THE BATTLE OVER IMPLIED PREEMPTION: PRODUCTS LIABILITY AND THE FDA

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Abstract: A mere five years ago, the Food and Drug Administration (the “FDA”) began, for the first time in its 100-year history, to take the position that its prescription drug labeling regulations defeated the ability of injured plaintiffs to pursue common law tort claims based on the adequacy of the labeling. 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 promoting product safety. The U.S. Supreme Court has contributed to this debate with several 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. It explores the history of preemption doctrine as it relates to the food and drug laws, evaluates the arguments posited in favor of and against preemption, assesses the FDA’s position on the application of that doctrine to current litigation, and provides direction to courts in defining the boundaries of implied preemption.

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 fed-

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†See Ralph Lindeman, Agencies Move to Override State Law as Part of Federal Rulemaking Process, 34 BNA PRODUCT SAFETY & LIAB. REP. 364, 364 (2006); Margaret H. Clune, Ctr. for Progressive Reform, Stealth Tort Reform: How the Bush Administration’s
eral level to chip away at state tort law, and on the other as a good thing, preferable to standards set by state juries, advocates on both sides of the preemption debate have an opinion about whether federal regulations should defeat state common law tort actions. The U.S. Supreme Court has addressed preemption of product liability claims on several occasions since its 1992 decision in Cipollone v. Liggett Group, Inc., which put federal preemption of product liability actions in the forefront of the debate over the role of federal regulation in effecting product safety. The political dimension of this debate continues, especially in the area of preemption of prescription drug product liability claims.

A mere five years ago, the Food and Drug Administration (the “FDA”) for the first time in its 100-year history asserted that its prescription drug labeling regulations preempted injured plaintiffs’ common law tort claims based on the adequacy of the labeling. Common law products liability doctrines typically do not treat federally approved prescription drug labeling as conclusive on the question of the label’s adequacy. The classic reasoning underlying this con-

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2 Lindeman, supra note 1, at 364 (quoting Susan Frederick, Senior Director with the National Conference of State Legislatures); id. (federal agency statements favoring preemption are a “sneak attack on consumer rights”); see also Clune, supra note 1, at 1 (describing new FDA position on preemption as “anti-consumer tort reform agenda”).

3 Lindeman, supra note 1, at 364 (quoting David Price, Senior Counsel with the Washington Legal Foundation, a conservative legal reform group).


10 Restatement (Third) of Torts: Liab. for Physical Harm § 16 cmts. b, e (Proposed Final Draft May 17, 2005) (noting that the lawmaking process is “insufficiently atten-
clusion is that governmental regulations are based on narrowly defined goals, supported by limited information provided substantially by the regulated entity, and typically 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. Consequently, more exacting state tort law standards of care do not conflict, but operate concurrently with the federal requirements.


On the subject of regulatory compliance regarding prescription drugs, see generally David R. Geiger & Mark D. Rosen, Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards, 45 DePaul L. Rev. 395 (1996) (advocating a regulatory compliance defense for pharmaceuticals); and Peter Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 Colum. L. Rev. 277, 335 (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.”).

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.


11 See Dobbs, supra note 10, § 224, at 573. Dan Dobbs notes:
When state laws, including tort claims, do conflict with federal regulation, they are preempted under authority of the Supremacy Clause of the U.S. Constitution.\textsuperscript{13} The key to establishing preemption is a finding of congressional intent to preempt, called “the ultimate touchstone” of preemption analysis.\textsuperscript{14} Congress may evidence this intent by including in a law an express preemption provision, which must be analyzed to determine the extent of that intent.\textsuperscript{15} When Congress does not include such a provision, implied preemption doctrines operate.\textsuperscript{16} The Federal Food, Drug, and Cosmetic Act (the “FDCA”)\textsuperscript{17} does not contain a generally applicable express preemption provision.\textsuperscript{18} Consequently, implied preemption doctrines apply.\textsuperscript{19}

The FDA’s recent position favoring preemption—that its labeling regulations establish optimal standards in some cases from which state law may not deviate\textsuperscript{20}—places federal preemption of prescription


\textsuperscript{15} Cipollone, 505 U.S. at 516. See generally Mary J. Davis, Unmasking the Presumption Against Preemption, 53 S.C. L. Rev. 967 (2002) (explaining history of preemption doctrine).

