

The Final Battle For Preemption: The FDA and Prescription Drug Labeling Product Liability Actions

BY MARY J. DAVIS

The Food and Drug Administration (FDA) has promulgated a new 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 prescription drug labeling regulations preempt common law tort claims until the last few years, beginning with *Motus v. Pfizer* in 2002. This position, radical to many and rational to others, places federal preemption of prescription drug labeling actions directly in the center of the debate over the proper roles of federal regulation and state tort laws in effecting product safety. The Supreme Court has added to that debate with a number of product liability preemption decisions in the past two decades. Seeking to promote both understanding and balance regarding the operation of preemption doctrine within products liability, this Article provides a comprehensive explanation of the applicability of preemption doctrine to prescription drug product liability actions. This Article explores the history of preemption doctrine specifically as it relates to the food and drug laws, evaluates the importance of the FDA's position on the application of that doctrine to current litigation, and provides direction to courts seeking to navigate the battlefield of federal preemption.

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I. INTRODUCTION

Federal preemption of common law tort actions has become the subject of conspiracy theorists, dedicated tort reformers, and all those in between. Described on the one hand as a “massive effort at the federal level to chip away at state tort law,”¹ and, on the other, “a good thing instead of standards set by . . . state juries,”² advocates on both sides of the preemption debate have an opinion about whether, and, if so, how, federal regulations should defeat state common law tort actions.³ The Supreme Court has addressed preemption doctrine a number of times in the last fifteen years since *Cipollone v. The Liggett Group, Inc.*⁴ put federal preemption of product liability actions on the map. The political dimension of this issue has been widely explored,⁵ but this Article does not enter that debate. Rather, this Article provides insight into the important doctrinal battle the issue represents, one fairly described as the final battle in federal preemption. This “final” battle is over whether federal prescription drug labeling regulations impliedly preempt state common law product liability actions. The Supreme Court has addressed express preemption on a number of occasions since *Cipollone*⁶ but most express preemption provisions either do not clearly outline their scope and, therefore, implied preemption

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¹ Ralph Lindeman, *Agencies Move to Override State Law as Part of Federal Rulemaking Process*, 34 *Prod. Saf. & Liab. Rptr.* (BNA) at 364 (April 10, 2006) (quoting Susan Frederick, with the National Conference of State Legislatures); *id.* at 364 (federal agency statements favoring preemption are “sneak attack on consumer rights,”. *See also* 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 on preemption as “anti-consumer tort reform agenda”).

² *Id.* at 364 (quoting David Price, with the Washington Legal Foundation, a conservative legal reform group).

³ For a discussion of the general debate on preemption by agency action, see Catherine Sharkey, *Preemption by Preamble*: DEPAUL L. REV. (forthcoming 2006); and Catherine Sharkey and Samuel Issacharoff, *Backdoor Federalism*, UCLA L. Rev.

⁴ *Cipollone v. The Liggett Group, Inc.*, 505 U.S. 504 (1992)(involving express preemption of product liability actions by federal cigarette labeling laws).

⁵ Compare Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration’s Aggressive Use of the Preemption Doctrine Hurts Consumers*, Center for Progressive Regulation White Paper (October 2004); News Release, *WLF Hails FDA Policy Statement on Preemption of Failure-to-Warn Suits*, Washington Legal Foundation (January 25, 2006).

⁶ *See infra* notes and accompanying text (discussing express preemption cases since 1992).

must operate,⁷ or no express preemption provision is contained in the relevant legislation, as is the case with the Food, Drug, and Cosmetic Act.⁸ Consequently, the final unanswered preemption question remains: When are common law tort actions impliedly preempted based on actual conflict with federal agency regulations?

The prescription drug labeling cases and the Food and Drug Administration's (FDA's)⁹ new position in favor of implied conflict preemption squarely raise the issue. Historically, federally approved prescription drug labeling has not been considered preemptive on the question of the label's adequacy under tort law because federal regulations in this field set a minimum standard of care rather than an optimal one and, therefore, more exacting state tort law standards of care do not conflict but operate concurrently with the federal requirements.¹⁰ The Supremacy Clause of the Constitution,¹¹ which defines federal law as supreme, does not prevent the operation of state laws in this instance. The FDA has promulgated a regulation which revises the

⁷ See, e.g., *Geier v. American Honda Motor Corp.*, 529 U.S. 861 (2000) (preemption regarding requirement for driver's side air bags found based on implied preemption doctrine).

⁸ 21 U.S.C. §§ 301 et. seq. (2000) (establishing federal Food, Drug and Cosmetic Act of 1938). See *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018, 1031 (S. D. Ill. 2001) (portion of FDA dealing with pharmaceuticals does not contain preemption provision); *McCallister v. Purdue Pharms L.P.*, 164 F. Supp. 2d 783 (S.D. W. Va. 2001) (same); *Eve v. Sandoz Pharm. Corp.*, 2002 WL 181972 at * 2 (S. D. Ind. Jan. 28, 2002) (same). 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, 290 (2003) (no express preemption provision in prescription drug labeling sections of FDCA); 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, 400 (1996) (same).

⁹ 21 U.S.C. § 393 (2000) (authorizes the creation of the Food and Drug Administration as the agency responsible for administering the Food, Drug and Cosmetic Act).

¹⁰ *Witczak 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). In general, an applicable regulatory standard is often considered relevant, but not conclusive, to a finding of negligence. See generally DAN B. DOBBS, THE LAW OF TORTS, § 373, at p. 1033 (2000); DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.3, at p. 888 (2005). The basic premise of this principle is that regulators, whether legislators or agency administrators, intend only to set minimum standards of care applicable to specific settings that will necessarily be revisited with time. See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16 cmt b (Proposed Final Draft) (May 17, 2005) (lawmaking process "insufficiently attentive" to interests of injured); RESTATEMENT (SECOND) OF TORTS § 288C (1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b) (1998). For a general discussion of the doctrine as applied to products liability actions, 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); 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).

¹¹ 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, . . .").

requirements for prescription drug labeling, and, in the process, is taking the position that the regulation preempts state products liability laws that seek to assess liability on the manufacturer for a label's warning adequacy.¹² 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.¹³

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 asked to resolve the battle over the boundaries of federal preemption in this critical area. Section II of the Article sets the factual stage for the FDA preemption battle. Section III defines the regulatory scheme under the FDCA in more detail to place the preemption issue in context. It also explains the FDA's new regulation on prescription drug labeling and how it is being used to support preemption. Section IV describes general preemption doctrine and gives a detailed treatment of that doctrine in the area of food and drug regulation. Section V analyzes critically the basis for implied conflict preemption under the FDCA and evaluates those arguments in a manner consistent with a deeper understanding of the Court's preemption doctrine. Section V addressed the effect of the FDA's change in position on the preemptive effect of its regulations. Agency position on preemption has been given some level of deference in the Supreme Court's modern preemption jurisprudence.¹⁴ The amount of deference to give an agency's determination of preemptive scope has generated much debate, both within the Court¹⁵ and among commentators.¹⁶ The Supreme Court has not answered the question of how agency position affects the operation of implied conflict preemption doctrine nor how the historic primacy of state regulation in the area of health and safety is to be considered in the balance.

Section VI concludes that implied conflict preemption of prescription drug labeling actions is inconsistent with the Supreme Court's modern preemption jurisprudence. The historical and detailed treatment provided by this Article leads to the conclusion that the Supreme

¹²71 Fed. Reg. 3922, 3934-3936 (Jan. 24, 2006). The prescription drug labeling regulation became final and effective on June 30, 2006. *Id.* at 3928.

¹³For a discussion of the history of the FDA's position on preemption based on prescription drug labeling, *see infra* notes and accompanying text.

¹⁴*See, e.g.,* *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (discussion of deference to FDA's preemption position regarding medical device regulations).

¹⁵ *See* *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (Justice Stevens, Justice Breyer, and Justice O'Connor disagreeing about level of deference to give to FDA preemption interpretation).

¹⁶ *See, e.g.,* Richard C. Ausness, "After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?, 80 TULANE L. REV. 727, 767-775 (2006); Allison Zieve and Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why It Is Wrong and Warrants No Deference*, 34 Prod. Saf. & Liab. Rptr. (BNA) 308 (March 27, 2006). *See generally* Paul McGreal, *Some Rice With Your Chevron?: Presumption and Deference in Regulatory Preemption*, 45 CASE WESTERN L. REV. 823 (1995); Nina Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004).

Court's preemption jurisprudence does not permit an agency's position to alter the historic balance between federal safety regulation and common law tort principles when that position has been consistent and longstanding even though modern events, and political positions, may cause the agency to retreat from it. Traditional tort law continues to play an important role in providing compensation for injured consumers and the Supreme Court's preemption doctrine requires much more than agency change of heart to alter that conclusion. 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. SETTING THE STAGE FOR PREEMPTION: *MOTUS V. PFIZER*¹⁷ AND THE NEW DRUG LABELING REGULATION

In late 2002, the FDA filed an amicus curiae brief in *Motus v. Pfizer, Inc.*,¹⁸ in which it 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 label's warning of the risk of suicide, from which the plaintiff had died.¹⁹ Before *Motus*, the FDA's position had been that "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."²⁰ An FDA official has explained the more aggressive recent stance in favor of preemption: "Our willingness to invoke implied preemption

¹⁷ *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004)(affirming summary judgment on causation and not reaching preemption issue).

¹⁸ Amicus 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).

¹⁹ *Motus*, 358 F.3d at 660. Zoloft is in a category of anti-depressants known as selective serotonin re-uptake 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).

²⁰ Margaret 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 United States' *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*, at 287 (discussing FDA change in position regarding preemption); Clune, *supra* note at 2-4 (describing FDA change in position under Troy).

can be traced to the growing propensity of bad scientific reasoning to seep into court cases involving FDA-regulated products.”²¹ The FDA and prescription drug manufacturers take the litigation position that approved prescription drug labeling preempts state tort claims based on alleged inadequacies in the labeling.²² According to opponents of the FDA position, traditional tort doctrine, through operation of the civil justice system, “establishes a duty of care that protects citizens when the federal government is too slow to act or when federal standards are insufficient.”²³

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.²⁴ Prior to and during the course of approving Zoloft in 1991, the FDA explored the potential associations between the use

²¹Mary Ellen Egan, *Tort Turf*, FORBES, vol. 173, issue 9, at 48 (April 26, 2004). *See also* Lindeman, *supra* note 1 at 365 (“State courts and juries often lack the information, expertise, and staff that the federal agencies rely upon in performing their scientific, risk-based calculation,” says White House Office of Management and Budget spokesman.).

Interestingly, after an 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. FDA 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 SSRI’s). The British equivalent of the FDA recommended a similar warning as early as 2002, 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 .

²²*Colacicco v. Apotex, Inc.*, ___ F. Supp. 2d ___, 2006 WL 1443357 (E. D. Pa. 2006) (summary judgment granted on FDA’s implied preemption of plaintiff’s warning claims regarding anti-depressant Paxil and risk of suicide); *Jackson v. Pfizer, Inc.*, ___ F. Supp. 2d ___, 2006 WL 1506886 (D. Neb. 2006) (summary judgment denied on implied preemption grounds in Zoloft case); *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163 (W.D. Wash. 2006) (summary judgment denied based on implied preemption in anti-depressant fluoxetine case); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051 (W.D. Wis. 2006) (no implied preemption in Prilosec warning case); *McNellis v. Pfizer, Inc.*, 2005 WL 3752269 (D.N.J. Dec. 29, 2005) (no implied preemption in Zoloft case); *Witczak v. Pfizer, Inc.*, 377 F. Supp.2d 726 (D. Minn. 2005)(summary judgment denied based on preemption argument in Zoloft case); *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 in Zoloft case); *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.

