.S.C. §§ 4301-4311 (2000).

²⁸⁶S. Rep. No. 92-248, at 1333-35, reprinted in 1971 U.S.C.C.A.N. 1333.

²⁸⁷*Sprietsma*, 537 U.S. at 58. The Coast Guard referred the study to the National Boating Safety Advisory Council, as required under the statute. 46 U.S.C. §§4302 (c)(4) (2000). The Advisory Council's 1990 recommendation stated that the data did not support the adoption of a regulation requiring propeller guards, but it would continue to monitor the issue for additional information on the state of the design art. *Sprietsma*, 537 U.S. at 59 (quoting 1990 letter to the Advisory Council).

²⁸⁸*Id.*

²⁸⁹*Id.* at 55.

²⁹⁰*Id.* at 55-56.

implied conflict preemption analysis.²⁹¹ The Court assessed the strength of the federal and state governmental policies at stake to determine whether an actual conflict was presented. The Court noted that the emphasis of Coast Guard regulations has been to preserve state authority pending the adoption of specific federal regulations.²⁹² The Coast Guard's position on preemption, therefore, was in favor of permitting state common law claims.²⁹³ While the Court noted that a federal agency decision not to regulate might have preemptive force, the Court found no such force in this case because of the more prominent safety objectives motivating the Coast Guard's decision.²⁹⁴

The Court's most recent preemption decision involved express preemption principles but the Court made some important, general observations about the delicate balance that must be achieved in determining the scope of preemption. *Bates v. Dow Agrosciences LLC*,²⁹⁵ involved whether common law tort actions challenging the labeling of defendant's pesticide were preempted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).²⁹⁶ The lower courts had found express preemption of all claims based on a statutory provision forbidding states from imposing requirements for labeling "in addition to or different from" those required under FIFRA.²⁹⁷ The lower courts reasoned that a jury finding under state law would *induce* the defendant to alter its pesticide labeling which the Environmental Protection Agency had approved (EPA).²⁹⁸ The EPA had taken inconsistent positions on preemption within the previous five years, first in favor of the operation of state tort law, as proposed in an amicus brief submitted in a prior case²⁹⁹ and then in favor of preemption as proposed in an amicus brief submitted in *Bates*.³⁰⁰

The Court's discussion of the history of FIFRA regulation reads much like the history of FDCA regulation. For example, the Court notes that "Prior to 1910, the States provided the primary and possibly the exclusive source of regulatory control over the distribution of poisonous substances."³⁰¹ The history of the FDCA regarding drugs is virtually identical. In addition, FIFRA imposes misbranding liability for labels that are false or misleading in any particular,³⁰² just as the FDCA does for prescription drugs and devices. The inclusion in 1972 of an express

²⁹¹Id. at 63-64.

²⁹²Id.

²⁹³Id. at 65-66. The Court emphasized the Government's consistent position that the regulation did not have any pre-emptive effect. Id. at 66.

²⁹⁴Id. at 69-70. Finally, the general federal interest in uniformity was an insufficient objective, without more, to create a conflict. Id. at 70.

²⁹⁵*Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788 (2005).

²⁹⁶Id.

²⁹⁷Id. at 1796.

²⁹⁸Id. at 1793-94 (emphasis supplied).

²⁹⁹*Etcheverry v. Tri-Ag Service, Inc.*, 993 P. 2d 366 (2000) (Brief Amicus Curiae for Unites States).

³⁰⁰125 S. Ct. at 1794, fn. 7.

³⁰¹Id. at 1794.

³⁰²Id. at 1795.

preemption provision which governs the continuing role of the states in pesticide regulation is the primary difference between the two statutory schemes.³⁰³ In addition, the EPA does not determine or endorse the efficacy of pesticides it approves for marketing,³⁰⁴ unlike the FDA's drug approvals which do review the efficacy claims in drug applications.