\textsuperscript{16} See, e.g., Geier, 529 U.S. at 867–68 (express preemption provision not exclusive in determining scope of preemption; implied preemption of claims based on failure to include driver’s side air bags).

\textsuperscript{17} 21 U.S.C.A §§ 301–397 (West 1999 & Supp. 2007).


\textsuperscript{19} See Geiger & Rosen, supra note 10, at 400.

drug labeling actions directly in the center of the debate over the proper role of federal regulation in effecting product safety.\textsuperscript{21} Seeking to promote both an understanding of and a balance in 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.\textsuperscript{22} The Article explores the relevance of the FDA’s changed position on that doctrine and provides direction to courts charged with defining the boundaries of implied preemption in this critical area.\textsuperscript{23}

Part I presents background on the recent cases that raise the preemption issue.\textsuperscript{24} Part II examines in greater detail the regulatory scheme under the FDCA, placing the preemption issue in context.\textsuperscript{25} Part III explores the evolution of implied preemption doctrine generally and then applies that understanding to food and drug regulation.\textsuperscript{26} Part IV 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 Supreme Court’s preemption jurisprudence.\textsuperscript{27} In doing so, Part IV addresses the effect the FDA’s recent change in position has on implied preemption analysis.\textsuperscript{28}

The proper weight of an agency’s determination of preemptive scope has generated much debate within the Supreme Court\textsuperscript{29} and among commentators.\textsuperscript{30} The Court has not answered the question of how an agency position affects the operation of implied conflict pre-


\textsuperscript{22} See infra notes 32–469 and accompanying text.

\textsuperscript{23} See infra notes 32–61 and accompanying text.

\textsuperscript{24} See infra notes 62–148 and accompanying text.

\textsuperscript{25} See infra notes 149–348 and accompanying text.

\textsuperscript{26} See infra notes 349–457 and accompanying text.

\textsuperscript{27} See infra notes 349–457 and accompanying text.

\textsuperscript{28} See, e.g., \textit{Medtronic}, 518 U.S. at 474–514 (Justices Stevens, Breyer, and O’Connor disagreed about level of deference to FDA’s preemption position regarding medical device regulations).

emtion doctrine, nor has it addressed how the historic primacy of state regulation in the area of health and safety is to be considered in the balance. Part IV evaluates the Court’s modern preemption jurisprudence and concludes that it does not support implied conflict preemption of prescription drug labeling products liability actions.31 An agency attempting to alter the long-standing, historic balance between federal safety regulation and common law tort principles and to establish actual conflict with underlying tort principles must justify its position with something more than evolving notions of valid scientific inquiry and shifting political positions. 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 an agency’s 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.

I. Setting the Stage for Preemption

Before 2002, the FDA maintained the position that its product approval process and state tort liability usually operate independently—each providing a significant, yet distinct, layer of consumer protection.32 In 2002, the FDA announced a significant shift in its position,

31 See infra notes 349–457 and accompanying text.
32 Margaret Jane Porter, The Lohr Decision: FDA Perspective and Position, 57 Food & Drug L.J. 7, 11 (1997) (Ms. Porter was FDA Chief Counsel at the time of the article’s publication); see also Foreign Rule, 63 Fed. Reg. 66378, 66384 (Nov. 28, 2003) (to be codified at 48 C.F.R. pt. 5125) (“FDA’s regulations establish the minimal standards necessary, but were not intended to preclude the States from imposing additional labeling requirements.”). See generally O’Reilly, supra note 18, at 288 (“Until DHHS [Department of Health & Human Services] asserted prescription drug preemption in [Motus v. Pfizer, Inc.], 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., 00 Civ. 4042 (LMM), 00 Civ. 4379 (LMM), 2002 U.S. Dist. LEXIS 16963, at *9–10 (S.D.N.Y. Nov. 16, 2002).