²³ Letter to Secretary Mike Leavitt, Department of Health and Human Services, re: Food and Drug Administration Final Rule on the Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics, from National Conference of State Legislatures, dated January 13, 2006.

²⁴*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.

of SSRI's and suicide that had been raised regarding other SSRI's, particularly Prozac.²⁵ Those concerns caused the FDA to convene a committee of experts, the Psycho-pharmacological Drugs Advisory Committee ("PDAC")²⁶ 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.²⁷ 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.²⁸

Pfizer moved for summary judgment in *Motus* on the basis of implied conflict preemption.²⁹ 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.³⁰ The trial court was persuaded also by the FDA Commissioner's statement that favored the role of unilateral manufacturer labeling changes to increase information provided to health care providers and enhance public safety.³¹ 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."³²

²⁵127 F.Supp.2d at 1090.

²⁶*Id.* at 1088, 1090.

²⁷*Id.* at 1090. During the PDAC proceedings, the Director of the Division stated a 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.*

²⁸*Id.* at 1088. Plaintiff contended that Pfizer drafted the ultimately approved labeling language, not the FDA. *Id.*

²⁹*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.

³⁰*Id.* at 1094 (referring to 21 C.F.R. § 314.70(c)).

³¹*Id.* 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)).

³²127 F. Supp. 2d at 1095.

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."³³ 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."³⁴ The brief concludes that any state common law damages action that resulted in requiring an unapproved warning would have misbranded the drug *per se*, thereby subjecting the manufacturer to penalties under the FDCA.³⁵ 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.³⁶ The manufacturer is entitled to a jury trial on the issue.³⁷

The trial court in *Motus* denied summary judgment on preemption.³⁸ The trial court reasoned that the FDA sets minimum standards and the regulatory scheme does not prohibit manufacturers from unilaterally strengthening approved labeling.³⁹ Though the preemption argument in *Motus* was not successful, an increasing number of prescription drug labeling cases have been defended successfully on preemption grounds.⁴⁰ The cases which reject preemption do so based on the traditional grounds relied upon in *Motus*.⁴¹

³³*Motus* Amicus Brief of United States, *supra* note at 13.

³⁴*Id.* at 14.

³⁵*Id.* at 16-17.

³⁶21 U.S.C. § 332 (2004). *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).

³⁷21 U.S.C. § 332(b) (2004)(jury trial available on issue regarding injunctions, criminal penalties, and seizures).

³⁸ *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1091 (C.D. Cal. 2001).

³⁹ *Id.* at 1095.

⁴⁰*Colacicco v. Apotex, Inc.*, ___ F. Supp. 2d ___, 2006 WL 1443357 (E. D. Pa. May 25, 2006) (Paxil warning litigation); *Needleman v. Pfizer, Inc.*, 2004 WL 1773697 (N. D. Tex. Aug. 6, 2004) (Zoloft warning litigation); *Dusek v. Pfizer, Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004)(Zoloft warning litigation). For a state case also finding preemption, *see Abramowitz v. Cephalon, Inc.*, 2006 WL 560639 (N. J. Super March 3, 2006)(Actiq warning litigation).

⁴¹*Jackson v. Pfizer, Inc.*, ___ F. Supp. 2d ___, 2006 WL 1506886 (D. Neb., May 31, 2006)(Zoloft warning litigation); *Laisure-Radke v. Par Pharms., Inc.*, 2006 WL 901657 (W. D. Wash., March 29, 2006)(Prozac warning litigation); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005)(Zoloft warning litigation); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051 (W. D. Wis. 2006) (Prilosec warning litigation); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018 (S. D. Ill. 2001) (Parlodel lactation suppressant warning litigation). For a state case also

The FDA's position on preemption, taken in *amicus* brief form in *Motus*, formally appeared in its revised prescription drug labeling regulation, published in January 2006 and effective June 30, 2006.⁴² The FDA first published the proposed new labeling regulation in December 2000.⁴³ The changes to the regulation were intended to make prescription drug labeling clearer, more concise, and accessible for the health care practitioner audience.⁴⁴ The proposed rule did not address, nor seek comments on, its possible preemptive effect on products liability actions.⁴⁵ The proposed rule's commentary specifically stated that it did not preempt state law and that, therefore, it did not implicate federalism concerns.⁴⁶ In the final regulation, however, the FDA takes the position, in the introductory commentary known as the preamble, that approved prescription drug labeling does preempt conflicting state product liability laws.⁴⁷ Immediately upon the heels of publication of the final rule, Pfizer asked a federal district judge to vacate an earlier order denying summary judgment on preemption grounds based on the new FDA preemption position,⁴⁸ and trial courts in other cases are increasingly being asked to do the same.⁴⁹

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

If state tort laws provided that compliance with a governmental regulation was conclusive on the tort standard of care, there would be no need for a preemption defense because the tort

finding no preemption, *see* *Coutu v. Tracy*, 2006 WL 1314261 (R. I. Super. May 11, 2006) (Propofol coma-inducing drug warning litigation).

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

⁴³65 Fed. Reg. 81082 (December 22, 2000).

⁴⁴71 Fed. Reg. at 3922.

⁴⁵FDA Revises Labeling Format for Drugs, 34 *Prod. Saf. & Liab. Rptr.* (BNA) p. 52, 53 (January 23, 2006).

⁴⁶65 Fed. Reg. at 81103 (labeling rule does not have federalism implications nor does it preempt state law; preemption assessment required by Exec. Ord. No. 13132).

⁴⁷71 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 *See id.* Letter available at <http://www.ncsl.org/programs/press/2006/060113Leavitt.html>.

⁴⁸*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).

⁴⁹*See, e.g., Colacicco v. Pfizer, Inc.*, ___ F. Supp. 2d ___, 2006 WL 1443357 (E. D. Pa. May 25, 2006); *Jackson v. Pfizer, Inc.*, ___ F. Supp. 2d ___, 2006 WL 1506886 (D. Neb. May 31, 2006).

laws would rely on the governmental regulations to establish, or defeat, liability.⁵⁰ 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.⁵¹ The classic reason for this is that governmental regulations are based on narrowly defined goals, often with limited information, which do not include setting optimal standards of care for all circumstances; rather, they set minimum standards not intended to prevent the operation of other remedial mechanisms such as common law tort claims.⁵²

Federal preemption doctrine, on the other hand, acts like a “super” government compliance defense because it relies on the constitutionally mandated supremacy of federal law to displace entirely a contrary underlying tort claim.⁵³ To establish preemption, congressional intent to preempt, which is the “ultimate touchstone” of preemption analysis, must be discerned.⁵⁴ Courts search for that intent to preempt through interpretation of an express preemption provision⁵⁵ or through the application of implied preemption principles.⁵⁶

⁵⁰In fact, critics of the tort system have encouraged state legislatures to make such a change, and some have. *See e.g.*, MICH. COMP. LAWS. ANN. § 600.2946(5) (1995)(immunity on drug manufacturers based on federal regulatory compliance); COLO. REV. STAT. § 13-21-403 (1) (2005) (regulatory compliance presumes due care); IND. CODE § 34-20-5-1 (1998)(same); KY REV. STAT. § 411.310 (1978)(same). *See generally* OWEN, PRODUCTS LIABILITY LAW *supra* note 1 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.”).

On the subject of regulatory compliance generally, *see* 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.”)

⁵¹RESTATEMENT (THIRD) OF TORTS; LIABILITY FOR PHYSICAL HARM, § 16 cmt. *e* (Proposed Final Draft, May 17, 2005).

⁵² *See* DOBBS, *supra* note 10, § 224, at 573 (“When it comes to technological standards, they are quickly outdated with no guarantee that the legislature or regulators will have time or information necessary to update them. Beyond that, many statutes are written in response to lobbying efforts of the industry they purport to regulate, and they are not likely to represent a balanced attempt by neutral parties to achieve appropriate safety.”); MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note 10, § 16:3, at 134.

⁵³*See, e.g.*, *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).

⁵⁴*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*

The Food, Drug, and Cosmetic Act does not have a general express preemption provision,⁵⁷ nor one specifically applicable to prescription drug labeling, though Congress has written preemption provisions into the food and drug laws for specific contexts.⁵⁸ Implied preemption doctrine, therefore, necessarily will 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;⁵⁹ or (2) when inconsistent state regulation conflicts with a federal regulation so that (a) it is either impossible to comply with the federal mandate or (b) compliance with the state law would frustrate the objectives behind Congress' legislation.⁶⁰ The Supreme Court has rarely concluded that federal regulations comprehensively occupy a field to displace all state law so the narrower implied conflict preemption doctrine is more typically applicable.⁶¹

Preemption, Congressional Intent, and Conflict of Laws, 66 U. PITT. L. REV. 181, 198 (2004)(hereafter Davis, *On Preemption*) (discussing basic preemption doctrine); 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) (same).

⁵⁵*Cipollone*, 505 U.S. at 517.

⁵⁶*Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1974)(discussing implied preemption principles). *See also* Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 971 (2002) (explaining history of preemption doctrine)(hereafter Davis, *Unmasking the Presumption*). *See also*, Davis, *On Preemption*, *supra* note at 200-202 (2004)(discussing implied preemption doctrine).

⁵⁷*See supra* note . *See, e.g.*, *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).

⁵⁸*See, e.g.*, Medical Device Amendments of 1976, 21 U.S.C. § 360k(a)(2006) (preemption provision regarding medical device regulations); 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 latter 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).

⁵⁹*Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714-716 (1985) (discussing occupation of field implied preemption requirements).

⁶⁰*Id.* at 712-13 (discussing implied conflict preemption doctrines generally); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230-231 (1947) (same). *See generally*, Davis, *Unmasking the Presumption*, *supra* note at 969-971, 990-97; Ausness, *supra* note at 919.

⁶¹ *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714-716 (1985) (discussing occupation of field implied preemption requirements; not applicable to FDA blood plasma collection requirements). *See also* *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293 (1988)(federal Natural Gas Act occupied field governing financing activities of natural gas companies). Furthermore, the impossibility preemption doctrine is inapplicable to tort law because tort defendants can always pay damages and comply with regulations at the same time. *See Ausness, supra* note at 924.

Implied conflict preemption doctrine requires an assessment of the scope of the federal law in issue and its objectives to determine whether there exists an actual conflict with the operation of applicable state laws. Historically, the Supreme Court has rejected the notion that Congress would entirely defeat the operation of state tort laws that traditionally had operated concurrently with federal regulation without clearly saying so.⁶² Consequently, implied intent to preempt traditional state tort doctrines has only occasionally been found.⁶³ To apply implied conflict preemption doctrine, the federal regulatory scheme and its objectives must be discerned.⁶⁴ The objectives of the FDCA in prescription drug labeling and the nature of the regulatory scheme are the subject of the next section.

A. General Regulation under Federal Food and Drug Laws

Federal regulation of food and drugs occurred as early as the mid-nineteenth century but began in earnest in 1906 with enactment of the Pure Food and Drug Act.⁶⁵ 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.⁶⁶ The states had regulated the safety of food and drugs since the earliest days of our country's history.⁶⁷ State regulators encouraged, indeed implored,⁶⁸ the national government to create a federal agency because of concerns over the states' inability to reach the interstate sale of fraudulent products and, thus, to protect consumers from them.⁶⁹

⁶²*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *English v. Gen. Elec. Co.*, 496 U.S. 72, 83 (1990).

⁶³*See, 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 922-24, 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.”); 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).

⁶⁴*See 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.

⁶⁵For 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).

⁶⁶O'REILLY, FOOD AND DRUG ADMIN. 2D at § 3:2.

⁶⁷*Id.* at § 25:1.

⁶⁸*See* 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>, and <http://www.fda.gov/opacom/backgrounders/miles.html>.

⁶⁹O'REILLY, FOOD AND DRUG ADMIN. 2D at § 25:1 (overview of relationship between the FDA and state governments).