The Court noted that courts have entertained tort litigation for decades against pesticide manufacturers, both before and after the enactment of FIFRA in 1947, and that it was not until after *Cipollone* in 1992 that a "groundswell" of preemption arguments based on FIFRA preemption were advanced.³⁰⁵ The FIFRA regulatory scheme incorporates a significant role for the states, but the express preemption provision required the Court to determine its scope nevertheless. The Court found no preemption of most claims but remanded for further inquiry regarding the labeling claims.³⁰⁶

The Court rejected the claim, relied on by the lower courts, that simply because a jury verdict might have an effect on a manufacturer, that the damages action was therefore preempted because it might induce a labeling change.³⁰⁷ "A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement."³⁰⁸ Consequently, state law requirements that are "equivalent to or consistent with" FIFRA regulations survived.³⁰⁹ Parallel requirements imposed on manufacturers under state and federal law will provide an additional cause to comply with the federal requirements.³¹⁰

The Court took a dim view of expansively reading Congress' intent to preempt given "the long history of tort litigation against manufacturers of poisonous substances" which "adds force to the basic presumption against pre-emption."³¹¹ The Court reiterated that if Congress had intended to prevent the operation of "a long available form of compensation," it surely would have expressed that intent more clearly.³¹² Further, "private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA. . . . FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings,³¹³ noting that tort suits can act "as a catalyst" in this effort.³¹⁴

³⁰³Id. at 1795-96.

³⁰⁴Id. at 1796.

³⁰⁵Id. at 1796-97.

³⁰⁶Id. at 1803-04.

³⁰⁷Id. at 1799.

³⁰⁸Id. "The inducement test is unquestionably overbroad . . . " Id.

³⁰⁹Id. at 1800.

³¹⁰Id. at 1801. The Court rejected the notion that FIFRA contained a "nonambiguous command to pre-empt" given that the EPA had just five years earlier advocated the position the Court adopted. Id.

³¹¹Id. at 1802.

³¹²Id.

³¹³Id.

³¹⁴Id.

F. *Synthesis of Preemption Doctrine*

Building on the analysis of the Court's recent preemption opinions, a number of principles inform how the Court is likely to treat implied preemption regarding prescription drug labeling. The presumption against preemption maintains vitality in cases involving traditional areas of historic state power, as seen in *Bates* and *Medtronic* and confirmed in *Buckman Co.*,³¹⁵ and is likely to be especially forceful in implied conflict preemption under the FDCA. Determining whether an actual conflict exists will involve an assessment of the federal objectives at stake, as identified through the legislation, its history, and the agency's views on the scope of the regulatory scheme, as evidenced particularly by *Geier*, *Buckman Co.*, *Sprietsma*, and, to a lesser extent, *Bates*.³¹⁶ The position of the relevant government agency on the preemptive effect of the regulations and the consistency of that position over time are related to those regulatory objectives and are important in their assessment. As early as *Hillsborough County*, the importance of the FDA's position on preemption, and the consistency of that position, is clear.³¹⁷

While federal regulatory action reflects a balancing of objectives with implementing choices, the importance of maintaining a particular balance has tipped the scales in favor of implied conflict preemption, as was the case in *Geier* but not in *Sprietsma* or *Bates*, consistent with the Supremacy Clause's command that federal legislation is supreme. Whether state tort claims actually conflict or whether they operate in a complementary way with the prescription drug labeling scheme will require close attention to the details of the regulatory scheme. Do such claims fall within the boundaries of federal regulation or outside them?

IV. DISCOVERING THE BOUNDARIES OF FEDERAL PRESCRIPTION DRUG LABELING PREEMPTION

A. *The Arguments for Implied Conflict Preemption*

The FDA has asserted three basic reasons why it supports preemption based on prescription drug labeling. First, the FDA's objectives, as the expert federal agency charged with insuring public health and safety, are impacted by the operation of state tort laws because of the sensitive balance that its labeling regulations achieve. The FDA asserts that permitting jury verdicts based on approved labeling will impact that balance by encouraging manufacturers to warn physicians of unsubstantiated risks and thereby make inappropriate medical treatment decisions. The potential over-warning of risks may also deter the use of an otherwise beneficial drug in circumstances when it is advised. Further, the FDA considers its labeling regulations to achieve, in some cases, more than a minimum standard. The FDA now considers those regulations, in most cases, to be optimal, or ceiling standards, from which deviation is neither required nor permitted absent specific FDA approval. The FDA's proposed final rule on labeling

³¹⁵See supra notes and accompanying text. The presumption against preemption has also surfaced as "an assumption of non-preemption" that is not triggered in areas of significant federal presence. *United States v. Locke*, 529 U.S. 89, 108 (2000)(involving preemption of state policies regarding Burma; foreign affairs exclusively federal; preemption found).

³¹⁶See supra notes and accompanying text.

³¹⁷See supra notes and accompanying text (discussing importance of absence of agency position in *Hillsborough County*).

incorporates these general considerations, as well as the more specific concern that in some instances, a manufacturer will be subject to a misbranding allegation if it satisfies a state common law damages action and alters a label that subsequently does not meet with FDA approval.