At the time of the United States’s 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 Preempt Tort Suits: Does It Close Off Vital Drug Data?, 26 Nat’l L.J. Mar. 1, 2004, at 1. Troy has been criticized for not disclosing his Pfizer ties. House Cuts OC’s Funds for Downplaying Troy’s Drug Industry Ties, FDA Wk., July 16, 2004, § 29; see also O’Reilly, supra note 18, at 287 (discussing FDA change in position regarding preemption); Clune, supra note 1, at 2–3 (describing FDA change in position under Troy).
one aggressively in favor of preemption, based on concerns over “the
growing propensity of bad scientific reasoning to seep into court cases
involving FDA-regulated products.” Prescription drug manufacturers,
with support from the FDA in the form of amicus briefs, began to take
the litigation position that approved prescription drug labeling pre-
empt state tort claims. Proponents of the continuing vitality of tradi-
tional tort doctrine, however, argue that it establishes a duty of care,
protection citizens in circumstances where the federal government is
late in acting or where federal standards are insufficient. Reason-

ing that common law tort claims are a critical component of the states’ tra-
ditional ability to protect the health and safety of their citizens, one
court has noted that “[t]he power of states to govern in this field is con-
siderable and undisputed.”

An example of the tension between these two positions is illus-
trated by Motus v. Pfizer, Inc., a 2004 case before the U.S. Court of Ap-
peals for the Ninth Circuit, in which the FDA first asserted its new pro-
preemption position. Plaintiff alleged that the warnings on the anti-
depressant Zoloft, a selective serotonin reuptake inhibitor (“SSRI”), 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. Prior to and during the course of approving Zoloft in 1991, the FDA explored the potential associations between the use of SSRIs and suicide. Concerns caused the FDA to convene a committee of experts, the Psycho-pharmacological Drugs Advisory Committee (the “PDAC”), to consider the issue. In 1991, the PDAC unanimously found that there was no credible evidence to support a conclusion that the antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors. The FDA subsequently made suggestions to Pfizer regarding warning language it should incorporate in Zoloft labeling and convinced Pfizer to use the proposed text verbatim.

Pfizer moved for summary judgment before the district court in Motus based on implied conflict preemption, arguing that to permit liability based on state tort laws would defeat the objectives of the regulatory scheme because federal regulators had decided, based on the available scientific evidence, that an additional warning was not required. The court denied the motion, finding that the federal regulation which permits a manufacturer to alter a warning without prior FDA approval prevented any conflict with state product liability laws. The trial court was persuaded by the FDA Commissioner’s previous statements favoring the role of unilateral manufacturer labeling changes to increase information provided to health care providers and enhance public safety. In addition, the trial court noted that,

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358 F.3d 659 (No. 02-55372), 2002 WL 32905084 [hereinafter Motus Amicus Brief of United States].
38 Motus, 127 F. Supp. 2d at 1087–90 (discussing regulatory history of Zoloft and other similar antidepressants known as SSRIs).
39 Id. at 1090. Suicidality and the use of SSRIs had been studied earlier in connection with the drug Prozac. Id.
40 Id. at 1088, 1090.
41 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.
42 Id. at 1088. Plaintiff contended that Pfizer drafted the ultimately approved labeling language, not the FDA. Id. at n.3.
43 Motus, 127 F. Supp. 2d 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.
44 Id. at 1094 (referring to 21 C.F.R. § 314.70(c) (2007)).
45 Id. The FDA Commissioner had stated, in support of the then-current regulation:
although 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.\textsuperscript{46}

In support of Pfizer’s appeal of the denial of summary judgment, the FDA argued that although FDA regulations permit a drug’s manufacturer to alter or strengthen a warning, it is the FDA, not each state court system applying its own standards, that must approve the warning.\textsuperscript{47} The FDA disagreed with the suggestion that, to constitute an actual conflict for preemption purposes, 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.\textsuperscript{48} The FDA concluded 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 un-

\textsuperscript{46} Id. (citing 21 Fed. Reg. 37,447 (1979)).

\textsuperscript{47} Motus Amicus Brief of United States, \textit{supra} note 37, at 13.