The modern version of the federal food and drug regulatory scheme dates from the Food, Drug and Cosmetic Act of 1938.⁷⁰ 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.⁷¹ The 1938 legislation extended control over more products and enlarged and stiffened the penalties for its disobedience.⁷² In 1962, the Kefauver-Harris Amendments were passed to add the requirement of drug efficacy as well as greater safety and introduced a rigorous new drug approval process.⁷³ A variety of amendments to the 1938 Act over the ensuing years⁷⁴ has added to the complexity of the regulatory scheme and heightened the FDA's ability to achieve its public safety goals.

The key protection against the marketing of ineffective or unsafe prescription pharmaceutical products comes from the New Drug Approval process which new drugs must complete before being marketed.⁷⁵ The Center for Drug Evaluation and Research (CDER) is the office primarily responsible for evaluating new drug approval applications and is the self-described "consumer watchdog for the roughly 11,000 drugs on the market."⁷⁶ Within the

⁷⁰Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et. seq. (2006). 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).

⁷¹21 U.S.C. § 331 (2006)(describing prohibited acts of adulteration and misbranding). See also *United States v. Diapulse Corp. of America*, 457 F.2d 25 (2d Cir. 1972)(discussing purposes of Act to prevent adulterated and misbranded food and drugs); *Pharmaceutical Mfrs. Ass'n v. Food and Drug Admin.*, 484 F. Supp. 1179 (D. Del. 1980)(same). See generally Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER (Jan./Feb. 2006) (found at http://www.fda.gov/fdac/features/2006/106_cder.html).

⁷²*United States v. Dotterweich*, 320 U.S. 277 (1943); *Research Labs. v. United States* 167 F.2d 410 (9th Cir. 1948).

⁷³Kefauver-Harris Amendments to FDCA, Pub. L. 87-781, 76 Stat. 788-89 (Oct. 1962). See Meadows, *supra* note 71 ("Before marketing a drug, firms now had to prove not only safety, but also provide substantial evidence of effectiveness for the product's intended use. . . . Also critically, the 1962 amendments required that the FDA specifically approve the marketing application before the drug could be marketed, another major change.") For a discussion of drug efficacy requirements, see Anita Bernstein, [article presented at R-P—call Anita for status).

⁷⁴See, e.g., Food Allergen Labeling and Consumer Protection Act of 2004, Pub.L. 108-282, Title II, § 201, 118 Stat. 905 (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).

⁷⁵*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).

⁷⁶ Meadows, *supra* note 71 at 1. See also Leaf, *supra* note 75 at 112-113 (explaining drug application process and its limitations);

CDER, an Office for New Drug Approval oversees the process.⁷⁷ Once a drug is approved and on the market, fewer regulations exist to enable the FDA to follow the experience of an approved drug's users. The office responsible for policing the safety of prescription drugs, the Drug Safety Oversight Board (DSOB), was created in 2005 at least in part as the result of the withdrawal from the market of the osteo-arthritis pain reducer, VIOXX and the perceived lack of action by the FDA in response to information regarding the risk of increased cardiac events in its users.⁷⁸ The DSOB was recently criticized by the Government Accountability Office which described it as "underfunded and understaffed, and lacks a clear and effective method to decide whether and how to act when it finds that a drug is unsafe."⁷⁹ The GAO Report stated: "The FDA lacks clear and effective processes for making decisions about providing management oversight of post-marketing safety issues."⁸⁰ The GAO Report, prepared at the request of Congress, concluded that the FDA needed increased legal authority to require post-marketing clinical trials to obtain risk information, describing "serious limitations in the data" which currently support post-marketing safety initiatives.⁸¹

The regulations also provide that, once approved, if a prescription drug manufacturer subsequently fails to comply with any applicable regulation, the prescription drug may, as a result, be considered misbranded or adulterated under the Act.⁸² Penalties for selling an adulterated or misbranded drug or device may be assessed against the seller,⁸³ non-compliant products may be seized,⁸⁴ and injunctive relief is available in federal district court.⁸⁵ Of course,

⁷⁷For a complete discussion of the CDER and the Office of New Drugs and their organization, see http://www.fda.gov/cder/cderorg/ond_reorg.htm. The application process is detailed at <http://www.fda.gov/cder/regulatory/applications/default.htm>.

⁷⁸See FDA Statement on Vioxx and Recent Allegations and the Agency's Continued Commitment to Sound Science and Peer Review, FDA Press Release (Nov. 14, 2004); Hearings before Senate Health, Education and Pensions Committee (Feb. 28, 2005; March 3, 2005). For a description of the DSOB, see FDA Improvements in Drug Safety Monitoring, FDA Press Release (Feb. 15, 2005) ("emboldened vision" of FDA includes DSOB to oversee management of drug safety issues, and will provide emerging information to health providers and patients about the risks and benefits of medicines).

⁷⁹ Government Accountability Office Report, Drug Safety: Improvement Needed in FDA's Post-Marketing Decision-making and Oversight Process, at 1, 6 (March 2006). See also Ricardo Alonso-Zaldivar, "GAP Rips Effectiveness of FDA's Safety Office, L.A. TIMES (April 26, 2006).

⁸⁰GAO Report, *supra* note 79 at 6.

⁸¹ *Id.* at 34.

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

⁸³*Id.* at § 333.

⁸⁴*Id.* at § 334.

⁸⁵*Id.* at § 332.

the FDA must have sufficient information on which to base an action for penalties. Mandatory reporting by manufacturers of the results of post-marketing clinical trials is not required.⁸⁶

To be misbranded, a regulated product's labeling must be "false or misleading in any particular."⁸⁷ 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.⁸⁸ Proper labeling also includes the established name of the drug and information on the proportion of active ingredients and their established names, if any.⁸⁹

Most importantly, proper labeling includes "adequate directions for use" and "adequate warnings against use . . . where its use may be dangerous to health, or against unsafe dosage."⁹⁰ Labeling is written for the health care practitioner because prescription drugs require "professional supervision of a practitioner licensed by law to administer such drug."⁹¹ A physician acts as the "learned intermediary" between the manufacturer and the patient who is intended to use and benefit from the drug but who needs the physician to assess the risk and possible benefit of the product for the patient's condition.⁹² Tort liability for prescription drugs is based primarily on allegations of inadequate warnings of risk or improper use on the labeling resulting in insufficient advice to the prescribing physician about the potential harms of the drug.⁹³ How such warnings are created, approved, and modified through the FDA's labeling approval process is explored in the next sub-section.

⁸⁶ Leaf, *supra* note at 120 ("PhRMA, the industry's powerful trade group, continues to fight the idea of mandatory reporting, but promises that its member companies will offer more data voluntarily.").

⁸⁷*Id.* at § 352 (a).

⁸⁸*Id.* at § 352(b), (c). FDA approved labeling is defined generally at § 321(m).

⁸⁹*Id.* at § 352(e).

⁹⁰*Id.* at § 352 (f).

⁹¹*Id.* at § 353(b).

⁹²MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note at § 22:8 – 22.11, p. 564-75. 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 products. *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).

⁹³*See* MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note at §§ 22:9, 22:10. *See also* Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966)(one of earliest cases discussing manufacturer's 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

B. Prescription Drug Labeling Regulations

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.⁹⁴ "Labeling" is the set of documents that accompany the drug to the prescribing physician and the end user.⁹⁵ The FDA must assure that the statutorily required information is adequately communicated to those users but it does not create the labeling. It approves proposed labeling provided to it by the manufacturer after review of the manufacturer's application pursuant to the New Drug Approval regulations.⁹⁶ A number of regulations have been adopted by the FDA to accomplish its task.

The FDA labeling regulations include general requirements on the content and format of labeling for prescription drugs.⁹⁷ These regulations then refer to more specific requirements detailing what is to be included in the required labeling.⁹⁸ 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.⁹⁹ The labeling regulation states that "serious adverse reactions and potential safety hazards" must be described.¹⁰⁰ New drug applications are required

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).

⁹⁴For 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 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.

⁹⁵21 U.S.C. § 321(m). See also, O'REILLY, FOOD & DRUG ADMIN 2D, *supra* note at § 15:9.

⁹⁶21 U.S.C. § 355 (2004)(defining application requirements for new drug approvals). See also 71 Fed. Reg. at 3922 ("A prescription drug product's FDA-approved labeling . . . is a compilation of information about the product, approved by the FDA, based on the agency's thorough analysis of the new drug application (NDA) . . . submitted by the applicant.").

⁹⁷21 C.F.R. § 201.56 (2006).

⁹⁸*Id.* at § 201.57.

⁹⁹*Id.* at § 201.57(a), (b), (c), (d).

¹⁰⁰*Id.* at § 201.57(e), (f).

to contain copies of the labeling proposed by the manufacturer¹⁰¹ as well as a summary of the contents of that labeling.¹⁰²

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.”¹⁰³ The labeling formulation process is one of give-and-take with oversight by the FDA. The burden is on the manufacturer to submit information consistent with the regulations in support of its application.

Post-approval changes to 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.¹⁰⁴ These “major changes” include changes in the formulation of the drug or its substance.¹⁰⁵ 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 serious hazard with a drug; a causal relationship need not have been proved.”¹⁰⁶ 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.¹⁰⁷ 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

¹⁰¹21 C.F.R. § 314.50(e)(2)(ii)(2006).

¹⁰²*Id.* at § 314.50(c)(2)(i).

¹⁰³*Motus* Amicus Brief of United States, *supra* note at 5.

¹⁰⁴21 C.F.R. § 314.70(b) (“major” labeling changes require prior FDA approval).

¹⁰⁵ *Id.* (“major changes” include changes in the qualitative or quantitative formulation of the drug or changes that may affect drug substance).

¹⁰⁶*Id.* 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 known as a “black box warning.”

¹⁰⁷*Id.* at §314.70(c)(6)(iii)(A). *See also* Witezak 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).

approved.¹⁰⁸ The FDA must ultimately approve the labeling change,¹⁰⁹ but the regulation “was promulgated precisely to allow drug-makers to quickly strengthen label warnings when evidence of new side effects is discovered.”¹¹⁰ Nevertheless, manufacturers initiate labeling changes but commonly do not implement them without FDA approval.¹¹¹ Typically, the FDA and the manufacturer negotiate about any labeling change contemplated prior to implementation.¹¹²

In the preamble to the FDA’s new final labeling regulation, the FDA takes the position that any approved labeling preempts state common law tort actions, in spite of the manufacturer’s obligation to alter labeling when important safety information is acquired, 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 and its attempt to affect preemption doctrine are discussed in the next sub-section.

C. New Regulation on Labeling for Prescription Drugs

The new labeling 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.¹¹³ The new regulation has the following features: (1) introduces a “Highlights” section to labeling which will provide immediate access to a drug’s most commonly referenced material;¹¹⁴ (2) reorders and reorganizes the contents of labeling, introducing graphical requirements;¹¹⁵ and (3) makes warning and adverse reaction information more accessible.¹¹⁶ The

¹⁰⁸O’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).

¹⁰⁹21 C.F.R. at § 314.70(c)(6)(iii).

¹¹⁰*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).

¹¹¹See 71 Fed. Reg. 3922, 3934 (January 24, 2006)(discussion of labeling procedures in comments to new labeling regulation); See also *Motus Amicus Brief of United States*, *supra* note at 17 (discussing ultimate FDA approval required for all labeling changes).

¹¹² See *Vioxx data development press release*, *supra* note . See also, GAO Report on Drug Safety, *supra* note at .
¹¹³71 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 find specific information and to discern the most critical information.” 71 Fed. Reg. at 3922.

¹¹⁴71 Fed. Reg. at 3923.