Motus v. Pfizer, Inc.,³¹⁸ well illustrates the arguments being made for implied conflict preemption for prescription drug labeling.³¹⁹ The FDA studied the alleged association between SSRI anti-depressants and the risk of suicide on a number of separate occasions, both before and during the approval process for Zoloft.³²⁰ Zoloft was first approved in 1991 and subsequently approved for four additional medical conditions.³²¹ During those subsequent approvals, the FDA determined on each occasion that a stronger warning of the causal connection between use of SSRIs and the risk of suicide was not necessary.³²² The FDA never prohibited Pfizer or other SSRI manufacturers from altering the labeling, however,³²³ though the common practice is for manufacturers not to alter labels without prior FDA approval. Based on its conclusions, the FDA argued in *Motus* that a common law damages action based on the alleged inadequacy of the warning of the risk of suicide would directly conflict with the FDA regulations because any label other than the one approved by the FDA would be misleading and, therefore, would constitute misbranding under the FDCA.³²⁴

The FDA asserted more generally that, given its objective “to ensure each drug’s optimal use through requiring scientifically substantiated warnings,” a common law tort action would frustrate those purposes.³²⁵ The FDA expressed concern for the potential “under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment.”³²⁶ According to the FDA, a common law tort action might encourage the use of a warning that would diminish the impact of valid warnings, “creating an unnecessary distraction.”³²⁷

Each of these concerns, under-utilization of an effective drug, dilution of otherwise valid warnings from over-warning, and the potential misbranding violations that may result, are the federal objectives identified in the proposed final labeling regulation on which implied conflict

³¹⁸*Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1088 (C. D. Cal. 2000) (background information on Zoloft), rev’d on other grounds, 358 F. 3d 659 (9th Cir. 2004).

³¹⁹For a discussion of *Motus*, see supra notes and accompanying text.

³²⁰127 F.Supp. 2d at 1089-1090.

³²¹*Id.* at 1089.

³²²*Id.* at 1090; see also *Motus Amicus Brief of United States*, supra note at 13.

³²³*Motus*, 127 F. Supp. 2d at 1093-94.

³²⁴*Motus Amicus Brief of United States*, supra note at 15-17. In addition, the FDA posited that even though manufacturers are permitted to alter warnings before FDA approval, the FDA must ultimately approve an altered label, which, if found to be misleading, would not be approved. *Id.* at 17. The brief stated that the FDA would have disapproved an altered Zoloft label. *Id.* at 18.

³²⁵*Id.* at 23.

³²⁶*Id.*

³²⁷*Id.* at 23-24.

preemption is based.³²⁸ The next sub-section analyzes how these objectives will fare under the Court's implied conflict preemption principles when compared to the state tort principles with which they are alleged to conflict.

B. Application of Implied Conflict Preemption

Based on preemption doctrine as it has evolved both under the FDCA and generally, the circumstances of prescription drug labeling raise the following issues to be resolved. First, how are the federal objectives to be defined in the case of prescription drug labeling with which state tort laws arguable conflict? Second, what is the effect of the presumption that historic state regulation in the field of public health and safety is not preempted absent clear congressional intent? Third, does the indirect regulatory effect of common law damages actions actually, directly conflict with the objectives of the prescription drug labeling regulatory regime, either in general or more specifically based on a particular labeling requirement? Subsumed in this third question are the sub-issues of whether FDA regulations set minimum or maximum standards, the nature of the acquisition of scientific evidence of risk information regarding the use of prescription drugs on such standards, and the effect of the FDA's recently altered position on preemption.

1. Federal Objectives of the Prescription Drug Labeling Regulations

As early as *Savage v. Jones*³²⁹ and *McDermott v. Wilson*,³³⁰ the objective of the food and drug laws has been clear: to protect the public health and safety from adulterated and misbranded drugs.³³¹ The FDA, as the undisputed expert federal public health agency charged with insuring the safety and efficacy of the nation's drug supply,³³² must be permitted to satisfy its public health mission substantially unimpeded. The federal objectives of public safety, however, are not inconsistent with the historic primacy of the states in the field of public health and safety. Because Congress has not expressed its intent to preempt state regulation, even though it is capable of doing just that, the states have continued to be free to fulfill their historic and primary regulatory role.³³³

Had Congress desired to alter that balance it could have enacted a general FDCA preemption provision, or one directed toward prescription drug labeling, but it has not. On a number of occasions in the federal food and drug laws, beginning with the Medical Device

³²⁸71 Fed. Reg. 3922, 3934-3935 (January 24, 2006). See also *supra* notes and accompanying text.