\textsuperscript{48} Id. at 14.
der the FDCA.\textsuperscript{49} Notably, however, the FDA must make a determina-
tion that a drug is misbranded and then seek injunctive relief from a fed-
eral district court before a final determination on misbranding
results in the assessment of penalties.\textsuperscript{50}

A number of subsequent cases have addressed this specific issue.\textsuperscript{51}
In \textit{Colacicco v. Apotex, Inc.}, a 2006 case in the United States District Court
for the Eastern District of Pennsylvania, the plaintiffs made similar
claims regarding the failure to warn of increased risk of suicidality on
labeling for Paxil, another SSRI, manufactured by GlaxoSmithKline
and Apotex.\textsuperscript{52} Defendants moved for summary judgment on the same
bases as had Pfizer in \textit{Motus}. Unlike Pfizer, however, the \textit{Colacicco} de-
defendants were successful, in large part because the trial court deferred
to the FDA’s position in favor of preemption.\textsuperscript{53} An increasing number
of prescription drug labeling cases have been defended successfully on
similar grounds.\textsuperscript{54}

Most cases, however, have denied preemption.\textsuperscript{55} For example, \textit{Perry
v. Novartis Pharma. Corp.}, another 2006 case from the United States Dis-
trict Court for the Eastern District of Pennsylvania, concluded that the
federal law did not preempt the plaintiffs failure-to-warn claims because
a state law requirement to provide an additional warning would not
force the drug company to choose between violating federal or state
law.\textsuperscript{56} The court noted that no federal law prevented the manufacturer
from adding a warning of increased cancer risk to children who used

\textsuperscript{49} Id. at 16.
\textsuperscript{50} 21 U.S.C. § 332 (2000); see also \textit{Motus} Amicus Brief of Public Citizen, supra note 46,
at 16 (arguing that threat of enforcement action not enough to create a conflict; filing of
enforcement does not guarantee that the FDA will prevail). The manufacturer is entitled
to a jury trial of the issue. 21 U.S.C. § 332(b).
\textsuperscript{51} See, e.g., \textit{Colacicco}, 432 F. Supp. 2d at 525–35.
\textsuperscript{52} Id. at 519–20.
\textsuperscript{53} Id. at 525–35.
\textsuperscript{54} Needelman, 2004 WL 1773697, at *5 (Zoloft warning litigation); Dusek, 2004 WL
2191804, at *10 (Zoloft warning litigation); Abramowitz v. Cephalon, Inc., 2006 WL
\textsuperscript{55} In re \textit{Vioxx} Prods. Liab. Litig., No. MDL 1657, 2007 WL 1952964, at *10 (E.D. La.
July 3, 2007); In re \textit{Zyprexa} Prods. Liab. Litig., 489 F. Supp. 2d. 230, 291 (E.D.N.Y. 2007);
Perry, 456 F. Supp. 2d at 688; \textit{Laisure-Radke, Inc.}, 426 F. Supp. 2d at 1174 (Prozac warning
litigation); \textit{Jackson}, 432 F. Supp. 2d at 969 (Zoloft warning litigation); \textit{Peters}, 417 F. Supp. 2d
at 1058 (Prilosec warning litigation); \textit{Witzak}, 377 F. Supp. 2d at 732 (Zoloft warning litiga-
tion); \textit{Caraker v. Sandoz Pharm. Corp.}, 172 F. Supp. 2d 1018, 1044 (S.D. Ill. 2001) (Par-
lodel lactation suppressant warning litigation); \textit{Coutu v. Tracy}, No. C.A. PC/00-3720, 2006
litigation).
\textsuperscript{56} 456 F. Supp. 2d at 685.
Elidel, an eczema treatment. The court recognized that state law tort lawsuits provide an important backstop to the federal regulatory scheme. In addition, the court was persuaded by the absence of an FDA rejection of the particular warning the plaintiffs sought, as well as the ability of manufacturers to modify their labeling without FDA approval.

When it applies, federal preemption doctrine acts like a “super” government compliance defense because it permits complete displacement of state law by the federal regulation. Because implied conflict preemption doctrine requires an assessment of federal regulatory objectives to determine whether an actual conflict exists with the operation of applicable state laws, an understanding of the regulatory scheme for prescription drug labeling and the objectives served is critical, and is the subject of the next Part.

II. Labeling Regulations Under the Federal Food and Drug Laws

This Part examines in greater detail the regulatory scheme under the FDCA, providing context for the preemption debate. It begins by describing the labeling requirements of the federal food and drug laws and then exploring how drug labeling is created, approved, and modified. Finally, it details the FDA’s new regulation for drug labeling and its proposed preemptive effect.