¹¹⁵*Id.*

final regulation applies to new and recently approved drugs, those approved after 2001, and the former labeling requirements will continue to apply to older approved drugs.¹¹⁷

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.¹¹⁸ The drug manufacturer chooses the information to be included in each of section, including the “Warning and Precautions” section of the new labeling.¹¹⁹ “Judgment will continue to be necessary” in deciding which information must be emphasized.¹²⁰

Physicians and health care practitioners expressed “unequivocal enthusiasm” for the “Highlights” section while manufacturers were either opposed or “strongly” opposed to it.¹²¹ Manufacturer opposition was based, in part, on the obligation to choose the important warnings or other information to include while omitting other information which might cause the “Highlights” section to be misleading.¹²² Similarly, several comments suggested more specific criteria were needed to enable manufacturers to choose consistently the appropriate information to be included in the central “Highlights” section.¹²³ The manufacturers were concerned at least in part about potential competitive disadvantages that might result.¹²⁴ The FDA, acknowledging the concerns, suggested that it is “essential for FDA to review and approve most proposed

¹¹⁶*Id.*

¹¹⁷ *Id.* at 3923-26. 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. *Id.* at 3929. Guidance documents are authorized to provide additional information to regulated industries about compliance with FDA regulations and to inform the general public about FDA actions. 21 U.S.C. § 371(h)(1) (2004).

¹¹⁸*Id.* at 3924.

¹¹⁹*Id.* at 3930. FDA's guidance document on “Warnings and Precautions,” intended to assist manufacturers with how to determine the contents of that 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 <http://www.fda.gov/cder/guidance/index.html> (January 18, 2006).

¹²⁰71 Fed. Reg. at 3932.

¹²¹*Id.* at 3931.

¹²²*Id.*

¹²³*Id.* at 3932.

¹²⁴*Id.*

changes to the information in Highlights” and consequently is revising its regulations on supplementing approvals.¹²⁵

Consistent with its predecessor, the new regulation requires manufacturers to revise labeling unilaterally to include warnings about “clinically significant hazards” as soon as there is “reasonable evidence of a causal association” with the drug.¹²⁶ This language is slightly more rigorous in that it requires evidence of a connection between a drug and the risk to be warned about of “clinically significant hazards” before changing approved labeling, though a causal relationship still is not required.¹²⁷ Manufacturers continue to have “permission to add risk information to the Full Prescribing Information (FPI) without first obtaining FDA approval.”¹²⁸

Manufacturers maintain some discretion under the new regulation to choose what to say in drug labeling and how to say it, 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 preamble about the product liability implications of the proposed rule.¹²⁹

D. Proposed Preemptive Effect of the New Labeling Regulation

The FDA’s historical position on preemption 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.¹³⁰ The FDA favored the concurrent operation of state tort law for almost the entire first century of its existence based on (1) its 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.¹³¹ The preamble to the new labeling regulation now

¹²⁵*Id.* 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.*

¹²⁶New 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.

¹²⁷ See discussion of current labeling regulation *supra* notes and accompanying text.

¹²⁸71 Fed. Reg. at 3934, 3969.

¹²⁹*Id.* at 3933.

¹³⁰See *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).

¹³¹*Motus Amicus Brief of Public Citizen, supra note* at 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

argues, however, that product liability lawsuits have “directly threatened the agency’s ability to regulate manufacturer dissemination of risk information for prescription drugs.”¹³²

The FDA has formally regulated on preemption before, in its implementation of the Medical Device Amendments of 1976 to the FDCA.¹³³ 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.¹³⁴ As the Supreme Court said in *Medtronic, Inc. v. Lohr*,¹³⁵ “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.”¹³⁶

Unlike the formally promulgated regulation under the MDA, the new prescription drug labeling regulation does not contain a section on its preemptive effect but, rather, discusses preemption in the preamble.¹³⁷ That discussion reiterates the litigation positions taken in *Motus*

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 .

¹³²71 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.

¹³³21 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.

¹³⁴21 U.S.C. § 360k(a)

¹³⁵*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (interpreting express preemption provision of MDA; finding no preemption of common law damages claims).

¹³⁶*Id.* at 496.

¹³⁷71 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.

and other product liability cases.¹³⁸ The preamble suggests that preemption of state tort law is the FDA's "longstanding view" on preemption,¹³⁹ but that description appears at odds with prior statements of the FDA.¹⁴⁰

The preamble articulates the preemption position by generally arguing, consistent with what implied conflict preemption doctrine requires, that state law tort actions frustrate the agency's implementation of federal objectives.¹⁴¹ 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."¹⁴² The FDA takes the position that its regulations can establish both a floor and a ceiling.¹⁴³ 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."¹⁴⁴ The FDA has expressed the overwarning concern in recent medical device cases seeking greater preemptive effect of those regulations.¹⁴⁵

After articulating the arguments in favor of preemption, the FDA identifies those claims which would be impliedly preempted by its new labeling regulation.¹⁴⁶ It protects manufacturers for choices they make about what to include in the new "Highlights" section of the regulation.¹⁴⁷ It also seeks to codify its position in *Motus* that if a label was proposed to the FDA and

¹³⁸71 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 would be useful to set forth in some detail the arguments made in those amicus briefs."

¹³⁹ *Id.*

¹⁴⁰ See *supra* note 131 and accompanying text.

¹⁴¹71 Fed. Reg. 3922, 3934.

¹⁴²*Id.* at 3934-35.

¹⁴³*Id.* at 3935.

¹⁴⁴*Id.* To illustrate the overwarning concern, the preamble uses a case in which a state court found federal preemption of an inconsistent state regulation, not a product liability action. 71 Fed. Reg. at 3935. Ironically, the overwarning concern was raised in *Motus* and other 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.

¹⁴⁵*Horn v. Thoratec Corp.*, 376 F.3d 163, 171 (3d Cir. 2004).

¹⁴⁶*Id.* at 3935-36.

¹⁴⁷*Id.* at 3936.

ultimately not required by the time plaintiff claims it should have been, the plaintiff's claim based on a failure to warn is preempted.¹⁴⁸

The FDA admits that its position on preemption in the regulation is, in essence, a reiteration of its prior litigation position¹⁴⁹ which may change depending on the factual circumstances presented. The FDA acknowledges that some state common law damages actions will not be preempted.¹⁵⁰ It does not address the potential complementary way in which common law damages actions operate concurrently with FDA regulations by permitting compensation for injury and thereby creating an additional incentive to public safety.

The FDA claims that existing preemption principles support its preemption analysis. The proposed new regulation affects new and recently approved drugs, but the former regulation continues to apply to older drugs.¹⁵¹ Consequently, the FDA is attempting to alter its historical position against preemption and apply its new position retroactively to all drugs approved and 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 will now be fully explored in the next Section.

IV. 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 interest¹⁵² and that scholarship informs the following discussion.

¹⁴⁸*Id.*

¹⁴⁹*Id.*

¹⁵⁰*Id.* at 3936 (those based on parallel federal and state requirements).

¹⁵¹*See supra* note and accompanying text.

¹⁵²Symposium, *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).

A. *Preemption Doctrine Under the Pure Food and Drug Act of 1906*¹⁵³

Shortly after enactment of the first federal food and drug law, questions arose regarding how much state authority it displaced. In *Savage v. Jones*,¹⁵⁴ 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.¹⁵⁵ 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.¹⁵⁶ Further, because Congress had regulated in the field, the seller argued that the states were entirely foreclosed from regulating.¹⁵⁷

The Court, after rejecting the argument that the Indiana statute was unconstitutional because of its interference with interstate commerce,¹⁵⁸ noted that Congress did not expressly declare its intention to prevent the States from regulating within the subject of food and drugs.¹⁵⁹ The Court then described the applicable implied preemption inquiry:

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.¹⁶⁰

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

¹⁵⁴225 U.S. 501 (1912).

¹⁵⁵*Id.* at 509.

¹⁵⁶*Id.* at 511.

¹⁵⁷*Id.* at 512.

¹⁵⁸*Id.* at 528.

¹⁵⁹*Id.* at 533.

¹⁶⁰*Id.* (citations omitted) (emphasis added).

The Court concluded that 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.¹⁶¹ 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.¹⁶²

Savage v. Jones was decided decades before the onslaught of post-Depression era economic regulation and post-World War II civil rights and other public interest legislation. Preemption doctrine was in its infancy. Nevertheless, *Savage* is an important foundational case because it articulated a quite rigorous implied conflict preemption analysis in an early food and drug labeling matter. Indeed, the Court continues to refer to *Savage's* implied conflict preemption analysis, suggesting its continuing influence.¹⁶³

Building on its discussion of implied preemption in *Savage*, the Court in 1913 decided *McDermott v. Wisconsin*.¹⁶⁴ In *McDermott*, Wisconsin had enacted a food labeling provision which appeared to be in direct conflict with a federal regulation.¹⁶⁵ The U.S. Secretary of Agriculture had concluded that the defendant's corn syrup label was in compliance with the federal statute's misbranding provision.¹⁶⁶ The Wisconsin statute required that, before sale, the complying federal label had to be removed and replaced with an alternate label.¹⁶⁷ To comply with the Wisconsin statute, therefore, the seller had to remove the conforming federal label and,

¹⁶¹*Id.* 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)).

¹⁶²*Savage*, 225 U.S. at 539.

¹⁶³*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).

¹⁶⁴228 U.S. 115 (1913).

¹⁶⁵*Id.* at 125-126.

¹⁶⁶*Id.* at 127.

¹⁶⁷*Id.* at 133.

possibly, suffer penalties as a result of misbranding.¹⁶⁸ This is the first case in which the federal government, at that time through the Secretary of Agriculture, took a position in favor of federal preemption of a state food or drug regulation.

The Court concluded that the state's attempt to regulate exclusively was an improper interference with Congress' authority.¹⁶⁹ 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. . . .¹⁷⁰

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.¹⁷¹

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.¹⁷² 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.¹⁷³ During this time, the Supreme Court defined implied preemption doctrine more clearly.¹⁷⁴

¹⁶⁸*Id.*

¹⁶⁹*Id.* at 134.

¹⁷⁰*Id.*

¹⁷¹See, 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.

¹⁷²See *supra* notes and accompanying text.

¹⁷³Davis, *Unmasking the Presumption*, *supra* note at 978.

¹⁷⁴*Id.* at 997.

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.¹⁷⁵

Occupation of the field preemption occurs where Congress' legislation is so comprehensive that it occupies the entire field, displacing all state law.¹⁷⁶ An important early example of such field preemption is *Hines v. Davidowitz*.¹⁷⁷ *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.¹⁷⁸ The Court found implied congressional intent to legislate exclusively because of the core national interest at stake.¹⁷⁹ The Court has rejected occupation of the field preemption under the FDCA.¹⁸⁰

Conflict preemption occurs most frequently when the state law "stands as an obstacle" to the accomplishment of federal objectives and, therefore, must yield.¹⁸¹ Preemption issues under the FDCA have typically involved state or local regulation which allegedly impacted federal regulatory objectives. An early example is *Cloverleaf Butter v. Patterson*,¹⁸² in which Alabama officials seized substantial quantities of packing stock butter, used by the defendant in the manufacture of processed butter sold in interstate commerce, because of concerns over its quality under state food and drug regulation.¹⁸³ The federal Department of Agriculture regulated the use of the packing stock butter¹⁸⁴ and was not authorized to seize the product until after it was manufactured and moved in interstate commerce, when it might be considered adulterated.¹⁸⁵ Consequently, the state law required seizure at a time which the federal law did not permit. The

¹⁷⁵*Id.* at 988.

¹⁷⁶*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).

¹⁷⁷*Hines v. Davidowitz*, 312 U.S. 52 (1941).

¹⁷⁸*Id.* at 72-74.

¹⁷⁹See Davis, *Unmasking the Presumption*, *supra* note at 978-79, 988-89.