³²⁹*Savage v. Jones*, 225 U.S. 501 (1912).

³³⁰*McDermott v. Wilson*, 228 U.S. 115 (1913).

³³¹See *supra* notes and accompanying text.

³³²71 Fed. Reg. at 3934.

³³³*Hillsborough County, Fla. v. Automated Medical Labs., Inc.*, 471 U.S. 707, 718 (1985). See also *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018, 1035-1036 (S.D. Ill. 2001)(discussing FDA preemption position history).

Amendments of 1976,³³⁴ Congress has written such express preemption provisions. That it has not done so in the case of prescription drug labeling suggests, at the least, that it is aware of the current regulatory status quo and is content to leave it alone, including permitting its authorized agency to address the matter. Even though congressional intent is not directly in issue, the fact that Congress has not defined a specific preemptive scope in this area suggests that federal objectives to be considered in determining the implied preemptive scope of authorized regulations should be carefully circumscribed. Such was the case in *Geier* in which the Court was influenced by the particularized federal objectives which supported finding an actual conflict between the specific “variety and mix” of passive restraint systems required and tort actions based on a different manufacturer choice. The “long history of tort litigation”³³⁵ in the prescription drug labeling area, and the oft-repeated view that Congress would not defeat the operation of “a long available form of compensation” without making its intent to do so clear³³⁶ support the requirement of clear, particularized federal objectives to which implied conflict preemption principles are applied in the prescription drug labeling context.³³⁷

As in *Hillsborough County*, those seeking to preempt state health and safety regulations, therefore, have an “uphill battle.”³³⁸ “Strong evidence” is needed to defeat the presumption that state health laws are not preempted,³³⁹ either in their entirety, through a federal occupation of the field³⁴⁰ or through actual conflict. When implied conflict preemption is in issue, therefore, federal objectives must be defined on a narrow, particularized basis³⁴¹ as a way of insuring that an unnecessarily broad definition is not used to usurp state regulation where Congress has not expressed its intent to do so. The Court, therefore, has been restrictive in its definition of what constitutes an “actual, direct” conflict with federal objectives.³⁴² General observations about the

³³⁴21 U.S.C. § 360k (2000). See also supra notes and accompanying text.

³³⁵*Bates v. Dow Agrosiences LLC*, 125 S. Ct. 1788, 1802 (2005)

³³⁶*Id.* at 1802. See also supra notes and accompanying text.

³³⁷See, e.g., *Witzak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp.2d 1018, 1031-43 (S. D. Ill. 2001).

³³⁸*Hillsborough County*, 471 U.S. at 714.

³³⁹*Id.* at 719.

³⁴⁰See *Motus Amicus Brief for United States*, supra note at 19-20 (recognizing that some state required labeling would be permissible and thus eschewing occupation of the field preemption).

See also *Hillsborough County, Fla.*, 471 U.S. at 717 (“We are even more reluctant to infer pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes. As a result of their specialized functions, agencies normally deal with problems in far more detail than does Congress. To 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 embodied in our Supremacy Clause jurisprudence.”).

³⁴¹See *Hillsborough County, Fla.* 471 U.S. at 720-21 (defining federal goal narrowly in assess actual conflict preemption).

³⁴²See supra notes and accompanying text for a discussion of actual conflict as assessed in *Hillsborough County, Fla. v. Automated Medical Labs.*, 471 U.S. 707 (1985), *Geier v. American*

possible negative implications of common law tort actions on the regulatory scheme should be unpersuasive.

2. *The Presumption Against Preemption*

The Court has recently struggled with whether the presumption against preemption of state police powers regulation is relevant in express preemption analysis because congressional intent to preempt is directly in issue.³⁴³ The importance of the presumption against preemption in the implied preemption context is much less clear because the Court does not discuss it in the same way. As congressional intent is not specifically in issue, the presumption against preemption becomes useful in defining whether an actual conflict is present.

For example, in *Hillsborough County*, the Court considered the presumption against preemption to apply strongly and defeat implied field preemption.³⁴⁴ Regarding conflict preemption, the Court was less concerned with the presumption because it found no evidence of an actual conflict with federal objectives because those stated objectives were too speculative to be credited.³⁴⁵ Had the agency's position been made clearer, the Court would then have had to assess the value of the presumption against preemption in defining whether an actual conflict existed.