A. Requirements of the 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 the enactment of

57 Id.
58 Id. at 687.
59 Id. at 686. The court also noted that other methods were available for manufacturers to use to communicate increased risks, in addition to the federally approved labeling, that would not be subject to preemption analysis. Id.
61 See infra notes 62–148 and accompanying text.
62 See infra notes 65–148 and accompanying text.
63 See infra notes 65–111 and accompanying text.
64 See infra notes 112–148 and accompanying text.
the Pure Food and Drug Act. 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. The states had regulated the safety of food and drugs since the earliest days of the United States’s history. State regulators encouraged, indeed implored, the national government to create a federal agency to aid in regulation because of concerns over the states’ inability to reach the interstate sale of fraudulent products and, thus, to protect consumers from them.

The modern version of the federal food and drug regulatory scheme dates from the Food, Drug and Cosmetic Act of 1938. Congress adopted the 1938 Act to protect the public health by enforcing certain standards of purity and effectiveness, and also to prevent the sale of misbranded or adulterated products. The 1938 legislation extended control over more products and enlarged and stiffened the penalties for disobedience. In 1962, Congress passed the Kefauver-Harris Amendments to add the requirement of drug efficacy, mandate greater safety, and introduce a rigorous new drug approval process. Several amendments to the 1938 Act over the ensuing years have

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65 For a history of the early regulation of food and drugs in the United States, see 1 James T. O’Reilly, Food and Drug Administration §§ 3:1–:4 (2d ed. 2005).
66 Id. § 3:2.
67 2 O’Reilly, supra note 65, § 25:1.
69 See 2 O’Reilly, supra note 65, at § 25:1 (overview of relationship between the FDA and state governments).
72 See United States v. Dotterweich, 320 U.S. 277, 282 (1943); Research Labs. v. United States, 167 F.2d 410, 421 (9th Cir. 1948).
73 Kefauver-Harris Amendments to FDCA, Pub. L. No. 87-781, 76 Stat. 780 (1962); see Meadows, supra note 71, at 1 (‘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.’).
added to the complexity of the regulatory scheme and heightened the FDA’s ability to achieve its public safety goals.\textsuperscript{74}

The key protection against the marketing of ineffective or unsafe prescription pharmaceutical products comes from the New Drug Approval process, which a company must complete before it can market a drug.\textsuperscript{75} 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. An office responsible for policing the postmarketing safety of prescription drugs, the Drug Safety Oversight Board (the “DSOB”), was created in 2005, in part as a result of the perceived lack of action by the FDA in response to information regarding an increased risk of serious side effects in those using the osteoarthritis drug Vioxx.\textsuperscript{76} The U.S. Gov-


ernment Accountability Office (the “GAO”) recently criticized the DSOB as being underfunded, understaffed, and lacking a clear and effective method to decide whether and how to act when it finds that a drug is unsafe.\textsuperscript{77}

If a prescription drug manufacturer fails to comply with any applicable regulation, the approved prescription drug may be considered misbranded or adulterated under the FDCA.\textsuperscript{78} Penalties for selling an adulterated or misbranded drug or device may be assessed against the seller,\textsuperscript{79} and include the seizure of noncompliant products\textsuperscript{80} and injunctive relief.\textsuperscript{81} The FDA must have sufficient information on which to base an action for misbranding. Manufacturers are not required to report the results of the postmarketing clinical trials.\textsuperscript{82}

To be misbranded, a regulated product’s labeling must be false or misleading in any particular.\textsuperscript{83} 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 ensure readability.\textsuperscript{84} Most importantly, proper labeling includes adequate directions for use, adequate warnings against dangerous use, and sufficient warnings against unsafe dosage.\textsuperscript{85}


\textsuperscript{80} \textit{Id.} § 334.

\textsuperscript{81} \textit{Id.} § 332.

\textsuperscript{82} Leaf, \textit{supra} note 75, 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.”).

\textsuperscript{83} 21 U.S.C. § 352(a).

\textsuperscript{84} \textit{Id.} § 352(b), (c). FDA-approved labeling is defined generally at 28 U.S.C. § 321(m). Proper labeling also includes the established name of the drug and information on the proportion of active ingredients and their established names, if any. \textit{Id.} § 352(e).