¹⁸⁰ *Hillsborough County, Florida v. Automated Medical Labs., Inc.*, 471 U.S. 707, 718 (1985).

¹⁸¹See *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).

¹⁸²*Cloverleaf Butter Co. v. Patterson*, 315 U.S. 786 (1942).

¹⁸³*Id.* at 165.

¹⁸⁴*Id.* at 150. The Internal Revenue Service was also involved in regulating the product. *Id.*

¹⁸⁵*Id.* at 166.

Company sought an injunction against the Alabama officials prohibiting them from seizing the packing stock butter.¹⁸⁶

The Supreme Court, relying on *Savage* and *McDermott*, concluded that the Alabama law was preempted.¹⁸⁷ 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 provisions are inconsistent with those of the state to justify thwarting the state regulation.”¹⁸⁸ 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.¹⁸⁹ The Court distinguished *Savage* because the state law in issue in that case merely required additional disclosures that the federal law neither required nor prohibited.¹⁹⁰ 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 conflict¹⁹¹ 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.¹⁹² 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.¹⁹³ 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.”¹⁹⁴ Sixty years after *Cloverleaf Butter Company* was decided, similar arguments continue to be made on both sides of the preemption debate.

¹⁸⁶*Id.* at 151.

¹⁸⁷*Id.* at 158-59.

¹⁸⁸*Id.* at 156.

¹⁸⁹*Id.* at 158-59.

¹⁹⁰*Id.* at 158.

¹⁹¹See 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”).

¹⁹²*Cloverleaf Butter Co.*, 315 U.S. at 169.

¹⁹³*Id.*

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

The Court did not address another FDCA preemption case until 1985 in *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*¹⁹⁵ In the intervening years, the Court decided a number of implied preemption cases. Importantly, in *San Diego Building Trades Council v. Garmon*,¹⁹⁶ the Court was faced with an application of implied preemption doctrine to state common law damages actions.¹⁹⁷ *San Diego Building Trades Council* involved whether the National Labor Relations Act (NLRA) preempted state tort actions by employers allegedly injured in the course of peaceful picketing by labor activists.¹⁹⁸ 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.¹⁹⁹ In finding 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,”²⁰⁰ and (2) state regulation can be exerted through common law damages actions as effectively as through more direct regulatory means.²⁰¹ The Court continues to refer to *Garmon* for these propositions.²⁰² These two fundamental features of implied preemption analysis, how to define the federal objectives with which state law arguably conflicts and the how to assess 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.*,²⁰³ the Court was called upon to determine whether the Atomic Energy Act (AEA),²⁰⁴ which regulated the nuclear energy industry, permitted state common law damages actions as a means of concurrent state

¹⁹⁵*Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

¹⁹⁶*San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959).

¹⁹⁷*Id.* at 237-39.

¹⁹⁸*Id.* at 241-46 (describing NLRA, as amended by the Labor Management Relations Act, 29 U.S.C. §§ 157, 158).

¹⁹⁹*Id.* at 240.

²⁰⁰*Id.*

²⁰¹*Id.* 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.

²⁰² See Davis, *Unmasking the Presumption*, *supra* note at 982-983, 1001.

²⁰³*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).

²⁰⁴42 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).

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.²⁰⁵

The AEA was enacted in 1954 to free the nuclear energy industry from total federal control and to provide for private involvement.²⁰⁶ Some limited regulatory authority was given to the states which had never before had any authority over nuclear power.²⁰⁷ The states were precluded, however, from regulating the safety aspects of nuclear material.²⁰⁸ 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.²⁰⁹ The Court, after reviewing the Act's legislative history and other congressional actions regarding the AEA,²¹⁰ stated, "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."²¹¹ 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. As an aside, and to be discussed in more detail shortly, for a time in the 1990s after *Cipollone* and other cases failed to follow *Silkwood's* approach to common law damages actions, *Silkwood* was considered an anomaly in preemption analysis,²¹² but recent decisions have resurrected the importance of its position on the effect of common law damages actions.²¹³

One year after *Silkwood*, the Court addressed a preemption challenge under the FDCA, though not one involving the regulatory effect of common law damages actions. In *Hillsborough*

²⁰⁵*Silkwood*, 464 U.S. at 243.

²⁰⁶The Atomic Energy Act of 1954, 68 Stat. 919, 42 U.S.C. §§ 2011-2284.

²⁰⁷*Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983).

²⁰⁸42 U.S.C. § 2021(c)(4).

²⁰⁹*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.*

²¹⁰*Id.* at 249.

²¹¹*Id.* 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.").

²¹² See, Davis, *Unmasking the Presumption*, *supra* note at 1001, 1013-14.

²¹³ See *infra* notes and accompanying text.

County Florida v. Automated Medical Laboratories, Inc.,²¹⁴ a Florida county sought to regulate the collection of blood plasma from paid donors by requiring additional limitations to those required under federal regulations.²¹⁵ The defendant blood plasma center argued for preemption under both implied occupation of the field and conflict preemption.²¹⁶ The Supreme Court disagreed on both issues and reversed an appellate court finding of preemption.²¹⁷

The Court, after describing the basic implied preemption doctrines applicable,²¹⁸ 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;²¹⁹ and (2) the presumption that state or local regulation of matters related to health and safety can constitutionally coexist with federal regulation.²²⁰

Regarding the FDA’s position against preemption, the court noted that its prior statement “is dispositive on the question of implicit intent to pre-empt unless either the agency’s position is inconsistent with clearly expressed congressional intent, . . . or subsequent developments reveal a change in that position.”²²¹ The FDA’s position against preemption had been made clear in commentary to the blood collection regulations²²² and even though the regulations had been broadened since then, the FDA had not indicated that the new regulations “affected its disavowal . . . of any intent to pre-empt.”²²³ The Court thus rejected occupation of the field preemption even though the regulations were comprehensive,²²⁴ noting that “merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean

²¹⁴*Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

²¹⁵*Id.* at 710.

²¹⁶*Id.* at 714.

²¹⁷*Id.* at 712.

²¹⁸*Id.* at 713. Preliminarily, the Court confirmed that preemption of local ordinances is analyzed in the same way as the preemption of statewide laws. *Id.*

²¹⁹*Id.* at 714.

²²⁰*Id.* at 715.

²²¹ *Id.* at 714-15 (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)).

²²² *Id.* at 714.

²²³ *Id.* at 716-17. The Court states: “Thus, if an agency does not speak to the question of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to pre-empt. . . [W]e will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety.” *Id.* at 718.

²²⁴*Id.* at 716.

that States and localities were barred from identifying additional needs or imposing further requirements in the field.”²²⁵ 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.”²²⁶ The federal interest was not so dominant to justify occupying the field given the historic primacy of state regulation in matters of health and safety.²²⁷

The Court’s discussion of field preemption, and the importance of the FDA’s position against preemption, informed its rejection of implied conflict preemption as well.²²⁸ The defendant had argued that the local ordinances place more stringent requirements than the federal requirements and, therefore, present a serious obstacle to the federal goal of “ensuring an adequate supply of plasma.”²²⁹ The Court found this concern to be too speculative to support pre-emption.²³⁰ First, there was little evidence in the record to support the factual assertion of increased costs from the local regulations or the effect they would have on blood plasma collection.²³¹ Second, even if there had been evidence of increased costs to plasma collection operators and an increased burden on donors imposed under the local regulation, they did not necessarily interfere with the federal goal of maintaining an adequate plasma supply.²³² According to the Court, neither Congress nor the FDA “has struck a particular balance between safety and quantity;”²³³ rather, “the regulations which contemplated additional state and local requirements merely establish minimum safety standards.”²³⁴

Finally, the Court noted that the FDA could promulgate preemption regulations “with relative ease” but it had not done so.²³⁵ The Court attached significance to the absence of either a FDA position or formal regulation on preemption: “Thus, since the agency has not suggested

²²⁵*Id.* at 717.

²²⁶*Id.*

²²⁷*Id.* 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)).

²²⁸*Id.* at 720.

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ *Id.* at 720-21.

²³²*Id.* at 721.

²³³ *Id.*

²³⁴*Id.* at 721.

²³⁵*Id.*

that the county ordinances interfere with federal goals, we are reluctant in the absence of strong evidence to find a threat to the federal goal of ensuring sufficient plasma.”²³⁶ Because Congress had delegated to the FDA administration of the federal program, the Court was strongly influenced by the FDA’s position as reflected in the prior regulatory commentary and the FDA’s silence on the matter in the case before it.²³⁷ *Hillsborough County* is a strong pro-state regulation preemption decision under the FDCA that also provides insight into how important the Court considers the agency’s position on preemption to be.

In summary, until the late 1980’s, the Court had found preemption under the FDCA only in two narrow cases, both arguably involving impossibility.²³⁸ Those cases can now be said to rest on shaky ground because of the increasingly narrow definition of actual conflict the Court began to use in subsequent years.²³⁹ The Court certainly was influenced by the importance of historic state regulation in the area of public health and safety in all these cases. After *Silkwood*, it would appear that common law damages actions would survive the implied conflict preemption hurdles defined by the Court, absent clear indication of agency position to the contrary. 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 likely 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 re-evaluated preemption doctrine as it applied to common law damages actions. In *Cipollone v. Liggett Group, Inc.*,²⁴⁰ 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.²⁴¹ In such a case, the Court’s task was only to determine the scope of the provision.²⁴² Rarely had the Court given exclusive control to an express preemption provision,

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ See *supra* notes ____ and accompanying text (discussing *McDermott* and *Cloverleaf Butter*).

²³⁹ See *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).

²⁴⁰ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

²⁴¹ *Id.* at 517.

²⁴² *Id.* at 518, 523.

particularly as it applied to common law damages actions.²⁴³ *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 may continue to be important, however, in the implied preemption context.

Cipollone involved the preemptive effect of the federal cigarette labeling and advertising laws on products liability actions.²⁴⁴ The Court mentioned the presumption against federal preemption of matters historically within the states' police powers, and emphasized the prominence of discerning congressional intent.²⁴⁵ The plurality opinion, written by Justice Stevens, used the text of the provisions and the legislative history to preempt some, but not all, common law damages actions.²⁴⁶ The plurality acknowledged that common law damages actions can have an indirect regulatory effect²⁴⁷ 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."²⁴⁸

In its next several products liability preemption cases, the Court adhered to its *Cipollone* analysis and exclusively analyzed express preemption provisions. In *Freightliner Corp. v. Myrick*,²⁴⁹ the Court found that the National Traffic and Motor Vehicle Safety Act (NTMVSA)²⁵⁰ did not preempt state law claims based on the absence of anti-lock brakes on certain trucks

²⁴³See Davis, *Unmasking the Presumption*, *supra* note ___, at 1001.

²⁴⁴Federal 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).

²⁴⁵*Cipollone*, 505 U.S. at 516.

²⁴⁶505 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.

²⁴⁷*Id.* at 524.

²⁴⁸*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)).

²⁴⁹ *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).

²⁵⁰15 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).

because no federal standard existed requiring them.²⁵¹ 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, however.²⁵² Similarly, the Court found in *CSX Transportation, Inc. v. Easterwood*²⁵³ that the Federal Railroad Safety Act did not expressly preempt state common law damages actions based on the location of railroad crossing devices because Congress' intent clearly permitted more rigorous state regulation.²⁵⁴ Interestingly, the Federal Highway Administration (FHWA), authorized to implement the FRSA, supported a broad reading of the preemption provision but the Court rejected that reading as inconsistent with the statute's plain language.²⁵⁵

Preemption under the FDCA came before the Court next in *Medtronic, Inc. v. Lohr*²⁵⁶ which involved the express preemption provision of the Medical Device Amendments of 1976 (MDA).²⁵⁷ The MDA directs the FDA to regulate the safety and effectiveness of medical devices based on the type of device involved and the method by which it is approved for marketing.²⁵⁸ 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.²⁵⁹ 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 which permits market approval if a device is substantially equivalent to one already on the market.²⁶⁰ The Court was divided on whether the MDA preempted the plaintiff's claims, but all justices agreed that the express preemption provision controlled the analysis.²⁶¹

²⁵¹*Freightliner Corp.*, 514 U.S. at 289-90.