The Court did not mention the presumption at all when discussing implied conflict preemption in *Geier*, though it was certainly interested in the importance of state tort law as an important mechanism to address health and safety concerns regarding automobile passive restraint design.³⁴⁶ In *Buckman Co.*, the Court rejected the notion that a presumption operated because the subject of regulation, policing fraud on the FDA, was not an area historically within the state's police power. The Court noted, however, that it might treat a traditional state tort action differently.³⁴⁷

One is left with some uncertainty as to the importance of the presumption against preemption as such. It is clear, however, that in assessing whether an actual conflict exists, the Court clearly considers the importance of traditional state regulation in the particular subject area as a strong counter weight to the stated federal objectives in the balance. For example, in *Sprietsma*, the Court rejected a finding of implied conflict preemption when a federal agency had decided *not* to regulate precisely because state tort actions had traditionally operated as a means of increasing incentives toward safety.³⁴⁸ The Court refused to permit an expert regulatory assessment to have greater effect than necessary. Arguably, an FDA decision not to require a particular warning in prescription drug labeling should be considered in the same fashion.

Honda Motor Corp., and Buckman Co. v. Plaintiffs' Legal Comm.,

³⁴³See supra notes and accompanying text.

³⁴⁴See supra notes and accompanying text.

³⁴⁵Id.

³⁴⁶See supra notes and accompanying text.

³⁴⁷Id.

³⁴⁸See supra notes and accompanying text.

In addition, the Court was openly hostile toward the proposed rejection of “longstanding” principles of tort compensation in *Bates*.³⁴⁹ The Court confirmed its dedication to the presumption against preemption in assessing Congress’ intent and noted that “private remedies . . . would seem to aid, rather than hinder” the functioning of a public health and safety regulatory scheme.³⁵⁰ *Bates* involved a labeling approval regime of less rigor than the FDA’s but the scheme in *Bates* also involved an express preemption provision which the Court was called upon to interpret. The concerns for the operation of traditional state tort principles expressed in *Bates* would seem to apply, *a fortiori*, more persuasively in the case of implied conflict preemption under the FDCA.

3. *Do state tort actions actually conflict with the proposed federal objectives?*

The stated federal objectives behind the prescription drug labeling regulation do not actually conflict with state common law tort actions. The main general objective, protection of the public health, is not in conflict with state tort actions but operates in a complementary way with them. There is no reason, other than the FDA’s change position on preemption, to now treat common law tort actions differently than in the traditional way.

The FDA proposes, however, that because labeling approval is solely within the FDA’s authority, state common law tort actions may interfere with the balance of risks that undergird that approval. The concern of overwarning and the possible disincentive created to prescribe an otherwise appropriate drug are at the core of this argument. Has the FDA’s balance established an optimal one, as the Court suggest had occurred in *Geier*, or has the FDA’s balance simply established a minimum as has traditionally been the case.?

The FDA’s authority to approve prescription drug labeling has not changed; its desire to use preemption based on that approval authority is all that has changed. The Court’s implied conflict preemption doctrine rejects such a change as insignificant in itself to support preemption. The FDA’s change in position regarding preemption is too recent and too tied to specific litigation to constitute the kind of formal, long standing agency position which has been credited in conflict preemption analysis. In neither *Sprietsma* or *Bates*, nor *Easterwood* was such a change in agency position credited.³⁵¹ *Bates* and *Easterwood* involved express preemption provisions as to which greater deference to agency interpretations might have been appropriate and the Court refused to credit it.³⁵²

In *Medtronic*, the plurality was “substantially informed” by the FDA’s position on preemption because Congress had expressly provided authority to the FDA to determine when state regulations would be preempted.³⁵³ The Court did not acknowledge that it was required to give any level of deference to the FDA’s interpretation of its preemption authority; Justice

³⁴⁹See supra notes and accompanying text.

³⁵⁰*Id.*

³⁵¹See supra notes and accompanying text.

³⁵²See supra notes and accompanying text.

³⁵³See supra notes and accompanying text.