\textsuperscript{85} \textit{Id.} § 352(f).
This labeling is directed at health care practitioners because prescription drugs require professional supervision by a practitioner licensed to administer such drugs.\textsuperscript{86} A physician acts as the “learned intermediary” between the manufacturer and the patient—the patient is intended to use and benefit from the drug but needs a physician to assess the risk and possible benefit of the product for the patient’s condition.\textsuperscript{87} Tort liability for prescription drugs is based primarily on allegations that the labeling contains inadequate warnings of risk or improper use resulting in insufficient advice to the prescribing physician about the potential harms of the drug.\textsuperscript{88} The next Section explores how such warnings are created, approved, and modified through the FDA’s labeling approval process.\textsuperscript{89}

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.\textsuperscript{90} A drug’s “labeling” is one of these sources. It refers to the set of documents from the manufacturer that accompany the drug when given to the prescribing physician and the

\begin{footnotes}
\item[86] Id. § 353(b).
\item[87] MADDEN AND OWEN ON PRODUCTS LIABILITY, supra note 10, § 22:8–11, at 564–77. For criticism of the learned intermediary doctrine as it applies to widely advertised prescription drugs, see generally Perez v. Wyeth Labs., 734 A.2d 1245 (N.J. 1999) (rejecting learned intermediary doctrine in case of direct to consumer advertised contraceptive device); and Richard C. Ausness, \textit{Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?}, 37 \textit{Wake Forest L. Rev.} 97 (2002).
\item[88] See MADDEN AND OWEN ON PRODUCTS LIABILITY, supra note 10, § 22:9, :10; see also Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966) (applying learned intermediary doctrine).
\item[90] See infra notes 90–111 and accompanying text.
\end{footnotes}
end user.\textsuperscript{91} The FDA does not create the labeling, but it must ensure that the statutorily required information is adequately communicated to those users. Pursuant to the New Drug Approval regulations, the FDA approves proposed labeling provided to it by the manufacturer after review of the manufacturer’s application.\textsuperscript{92} The FDA adopted a number of regulations to accomplish this task.\textsuperscript{93}

The FDA labeling regulations include general requirements on the content and format of labeling for prescription drugs.\textsuperscript{94} The regulations also contain more specific requirements detailing what is to be included in the required labeling.\textsuperscript{95} The specific requirements identify the data that the manufacturer must include, the order in which it must be included, and the indication and usage information that the manufacturer must provide.\textsuperscript{96} The labeling regulations state that manufacturers must describe serious adverse reactions and potential safety hazards.\textsuperscript{97} New drug applications are required to contain copies of the labeling proposed by manufacturers\textsuperscript{98} as well as a summary of the contents of that labeling.\textsuperscript{99}

The FDA has described this labeling formation process as follows:

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 product. Based on the known scientific evidence, appropriate warnings are drafted to express the known risks, while


\textsuperscript{92} 21 U.S.C. § 355 (defining application requirements for new drug approvals); see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (“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.”).

\textsuperscript{93} See 21 C.F.R. § 201.56–57 (2007).

\textsuperscript{94} Id. § 201.56.

\textsuperscript{95} Id. § 201.57.

\textsuperscript{96} Id. § 201.57(a), (b), (c), (d).

\textsuperscript{97} Id. § 201.57(e), (f).

\textsuperscript{98} 21 C.F.R. § 314.50(e)(2)(ii).

\textsuperscript{99} Id. § 314.50(c)(2)(i).
avoiding the statement of unsubstantiated risks that may unnecessarily deter use of the drug.\textsuperscript{100}

Per this description, the labeling formulation process is one of give-and-take with oversight by the FDA.

Postapproval changes to labeling are permitted under certain circumstances.\textsuperscript{101} 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 be proved.\textsuperscript{102} The FDA need not approve such labeling before the manufacturer implements it under this regulation, but the manufacturer must submit a supplemental application, called a Supplemental Submission for Changes Being Effected, to effect the change.\textsuperscript{103} Such a unilateral labeling change has been called a “safety valve” because it encourages the addition of new warnings when severe risks not anticipated when the drug was originally approved become known.\textsuperscript{104} The FDA must ultimately approve the labeling change,\textsuperscript{105} but the regulation was promulgated to allow drug-makers to strengthen label warnings quickly when evidence of new side-effects is discovered.\textsuperscript{106} Nevertheless, manufacturers commonly do not implement labeling changes without FDA approval.\textsuperscript{107} Typically, the FDA and