²⁵²*Id.* at 284.

²⁵³ *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658 (1993).

²⁵⁴*Id.* at 662 (preemption provision specifically exempts concurring, non-conflicting, state regulations from its operation).

²⁵⁵*Id.* at 664.

²⁵⁶*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

²⁵⁷21 U.S.C. § 360k (2000).

²⁵⁸*See Medtronic*, 518 U.S. at 475-80 (detailing history of MDA and its regulatory scheme).

²⁵⁹21 U.S.C. § 360k(a) (2000).

²⁶⁰518 U.S. at 477.

²⁶¹*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

Even though *Medtronic* involves express preemption analysis, a number of important features of the decision may affect implied conflict preemption under the FDCA more generally. First, 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.²⁶² Consequently, the majority opinion considered the language of the express preemption provision narrowly.²⁶³ The pre-market notification process, under which the pacemaker had been approved, did not include specific requirements.²⁶⁴ 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.”²⁶⁵ A majority of the justices, however, thought that common law damages actions generally do impose requirements, and, therefore, may be preempted under the statute if they differ from a clearly expressed federal requirement.²⁶⁶

Second, all three *Medtronic* opinions explored the importance of agency position and interpretation of agency regulations in determining the scope of preemption.²⁶⁷ 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

circumstances even when an express preemption provision was in issue, and cited *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995). *Id.* at 503.

²⁶²*Medtronic*, 518 U.S. at 475 (citing *Hillsborough County*, 471 U.S. 707, 719 (1985)).

²⁶³*Id.* at 487-88.

²⁶⁴The 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 generally* S. FOOTE, *MANAGING THE MEDICAL ARMS RACE: INNOVATION AND PUBLIC POLICY IN THE MEDICAL DEVICE INDUSTRY* (1992).

²⁶⁵*Medtronic*, 518 U.S. at 493-94.

²⁶⁶*Id.* at 509 (O’Connor, J., concurring in part and dissenting in part); *id.* at 505 (Breyer, J., concurring). Justice Breyer, whose opinion provided the final vote against preemption, 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 possesses a degree of leeway” to proscribe the preemptive effect of its regulation. *Id.* at 505.

²⁶⁷*Id.* 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).

scope of preemption where consistent with statutory language.²⁶⁸ The FDA had adopted a regulation which provided that preemption would occur only when the FDA had established regulations specific to a particular device.²⁶⁹ The FDA had maintained that its preemption position did not prohibit common law damages claims and, thus, narrowed the scope of preemption.²⁷⁰ The plurality opinion's interpretation of the scope of the preemption provision was "substantially informed" by the agency's regulations²⁷¹ because of the "unique role"²⁷² given to it by Congress to implement provisions of the Act.²⁷³ 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."²⁷⁴ The majority recognized, however, that a case in which the federal government "has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers"²⁷⁵ might present an entirely different case for preemption under the statute and its implementing regulations.

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."²⁷⁶ In particular, the FDA has a "special understanding of the likely impact

²⁶⁸CSX 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*).

²⁶⁹ 21 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").

²⁷⁰ Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 *Food & Drug L.J.* 7, 7 (1997). See also Ausness, *supra* note at 753.

²⁷¹*Medtronic, Inc.*, 518 U.S. at 495.

²⁷²*Id.* at 496.

²⁷³*Id.* (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)).

²⁷⁴518 U.S. at 501-02.

²⁷⁵ *Id.* at 501.

²⁷⁶*Id.* at 505-06 (citing *Hillsborough County*, 471 U.S. 707, 721 (1985)).

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.”²⁷⁷ Justice Breyer concluded that the express preemption provision did not fully answer the preemption question.²⁷⁸ 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.²⁷⁹

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*,²⁸⁰ 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.²⁸¹ The NTMVSA contains a preemption provision which states that whenever a federal motor vehicle safety standard, “FMVSS,”²⁸² is in effect, states may not establish or maintain any “safety standard applicable to the same aspect of performance” which is not identical to the federal standard.²⁸³ 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.”²⁸⁴

²⁷⁷*Id.* at 506.

²⁷⁸*Id.* at 505.

²⁷⁹*Id.* at 508. Justice O’Connor rejected the FDA’s interpretation of the preemption provision insofar as it purported to narrow the plain meaning of the statutory provision. *Id.* at 509, 512 (O’Connor, J., dissenting in part) (“It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735 (1996), but one pertaining to the clear statute at issue here is surely not.”).

²⁸⁰*Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

²⁸¹*Id.* 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).

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

²⁸³*Id.* § 1392(d) (codified at 49 U.S.C. 30103(b)(1)).

²⁸⁴*Id.* § 1397(k).

The Department of Transportation issued FMVSS 208 regarding Occupant Crash Protection in 1967.²⁸⁵ After several revisions, the 1984 version, in issue in *Geier*, permitted manufacturers to choose, with some restrictions, between air bags and seat belt systems.²⁸⁶ 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.²⁸⁷

Justice Breyer, writing for the majority, 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.²⁸⁸ 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?"²⁸⁹ 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."²⁹⁰ The Court's failure to rely on the express preemption provision has been much criticized given the Court's prior reliance on them in both *Cipollone* and *Medtronic*.²⁹¹ The Court's implied conflict preemption analysis, therefore, must be considered extremely important guidance to future implied preemption cases.

²⁸⁵See 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).

²⁸⁶*Geier*, 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).

²⁸⁷*Geier*, 529 U.S. at 865.

²⁸⁸*Id.* at 868.

²⁸⁹*Id.* at 869.

²⁹⁰*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)).

²⁹¹ See Davis, *Unmasking the Presumption*, *supra* note at 1005-1012; Ausness, *supra* note at 968.

The Court found that an “actual conflict”²⁹² existed and thus plaintiff’s common law actions were preempted.²⁹³ Two important components of its analysis need mentioning. First, the Court rejected as conclusive the statutory definition of federal standards as “minimum” standards of care.²⁹⁴ Instead, the Court reviewed carefully the history of the regulation which had been, at times, unpopular with almost everyone.²⁹⁵ Consequently, the views of the various Secretaries’ of Transportation were very influential,²⁹⁶ as well as the comments to the original standard²⁹⁷ and the current Secretary’s position, described in an amicus brief in the case, “[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.’”²⁹⁸ The Court’s review of the regulation’s tortured history identified the various Secretaries’ 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.²⁹⁹ The Court recognized that the standard reflected a variety of considerations, “deliberately sought variety,”³⁰⁰ and was, therefore, neither a minimum nor a maximum standard.

Second, in defining the federal objectives in issue, the Court “placed some weight” upon DOT’s own interpretation of those objectives and its conclusion that the tort actions would stand as an obstacle to those objectives.³⁰¹ The Court justified that level of deference to 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.³⁰² The consistency of the Secretary of Transportation’s position on preemption over time was also influential in supporting the Court’s

²⁹²By 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.

²⁹³*Id.* at 883.

²⁹⁴49 U.S.C. § 30102(a)(9).

²⁹⁵ 529 U.S. at 875-877.

²⁹⁶ *Id.* at 875.

²⁹⁷ *Id.*

²⁹⁸*Id.* at 881 (citing Brief for United States as Amicus Curiae at 25).

²⁹⁹*Id.* at 877-879.

³⁰⁰ *Id.* at 878.

³⁰¹ *Id.* at 883.

³⁰²*Id.*

position. That position had been taken in two recent cases, through amicus briefs.³⁰³ The lack of a formal statement on pre-emption was, therefore, not determinative.³⁰⁴ Relying on *Hillsborough County*, the Court clearly rejected the requirement of a formal agency statement on preemption to support conflict preemption, stating “While we certainly accept the dissent’s basic position that a court should not find pre-emption too readily in the absence of clear evidence of a conflict, . . . to insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be in certain cases to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended.”³⁰⁵

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 preemption³⁰⁶ but it discussed the state’s general interest in the health and welfare of its citizens.³⁰⁷ The Court was sympathetic to this important concern.³⁰⁸ 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.”³⁰⁹

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.³¹⁰ While acknowledging that Congress intended some non-uniformity 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.³¹¹ The Court recognized that “tort law may be somewhat different, and that related considerations--for example, the ability to pay damages instead of

³⁰³ *Id.* (citing *Freightliner Corp. v. Myrick*, and *Wood v. General Motors*).

³⁰⁴ *Id.* at 884. For 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 , at 50.

³⁰⁵ *Id.* at 885

³⁰⁶ *Id.* at 894 (Stevens, J., dissenting). See also Davis, *Unmasking the Presumption*, *supra* note , at 1008; Raeker-Jordan, *supra* note , at 8-9.

³⁰⁷ 529 U.S. at 880.

³⁰⁸ *Id.* at 881.

³⁰⁹ *Id.*.

³¹⁰ *Id.* at 882.

³¹¹ *Id.*.

modifying one's behavior--may be relevant for pre-emption purposes,"³¹² the Court found those 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*,³¹³ 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.³¹⁴ 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.³¹⁵ Because policing fraud on a federal agency was uniquely federal and not a subject which states had traditionally governed, the Court quickly concluded that no presumption against preemption would operate.³¹⁶

The Court began by identifying federal objectives: the federal regulatory scheme empowers the FDA to protect itself from and to deter fraud.³¹⁷ 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.³¹⁸ 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.³¹⁹

³¹²*Id.*

³¹³*Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001)

³¹⁴*Id.* at 344. For a complete description of the fraud allegations, see *Ausness*, *supra* note at ; and *Owen*, *supra* note at 427-28.

³¹⁵*Buckman Co.*, 531 U.S. at 347-348, n. 2 ("we express no view on whether these claims are subject to express preemption").

³¹⁶*Id.* at 347-48.

³¹⁷*Id.* at 348-349.

³¹⁸*Id.* at 349-350.

³¹⁹*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.").

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.³²⁰ Similarly, the cost that recognizing state law fraud claims would impose on the industry could create approval delays of valuable devices, agency administrative inefficiency, and delay in the provision of health care.³²¹ 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.³²² The Court noted, however, that a traditional state tort action might survive.³²³

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

The Court's next two preemption opinions, *Sprietsma v. Mercury Marine*³²⁴ and *Bates v. Dow Agrosciences LLC*,³²⁵ 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.³²⁶ The Federal Boat Safety Act of 1971 ("FBSA")³²⁷ 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.³²⁸ The Coast Guard, after

³²⁰*Id.* at 350.

³²¹*Id.* at 351.

³²²*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*).

³²³*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.").

³²⁴*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

³²⁵*Bates v. Dow Agrosciences LLC*, 125 S.Ct. 1788 (2005).

³²⁶*Id.* at 55. Plaintiff's wife had been thrown from a boat and was killed when struck by the propeller blades. *Id.*

³²⁷46 U.S.C. §§ 4301-4311 (2000).

³²⁸S. Rep. No. 92-248, at 1333-35, reprinted in 1971 U.S.C.C.A.N. 1333.

gathering data and holding public hearings over a several year period, decided *not* to require such guards for reasons of safety, feasibility and economics.³²⁹ Neither did the Coast Guard forbid the use of such guards.³³⁰ 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.³³¹ The FBSA contains both an express preemption provision and a savings clause.³³²

The Court, consistent with *Geier*, found no express preemption and engaged in an implied conflict preemption analysis.³³³ 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.³³⁴ The Coast Guard's position on preemption, therefore, was in favor of permitting state common law claims.³³⁵ 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.³³⁶

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*,³³⁷ involved whether common law tort actions challenging the labeling of defendant's pesticide were

³²⁹*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).