O'Connor in dissent noted uncertainty as to whether any deference was required in such circumstances.³⁵⁴

In contrast to *Medtronic*, there is no formal preemption regulation in the new prescription drug labeling regulation. There is only commentary in the preamble. There has been no comment from the health care community at large, either physicians or their organizations, or state public health officials, or industry representatives for that matter, on the FDA's formal position in favor of preemption. The proposed regulation specifically disclaimed any intent to alter the FDA's formal position on preemption, and, rather, simply asked for comments on the product liability implications of the proposed labeling regulation.³⁵⁵ The new preemption position is really only a re-articulation of the FDA's recent litigation positions in a few amicus briefs and not a formal regulatory policy adopted after notice and comment rule-making. Describing the change in position as a longstanding, formal regulatory policy is a misnomer that the Court's implied conflict preemption doctrine will see through.

An agency's interpretation of its own regulations is ordinarily accorded great deference.³⁵⁶ The degree of that deference has been the subject of much discussion in the Court's preemption opinions, including the opinions involving the FDA.³⁵⁷ Generally, though, the degree of deference due to government positions depends on, among other things, consistency, formality, and thoroughness.³⁵⁸ Briefs are not accorded great policy deference,³⁵⁹ particularly when the FDA interprets statutes or regulations in a particular case, "at such a time and in such a manner so as to provide a convenient litigating position" for a particular action.³⁶⁰ Its efforts to obtain greater deference in the MDA context has met with limited success³⁶¹ precisely because the FDA is interpreting its own regulation on preemption. That is not the case in the prescription drug labeling context.

The FDA's historical position in favor of the concurrent operation of traditional state tort

³⁵⁴Id. (*Medtronic*, 518 U.S. at 512).

³⁵⁵65 Fed. Reg. at 81103 (December 22, 2000) ("[T]his proposed rule does not preempt State law.") See also *supra* notes and accompanying text

³⁵⁶See generally *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). As to deference accorded FDA determinations, see generally O'Reilly, Food and Drug Admin. 2d, *supra* note at § 4:12.

³⁵⁷See *supra* notes and accompanying text (discussing *Hillsborough County, Medtronic*, and *Buckman Co.*).

³⁵⁸*United States v. Mead Corp.*, 533 U.S. 218, 228 (2001). See also *Witczak v. Pfizer, Inc.*, 277 F. Supp. 2d 725, 730 (D. Minn. 2005) (Motus amicus brief of United States in prior Zolofit warning case not given deference; reason to suspect that brief's interpretation does not reflect "fair and considered judgment" of agency on issue).

³⁵⁹*Witczak v. Pfizer, Inc.*, 277 F. Supp. 2d 726, 730 (D. Minn. 2005) *National Pharmaceutical Alliance v. Henney*, 47 F. Supp. 2d 37 (D. D. C. 1999). See generally O'Reilly, Food and Drug Admin. 2d, *supra* note at § 4:12.

³⁶⁰See O'Reilly, Food and Drug Admin. 2d, *supra* note at § 4:12.

³⁶¹*Horn v. Thoratec, Inc.*, 376 F.3d 163 (3d Cir. 2004).

claims is a significant barrier to recognition of its current preemption position as consistent with federal objectives. The Court has looked with disfavor on changed agency position, particularly for litigation purposes, as support for conflict preemption. Only in *Geier* in which the Court found implied conflict preemption, was agency position persuasive and that was based on the Secretary of Transportation's unwavering position on the importance of the federal objectives in issue.³⁶² In the railroad safety regulation cases,³⁶³ the agency's change in preemption position was rejected as inconsistent with the statutory scheme and, thus, of no effect in the express preemption analysis. While agency position is given some deference, in the case of implied conflict preemption of traditional state tort actions, consistency of position is more important than recency of position in assessing actual conflict.

Furthermore, in the labeling context, the dynamic nature of the scientific understanding of risk disfavors preemption. In *Bates* involving labeling of pesticides, the Court refused to give broad scope to the preemption provision in issue because doing so would stifle an otherwise dynamic need to continually evaluate risks about which warnings should be provided. Inertia is a powerful force: if preemption exists based on labeling choices, why would any manufacturer ever suggest a warning change? The onus would be on the FDA to police the scientific advances regarding each prescription drug it has approved and then propose warning label changes where necessary. Such an obligation is inconsistent with the statutory and regulatory scheme and with the FDA's limited resources to regulate a large number of prescription drug manufacturers.