³³⁰*Id.*

³³¹*Id.* at 55.

³³²*Id.* at 55-56.

³³³*Id.* at 63-64.

³³⁴*Id.*

³³⁵*Id.* at 65-66. The Court emphasized the Government's consistent position that the regulation did not have any preemptive effect. *Id.* at 66.

³³⁶*Id.* at 69-70. Finally, the general federal interest in uniformity was an insufficient objective, without more, to create a conflict. *Id.* at 70.

³³⁷*Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788 (2005).

preempted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).³³⁸ 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.³³⁹ 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).³⁴⁰ 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 case³⁴¹ and then in favor of preemption as proposed in an amicus brief submitted in *Bates*.³⁴²

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.”³⁴³ The history of the FDCA regarding drugs is virtually identical.³⁴⁴ In addition, FIFRA imposes misbranding liability for labels that are false or misleading in any particular,³⁴⁵ just as the FDCA does for prescription drugs and devices. The addition to FIFRA in 1972 of an express preemption provision which governs the continuing role of the states in pesticide regulation is the primary difference between the two statutory schemes.³⁴⁶ In addition, the EPA does not determine or endorse the efficacy of pesticides it approves for marketing,³⁴⁷ unlike the FDA’s drug approvals which do review the efficacy claims in drug applications.³⁴⁸

The Court noted that tort litigation has been ongoing 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

³³⁸*Id.*

³³⁹*Id.* at 1796.

³⁴⁰*Id.* at 1793-94 (emphasis supplied).

³⁴¹*Etcheverry v. Tri-Ag Service, Inc.*, 993 P. 2d 366 (2000) (Brief Amicus Curiae for Unites States).

³⁴²125 S. Ct. at 1794, fn. 7.

³⁴³*Id.* at 1794.

³⁴⁴ *See supra* notes and accompanying text.

³⁴⁵*Id.* at 1795.

³⁴⁶*Id.* at 1795-96.

³⁴⁷*Id.* at 1796.

³⁴⁸ *See supra* notes and accompanying text.

preemption were advanced.³⁴⁹ 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.³⁵⁰

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.³⁵¹ “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.”³⁵² Consequently, state law requirements that are “equivalent to or consistent with” FIFRA regulations survived.³⁵³ Parallel requirements imposed on manufacturers under state and federal law will provide an additional cause to comply with the federal requirements.³⁵⁴

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.”³⁵⁵ 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.³⁵⁶ 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,”³⁵⁷ noting that tort suits can act “as a catalyst” in this effort.³⁵⁸ The Court’s discussion in *Bates* of the benefit of tort suits in

³⁴⁹*Id.* at 1796-97.

³⁵⁰*Id.* at 1803-04.

³⁵¹*Id.* at 1799.

³⁵²*Id.* “The inducement test is unquestionably overbroad . . . “ *Id.*

³⁵³*Id.* at 1800.

³⁵⁴*Id.* 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 against preemption that the Court adopted. *Id.*

³⁵⁵*Id.* at 1802.

³⁵⁶*Id.*

³⁵⁷*Id.*

³⁵⁸*Id.*

warning cases and the value of those tort actions historically in regulating warnings may serve as an important bridge to the implied preemption issue under the FDCA.³⁵⁹

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.*,³⁶⁰ and is likely to be especially forceful in implied conflict preemption under the FDCA. Even though *Geier* did not mention it specifically, the Court was certainly sensitive to the role that tort actions play in motivating conduct and specifically left open the possibility that tort actions in some cases, even under the standard there in issue, might survive if narrowly drawn.³⁶¹ *Bates* discussion of the long-standing role of tort litigation both before and under FIFRA reiterate the important role of the state's in regulating public health and safety, particularly where the giving of important safety information through product labeling and literature is concerned, as is the case under the FDA with prescription drug labeling.

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*.³⁶² 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, though it remain unclear just how important the agency's position will be. As early as *Hillsborough County*, the importance to the Court of the FDA's position on preemption, and whether that position has been consistently held, is evident.³⁶³

While federal regulatory action reflects a balancing of objectives with methods that will properly implement those objective, the importance of maintaining a particular balance has

³⁵⁹ For a discussion of the effect of *Bates* on prescription drug labeling preemption, see OWEN, PRODUCTS LIABILITY, *supra* note at § 14:3 (2d ed. forthcoming 2008).

³⁶⁰ See *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).

³⁶¹ See *supra* notes and accompanying text.

³⁶² See *supra* notes and accompanying text.

³⁶³ See *supra* notes and accompanying text (discussing importance of absence of agency position in *Hillsborough County*).

tipped the scales in favor of implied conflict preemption, as was the case in *Geier* but not in *Sprietsma* or *Bates*. 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?

V. NEGOTIATING THE BATTLEFIELD OF PRESCRIPTION DRUG LABELING PREEMPTION

This section applies the previous analysis of implied preemption doctrine to the prescription drug labeling context. The FDA's arguments in favor of implied conflict preemption are reiterated, and then the Supreme Court's implied conflict preemption doctrine is applied to those arguments. Finally, insights gleaned from the Court's broader preemption doctrine aid in the final analysis and require the ultimate conclusion that the FDA's preemption arguments are unlikely to prevail.

A. *The Arguments for Implied Conflict Preemption*

Fundamentally, the FDA and manufacturers who support preemption must define an actual conflict between state law and federal objectives that requires the conclusion that those federal objectives will be frustrated by the concurrent operation of state tort laws. The Court has rejected imposing any "special burden" on proponents of conflict preemption;³⁶⁴ rather, the Court has stated, in various ways, that the presumption against preemption in the area of traditional state regulation of health and safety require a clear conflict, even one requiring "strong evidence" to support it.

The FDA has articulated three objectives that it considers impacted by the operation of state tort laws because of the sensitive balance that its labeling regulations achieve. First, 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.³⁶⁵ This potential over-warning of risks may also deter the use of an otherwise beneficial drug in circumstances when it is advised. The concern of over-warning is connected to the general concern that manufacturers will be motivated to alter warning labels without substantiation and therefore impact medical treatment provided by physicians.

Second, 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

³⁶⁴ See *supra* notes and accompanying text (discussing *Geier* and rejection of special burden notion).

³⁶⁵ See *supra* notes and accompanying text.

approval.³⁶⁶ The FDA also notes the further 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.

The Zoloft experience, as documented in *Motus v. Pfizer, Inc.*,³⁶⁷ well illustrates the arguments being made for implied conflict preemption and, indeed, may be the poster child for such preemption. 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.³⁶⁸ Zoloft was first approved in 1991 and subsequently approved for four additional medical conditions.³⁶⁹ 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.³⁷⁰ The FDA never prohibited Pfizer or other SSRI manufacturers from altering the labeling, however,³⁷¹ 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.³⁷²

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.³⁷³ 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.”³⁷⁴ According to the FDA, a common law tort action

³⁶⁶ See *supra* notes and accompanying text.

³⁶⁷*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).

³⁶⁸127 F.Supp. 2d at 1089-1090.

³⁶⁹*Id.* at 1089.

³⁷⁰*Id.* at 1090; see also *Motus* Amicus Brief of United States, *supra* note at 13.

³⁷¹*Motus*, 127 F. Supp. 2d at 1093-94.

³⁷²*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, somewhat self-servingly, that the FDA would have disapproved an altered Zoloft label. *Id.* at 18.

³⁷³*Id.* at 23.

³⁷⁴*Id.*

might encourage the use of a warning that would diminish the impact of valid warnings, “creating an unnecessary distraction.”³⁷⁵

Each of these concerns, over-warning resulting in 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 new labeling regulation.³⁷⁶ 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? This inquiry requires a careful assessment of the agency’s position over time with sensitivity to the history of those objectives. The debate over whether FDA regulations set minimum or maximum standards is central to this inquiry. Second, what effect does the historic presumption that state regulation in the field of public health and safety is not preempted have in the assessment of those objectives? The Court has been hesitant to permit an overly aggressive assessment of federal objectives to swamp the importance of state regulation, particularly in the area of longstanding traditional tort principles. Third, does the indirect regulatory effect of common law damages actions create an actual, direct conflict with the objectives of the prescription drug labeling regulatory regime? Subsumed in this third question is the debate over 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*³⁷⁷ and *McDermott v. Wilson*,³⁷⁸ the objective of the food and drug laws has been clear: to protect the public health and safety from adulterated and misbranded drugs.³⁷⁹ The FDA, as the undisputed expert federal public health agency charged with insuring the safety and efficacy of the nation’s drug supply,³⁸⁰ must be permitted to satisfy its public

³⁷⁵*Id.* at 23-24.

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

³⁷⁷*Savage v. Jones*, 225 U.S. 501 (1912).

³⁷⁸*McDermott v. Wilson*, 228 U.S. 115 (1913).

³⁷⁹*See supra* notes and accompanying text.

³⁸⁰71 Fed. Reg. at 3934.

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.³⁸¹

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 Amendments of 1976,³⁸² 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”³⁸³ 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 clear³⁸⁴ support the requirement of clear, particularized federal objectives to which implied conflict preemption principles are applied in the prescription drug labeling context.³⁸⁵

As in *Hillsborough County*, those seeking to preempt state health and safety regulations, therefore, have an “uphill battle.”³⁸⁶ “Strong evidence” is needed to defeat the presumption that state health laws are not preempted,³⁸⁷ either in their entirety, through a federal occupation of the

³⁸¹*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).

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

³⁸³*Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1802 (2005)

³⁸⁴*Id.* at 1802. *See also supra* notes and accompanying text.

³⁸⁵*See, e.g.*, *Witczak 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).

³⁸⁶*Hillsborough County*, 471 U.S. at 714.

³⁸⁷*Id.* at 719.

field³⁸⁸ or through actual conflict. When implied conflict preemption is in issue, therefore, federal objectives must be defined on a narrow, particularized basis³⁸⁹ 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.³⁹⁰ General observations about the possible negative implications of common law tort actions on the regulatory scheme should be met with skepticism.

The FDA’s stated objective to prevent over-warning sounds like the kind of general objective that is unpersuasive under this standard. Concerns about over-warning are often made by manufacturers in the products liability field because of the generalized concern that juries too easily require warnings based on the hindsight that a particular warning, not given, should have been, putting manufacturers in the position of having to warn about everything. Prescription drug labeling is directed at a very sophisticated physician audience. The over-warning concern is quite different when raised with a learned intermediary, and one that the FDA only substantiates with very general statements and no data supporting the concern. When offered the choice to have information in the new labeling regulation highlighted and emphasized, physicians uniformly greeted the new format with approval because they wanted more information, and not less.³⁹¹

It is hard to understand why having less information about the possible risks of a drug treatment would benefit a patient’s medical care rather than more. A physician who might be inclined to withhold a particular drug treatment because of disclosed risks may do so for an infinite variety of reasons related to the individual patient’s medical needs, only one of which may be sensitivity to “over-warning.” The potential harm, of course, from a lack of information

³⁸⁸See *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.”).

³⁸⁹See *Hillsborough County, Fla.* 471 U.S. at 720-21 (defining federal goal narrowly in assess actual conflict preemption).

³⁹⁰See *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 Honda Motor Corp.*, and *Buckman Co. v. Plaintiffs’ Legal Comm.*,

³⁹¹ See *supra* notes and accompanying text.

about those risks, which can be explained in the exacting scientific detail with which all prescription drug labels are written, should not be overstated.