Indeed, many commentators have complained of the FDA's inability to obtain full information from prescription drug manufacturers because the reporting process regarding adverse reaction events is too weak. The FDA does not have authority to require additional clinical trials after drug approval. Consequently, many have argued that the tort litigation system acts as an important avenue by which the health care community learns of safety and efficacy information.³⁶⁴

One example will illustrate the weakness of the FDA regulatory system that will weigh against preemption. Merck & Co. received approval from the FDA to market its anti-inflammatory drug Vioxx for use in treating arthritis pain in February 1999.³⁶⁵ In June 2000, Merck submitted data to the FDA disclosing a four-fold higher risk of heart attacks compared to another pain-reliever, but not until April 2002 did the FDA approve a new warning that referred to an increase in cardiovascular risks.³⁶⁶ Merck voluntarily recalled Vioxx from the market in

³⁶²See *supra* notes and accompanying text.

³⁶³See *supra* notes and accompanying text.

³⁶⁴Gary Young, *FDA Strategy Would Preempt Tort Suits: Does it Close off Vital Drug Data?*, National L. J., col 1, (March 1, 2004); Joe Pickett, *Pressure Building for FDA to Mandate Post-Approval Studies after Vioxx Incident*, Bioresearch Monitoring Alert, at 1 (December 1, 2004) (FDA cannot mandate post-marketing safety programs; FDA has never been given enough staff to "keep careful track of adverse reactions that are reported for drugs.").

³⁶⁵Key Events in the Development of Vioxx: From Merck's Application for FDA Approval to a Huge Ruling, Reuters, Aug. 19, 2005.

³⁶⁶*Id.*

September 2004 because results of a clinical trial indicated a doubled risk of cardiac events in those who used Vioxx.³⁶⁷ After Merck withdrew Vioxx from the market in October 2004, Congress held hearings on the FDA's alleged regulatory failure to require additional warnings sooner.³⁶⁸ The FDA spokesman stated the FDA needed more regulatory authority to add warning labels after safety concerns surface after a drug is approved. The Vioxx warning label change was delayed for one year while the FDA and Merck negotiated over it.

While the current practice may be that manufacturers wait for FDA approval before making labeling changes, that practice does not, nor should it, prevent manufacturers from acting on risk information. The statute imposes on such manufacturers a greater obligation for the public safety. Tolerating, or ignoring, a failure to fulfill that obligation is inconsistent with the statutory mandate. The FDA may tolerate the practice of permitting manufacturers to wait until a labeling change is approved, but permitting common law tort actions to operate concurrently does not conflict with either the statutory or regulatory mandate that requires more. Manufacturers may be more likely to seek FDA approval of a labeling change, pursuant to the obligation to add significant risk information unilaterally, based on scientific evidence when it becomes available.

Preemption based on an FDA approved label will create a disincentive to act promptly based on acquired evidence of risk. Adverse side effects and evidence of increased risk come to drug manufacturers in a wide variety of ways.³⁶⁹ The FDA approves or requires labels in the face of a variety of such information submitted to it by manufacturers.³⁷⁰ The FDA relies on its product manufacturers to provide the information required under its regulations.³⁷¹ The FDA is not an investigative agency; it is a regulatory agency. It, like other regulatory agencies, receives information from members of the industry it regulates and acts on that information. It typically does not actively seek out information to accomplish these goals unless information is brought to it highlighting a need to do so, and it does not have the authority to require manufacturers to engage in clinical trials to obtain that information.³⁷²

In the case of Zoloft, citizen petitions were presented to the FDA on three occasions seeking to convince the FDA to require an enhanced label regarding the risk of suicidality.³⁷³ The FDA refused to require such a label until 2004 when it issued a public health advisory to that effect. The FDA asked manufacturers for information about pediatric studies on other anti-depressants and ultimately acknowledged that additional data and analysis were needed, including increased public discussion. This information was slow to materialize and were it not for the actions of non-manufacturers, it might never have. If preemption were permitted, and no common law tort action had been available to bring some of this information to light, the warning might not yet be provided. The incentives provided by the tort system are a necessary

³⁶⁷Id.

³⁶⁸Hearings before Senate Health, Education, Labor and Pensions Committee (Feb. 28, 2005).

³⁶⁹See Motus Amicus Brief of Public Citizen, *supra* note at 18-19.

³⁷⁰21 C.F.R. § 314.50 (content for format of an application for new drug approval); § 314.

³⁷¹21 C.F.R. § 314.80 (post-marketing reporting of adverse drug experiences).

³⁷²See *supra* notes and accompanying text.

³⁷³See *supra* notes at and accompanying text.

complement to the federal objectives of public safety and not an impediment to them.