The generalized objectives the FDA has articulated do not have the level of historic, long-standing support which supported the “variety and mix” of objectives that were present in *Geier*. The regulatory objectives in *Geier* applied to a particular design features for all automobiles manufactured in the United States, not just one automobile model. Further, the design requirement, involving significant technical detail in automobile engineering, permitted a choice of designs to achieve a deliberate balance in the automobile fleet over time as the ultimate goal, air bags in all vehicles, could be achieved. By contrast, the prescription drug labeling preemption argument relates to certain prescription drugs whose manufacturers have information about risk, discovered post-approval, which could be disclosed, indeed may have to be disclosed according to the statutory scheme, but which they do not wish to disclose. Like *Bates*, in which the manufacturer had a continuing obligation to assure its label was not misleading, an agency’s approval of warning language, that may be subsequently and unilaterally altered, does not rise to the level of firm regulatory objectives as found in *Geier* that might support a direct conflict with state tort litigation. To substantiate the decision to withhold risk information from well-educated, sophisticated physicians requires a better explanation under the Court’s implied preemption cases than the generalized concern of over-warning currently articulated.

2. *Historic State Regulation and the Presumption Against Preemption*

The traditional role of the states in regulating food and drug safety, coupled with the historic recognition of the value of common law damages actions in that effort, will weigh heavily in the determination of whether state law directly and actually conflicts with federal objectives in the field. As early as *Savage v. Jones* and as recently as *Bates v. Dow Agrosciences LLC*, the Court has acknowledged the importance of state law, including state tort litigation, in providing a remedial component of the regulatory scheme as well as serving as a catalyst in aid of the federal regulatory effort.³⁹²

The Court has 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,³⁹³ but clearly returned to an emphasis on that presumption in *Bates*.³⁹⁴ The use of the presumption against preemption in the implied preemption context is different contextually because congressional intent is not specifically in issue but, rather, the presumption against preemption is critical in determining whether an actual conflict is present.

³⁹² See *supra* notes and accompanying text (discussion of *Savage v. Jones* and *Bates v Dow Agrosciences*).

³⁹³ See *supra* notes and accompanying text.

³⁹⁴ See *supra* notes and accompanying text.

For example, in *Hillsborough County*, the Court considered the presumption against preemption to apply strongly and defeat implied field preemption.³⁹⁵ Regarding conflict preemption, the Court was less concerned with the presumption because it found no evidence of an actual conflict to begin with because the stated federal objectives were too speculative to be credited.³⁹⁶ 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.³⁹⁷ *Geier* was sensitive to the need for tort law compensation and its regulatory effect and, in a very close call, exalted the federal objectives because of their specificity, comprehensiveness, and the background historic societal debate that passenger restraint regulation involved. In *Buckman Co.*, the Court rejected the notion that a presumption operated in the facts of that case 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.³⁹⁸

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 openly 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.³⁹⁹ The Court refused to permit an expert agency assessment to have greater effect than necessary. Arguably, an FDA decision *not* to require a particular warning in prescription drug labeling is, in effect, a decision *not* to regulate and should be treated in a similar fashion.

Similarly, the Court was openly hostile toward the proposed rejection of "longstanding" principles of tort compensation in *Bates*⁴⁰⁰ involving pesticide labeling under FIFRA. The Court

³⁹⁵See *supra* notes and accompanying text.

³⁹⁶*Id.*

³⁹⁷See *supra* notes and accompanying text.

³⁹⁸*Id.*

³⁹⁹See *supra* notes and accompanying text.

⁴⁰⁰See *supra* notes and accompanying text.

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.⁴⁰¹ *Bates* involved a labeling approval regime of fewer rigors than the FDA's but the regime 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.

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, and has traditionally. The addition of a remedial scheme based on long-standing state tort litigation "would seem to aid, rather than hinder" the functioning of a regulatory scheme based on warning misbranding claims, as the court found in *Bates*.⁴⁰² There is no reason, other than the FDA's changed position on preemption, to now treat common law tort actions differently than in the traditional way.

3. *Effect of the FDA's change in position on preemption*

The FDA argues that because labeling approval is solely within the FDA's authority, state common law tort actions may interfere with the balancing of risks that under gird that approval. The concern of over-warning and the possible disincentive created to physicians to prescribe an otherwise appropriate drug are at the core of this argument.

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 as relevant to assessing conflict preemption. In neither *Sprietsma*, *Bates*, nor *Easterwood* was such a change in agency position credited.⁴⁰³ *Bates* and *Easterwood* involved express preemption provisions as to which greater deference to agency interpretations might have been appropriate; nevertheless, the Court refused to credit it.⁴⁰⁴

In *Medtronic*, the plurality opinion was "substantially informed" by the FDA's position on preemption because Congress had expressly provided authority to the FDA to determine when

⁴⁰¹*Id.*

⁴⁰² *Bates*, 544 U.S. at 451. *See supra* notes and accompanying text.

⁴⁰³ *See supra* notes and accompanying text.

⁴⁰⁴ *See supra* notes and accompanying text.

state regulations would be preempted under the MDA.⁴⁰⁵ 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 O'Connor in dissent noted uncertainty as to whether any deference was required in such circumstances.⁴⁰⁶ In contrast to *Medtronic*, there is no formal preemption provision 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 itself.⁴⁰⁷ The new preemption position is merely a re-articulation of the FDA's recent litigation positions in a few amicus briefs. Describing the new 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.⁴⁰⁸ The degree of that deference has been the subject of much discussion in the Court's preemption opinions, including the opinions involving the FDA.⁴⁰⁹ Generally, though, the degree of deference due to government positions depends on, among other things, consistency, formality, and thoroughness.⁴¹⁰ Briefs are not accorded great policy deference,⁴¹¹ particularly when the FDA interprets statutes or regulations in a particular case, "at such a time and in such a

⁴⁰⁵See *supra* notes and accompanying text.

⁴⁰⁶*Id.* (*Medtronic*, 518 U.S. at 512).

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

⁴⁰⁸See 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. For additional discussion of the deference issue, see Mark C. Levy and Gregory J. Wartman, *Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA's Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 FOOD & DRUG L.J. 495 (2005); Allison M. Zieve and Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why it is Wrong and Warrants No Deference*, 34 Prod. Saf. & Liab. Rptr. (BNA) at 308 (March 27, 2006).

⁴⁰⁹See *supra* notes and accompanying text (discussing *Hillsborough County*, *Medtronic*, and *Buckman Co.*).

⁴¹⁰*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 Zolof warning case not given deference; reason to suspect that brief's interpretation does not reflect "fair and considered judgment" of agency on issue).

⁴¹¹*Witczak v. Pfizer, Inc.*, 377 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.

manner so as to provide a convenient litigating position” for a particular action.⁴¹² Its efforts to obtain greater deference in the MDA context have met with limited success⁴¹³ precisely because the FDA is interpreting its own regulation on preemption but even the change in FDA position in the MDA context is being met with significant skepticism.⁴¹⁴ Similarly, in *Bates*, the EPA changed its position on preemption within a few years, based on its interpretation of an express preemption provision, and the Court found those arguments “particularly dubious” because the agency reversed a longstanding no-preemption interpretation.⁴¹⁵

While the Court has rejected an absolute requirement of notice-and-comment rule-making to give “some weight” to an agency position on preemption, the consistency and thoroughness of the preemption position is critical before it is persuasive. The FDA’s historical position in favor of the concurrent operation of traditional state tort 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.⁴¹⁶ In the railroad safety regulation cases,⁴¹⁷ 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. *Bates* also rejected the change in agency position on preemption as persuasive. 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.

4. Establishing Direct Conflict: The Dynamic Nature of Risk Information and Minimum Standards

Finally, in assessing whether an actual, direct conflict exists to support implied preemption, the proponent of preemption must support the conflict with particularized evidence of conflict, as in *Hillsborough County*.⁴¹⁸ The Court is unpersuaded by speculation or hyperbole. In the prescription drug labeling context, the dynamic nature of the scientific understanding of risk and the way that risk is discovered and appreciated by manufacturers,

⁴¹²See O’REILLY, FOOD AND DRUG ADMIN. 2D, *supra* note at § 4:12.

⁴¹³Horn v. Thoratec, Inc., 376 F.3d 163 (3d Cir. 2004); Riegel v. Medtronic ___ F.3d ___, 2006 WL 1328835 (2d Cir. 2006)

⁴¹⁴ See Ausness, *supra* note at 767.

⁴¹⁵ *Bates*, 544 U.S. at 449.

⁴¹⁶See *supra* notes and accompanying text.

⁴¹⁷See *supra* notes and accompanying text.

⁴¹⁸ See *supra* notes and accompanying text.

regulators and physicians 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.⁴¹⁹ 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, and more recently the Government Accountability Office,⁴²⁰ have criticized the FDA's inability to obtain full information from prescription drug manufacturers because the reporting process for post-approval adverse reaction events and clinical trials 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.⁴²¹

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 1999.⁴²² 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.⁴²³ Merck voluntarily recalled Vioxx from the market in September 2004 because results of a clinical trial indicated a doubled risk of cardiac events in those who used Vioxx.⁴²⁴ After Merck withdrew Vioxx from the market in October 2004, Congress held hearings on the FDA's alleged regulatory failure to require additional warnings

⁴¹⁹ See *supra* notes and accompanying text.

⁴²⁰ See *supra* notes and accompanying text.

⁴²¹ Gary 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.").

⁴²² *Key Events in the Development of Vioxx: From Merck's Application for FDA Approval to a Huge Ruling*, REUTERS, Aug. 19, 2005. For a discussion of the Vioxx situation, see Jonathan O'Steen and Van O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting From Defective Drugs*, 48 ARIZ. L. REV. 67 (2006).

⁴²³ *Id.*

⁴²⁴ *Id.*

sooner.⁴²⁵ 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.⁴²⁶ Tort liability might increase the likelihood that manufacturers will seek FDA approval of a labeling change, pursuant to the obligation to add significant risk information unilaterally, based on evidence that is only available to it, and, perhaps, only likely to be disclosed through the litigation process.

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.⁴²⁷ The FDA approves labels based on a variety of such information submitted to it by manufacturers.⁴²⁸ The FDA relies on manufacturers to provide the information required under its regulations.⁴²⁹ 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 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 or report all adverse reactions to obtain that information.⁴³⁰

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.⁴³¹ The FDA refused to require such a label until 2004 when it issued a public health advisory to that

⁴²⁵Hearings before Senate Health, Education, Labor and Pensions Committee (Feb. 28, 2005).

⁴²⁶ See *supra* notes and accompanying text.

⁴²⁷ See *Motus Amicus* Brief of Public Citizen, *supra* note at 18-19.

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

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

⁴³⁰ See *supra* notes and accompanying text.

⁴³¹ See *supra* notes at and accompanying text.

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 was 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 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.⁴³² 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.

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 agencies 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 Agrosiences 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.⁴³³ 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

⁴³²See *supra* notes and accompanying text.

⁴³³See *supra* notes at and accompanying text.

in which manufacturers may unilaterally alter a warning.⁴³⁴ 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 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*. Such a situation may develop with a particular new prescription drug as the new regulation is implemented.

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.

VI. 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,⁴³⁵ pharmaceutical companies are in control of the research conducted on their products pre- and post-marketing,⁴³⁶ pharmaceutical sales representatives have increasing influence on the drugs that physicians prescribe,⁴³⁷ and the pharmaceutical industry is the largest lobbying group in the United States,⁴³⁸ the products

⁴³⁴*See supra* notes and accompanying text.

⁴³⁵*Proper Health Care Put at 55%*, ASSOC. PRESS. (March 16, 2006) (reporting on a study in the *New England Journal of Medicine*).

⁴³⁶Investment 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).

⁴³⁷Carl 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).

⁴³⁸*Id.* at 88.

liability litigation system is a critical component to create incentives for greater access to risk information to insure the public's health. The Supreme Court's implied conflict preemption doctrine as applied to the FDA's prescription drug labeling regulations supports this conclusion and weighs state tort litigation strongly in the battle between proponents and opponents of preemption.