The FDA's final argument that its regulations are optimal, not minimum, standards is inconsistent with the regulatory scheme it administers. Given that manufacturers may unilaterally alter warnings when substantial risk information comes to them, coupled with the FDA's inability to require stronger warnings absent the regulated manufacturers coming forward with such information of need substantially undercuts any argument that the labeling regulation was intended to provide a maximum standard of care. The FDA's regulatory scheme is quite unlike the air bag regulation in *Geier* which specifically permitted alternative design choices to the industry for specific means-related objectives that had been the subject of lengthy study and compromise with full information of risk.³⁷⁴ In the case of prescription drug labeling, there is unlikely ever to be full information of risk on which to base the conclusion that any labeling should be considered a maximum, or optimal, one.

Finally, the FDA has suggested that particularized labeling decisions preempt common law tort actions challenging those particularized labeling decisions, as in the case of Zolofit. The FDA argues that its concern for over-warning supports implied conflict preemption of any common law tort claim that would require a specific warning that the FDA has evaluated and not required. Government agency's typically argue for preemption based on generally applicable regulatory decisions, such as the air bag regulation in *Geier* or the propeller guard regulation in *Sprietsma*. It is unusual for a federal agency to argue for preemption based on an isolated decision that affects one regulated industry member. In *Bates*, the defendant Dow Agrosciences LLC argued for preemption based on its specific label that the EPA had permitted, but the Court found that common law tort actions based on that label's inadequacies could proceed if the state requirements were parallel to those imposed under federal law, consistent with the express preemption provision in issue.³⁷⁵ To argue for preemption based on the labeling required for a particular prescription drug would extend implied conflict preemption to any particularized federal government decision that might be made.

Implied conflict preemption based on one manufacturer's approved drug labeling would be an expansive application of the Court's conflict preemption doctrine. It is possible, however, that under the proposed new labeling regulation, such a result might ensue as it applies to new or recently approved products. The labeling regulation more narrowly defines those circumstances in which manufacturers may unilaterally alter a warning.³⁷⁶ In such a case, FDA approval of a specific label might be considered to reflect the specific balance of risk and benefit regarding the label's content that supports implied conflict preemption. The new, more specific, labeling regulation which contains more specific labeling requirements and makes it more difficult to change a label could constitute the specific balance between an over-warning concern and the desire minimally to interfere with the provision of medical care. A specifically defined regulatory balance could constitute the kind of specific federal objective that the Court recognized as preempting state common law tort actions in *Geier*.

³⁷⁴See supra notes and accompanying text.

³⁷⁵See supra notes at and accompanying text.

³⁷⁶See supra notes and accompanying text.

The FDA's position on preemption, applied not retroactively but prospectively, in such cases might one day be characterized as a consistent agency position on preemption for those prescription drugs which fall within it. The concern for over-warning balanced against the concern that FDA regulations not unnecessarily interfere with the provision of medical care might constitute the narrow means-related objectives that would support implied conflict preemption of state common law tort claims. That day has not arrived, however, regarding those prescription drugs which are regulated under the FDA's long-standing position against preemption.

V. CONCLUSION

The FDA's new labeling regulation makes many significant changes to prescription drug labeling to enable clearer, more concise prescribing information to come to medical care providers. But it is clear that no labeling regulation can create the perfect incentive for manufacturers to seek better and more complete information regarding the adverse side effects of the prescriptions we take. In a world where United States patients receive proper medical care from doctors and nurses only 55 percent of the time,³⁷⁷ pharmaceutical companies are in control of the research conducted on their products pre- and post-marketing,³⁷⁸ pharmaceutical sales representatives have increasing influence on the drugs that physicians prescribe,³⁷⁹ and the pharmaceutical industry is the largest lobbying group in the United States,³⁸⁰ the products liability litigation system is a critical component to create incentives for greater access to risk information to insure the public's health.

³⁷⁷Proper Health Care Put at 55%, Assoc. Press. (March 16, 2006) (reporting on a study in the New England Journal of Medicine).

³⁷⁸Investment in Pharmaceutical R&D Funded Predominantly by Industry, Pharmaceutical Manufacturers Association Annual Report 2004 (industry funds research at almost twice the level of the National Institutes of Health).

³⁷⁹Carl Elliott, The Drug Pushers, Atl. Monthly at 82 (April 2006) (studies in medical literature indicate that doctors who take gifts from a drug company are more likely to prescribe that company's drugs or ask that they be added to a hospital's formulary).

³⁸⁰Id. at 88.