\begin{itemize}
\item \textsuperscript{100} Motus Amicus Brief of United States, \textit{supra} note 37, at 5.
\item \textsuperscript{101} 21 C.F.R. \textsection 314.70(b) (“Major” labeling changes require prior FDA approval; “major” changes include changes in the drug’s formulation that affect its substance).
\item \textsuperscript{102} Id. \textsection 201.80(c). 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. \textit{Id.} This is known as a “black box warning.”
\item \textsuperscript{103} Id. \textsection 314.70(c)(6)(iii); \textit{see also} Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 729 (D. Minn. 2005) (discussing the process and effect of a Supplemental Submission for Changes Being Effected application).
\item \textsuperscript{104} O’Reilly, \textit{supra} note 18, 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.”); \textit{see also} Werner v. Upjohn Co., Inc., 628 F.2d 848, 859–60 (4th Cir. 1980).
\item \textsuperscript{107} \textit{See} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (discussion of labeling procedures in comments to new labeling regulation); \textit{see also} Motus Amicus Brief of United States, \textit{supra} note 37, at 17 (discussing ultimate FDA approval required for all labeling changes).
\end{itemize}
the manufacturer negotiate about any contemplated labeling change prior to implementation.\textsuperscript{108}

In the preamble to its new labeling regulation, the FDA takes the position that most approved labeling preempts state common law tort actions, despite the manufacturer’s obligation to alter labeling when additional safety information is acquired.\textsuperscript{109} The manufacturer, therefore, is not placed in the position of having to change labeling in response to possible tort liability, but instead may rest on prior FDA approval of labeling.\textsuperscript{110} This new regulation and its attempt to affect preemption doctrine are discussed in the next Sections.\textsuperscript{111}

\section*{C. New Regulation on Labeling for Prescription Drugs}

In 2006, the FDA issued a regulation that alters the requirements for the labeling of prescription drugs and is intended to make that labeling more clear, concise, and usable for physicians and patients.\textsuperscript{112} The 2006 regulation introduces three changes: it (1) introduces a “Highlights” section to labeling, which will provide immediate access to a drug’s most commonly referenced material;\textsuperscript{113} (2) reorders and reorganizes the contents of labeling, introducing graphical requirements;\textsuperscript{114} and (3) makes warning and adverse reaction information more accessible.\textsuperscript{115} The regulation applies to new drugs and those approved after 2001.\textsuperscript{116}

\begin{itemize}
  \item \textsuperscript{108}See GAO Report, Drug Safety, \textit{supra} note 77, at 10.
  \item \textsuperscript{109}Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934–35.
  \item \textsuperscript{110}Id. at 3935.
  \item \textsuperscript{111}See infra notes 112–148 and accompanying text.
  \item \textsuperscript{112}Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922; see also Press Release, FDA, FDA Announces Final Rule on the Requirements for Prescribing Information for Drug and Biological Products (Jan. 18, 2006), \textit{available at} http://www.fda.gov/cder/regulatory/physlabel/summary.pdf. 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.” Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922.
  \item \textsuperscript{113}Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3923.
  \item \textsuperscript{114}Id.
  \item \textsuperscript{115}Id.
  \item \textsuperscript{116}Id. at 3925. 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 informa-
The regulation lists the general categories of information to be placed into the new “Highlights” section including “Boxed Warning,” “Recent Major Changes,” “Indications and Usage,” “Contraindications,” and “Warnings and Precautions.” The drug manufacturer chooses the information to be included in each section, including the “Warning and Precautions” section. The regulation instructs that “judgment will continue to be necessary” in deciding which information must be emphasized.

Physicians and health care practitioners expressed unequivocal enthusiasm for the “Highlights” section, whereas manufacturers were either opposed or strongly opposed to it. Manufacturer opposition was based, in part, on the obligation to choose what important warnings or other information to include and what information to omit; an incorrect choice might cause the labeling to be misleading. 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. This language is slightly more rigorous than its
predecessor in that it requires evidence of a clinically significant hazard connected with a drug before changing approved labeling, though a causal relationship still is not required.\textsuperscript{123} Manufacturers continue to have permission to add risk information to the Full Prescribing Information without first obtaining FDA approval.\textsuperscript{124}

Manufacturers maintain discretion under the new regulation to choose what to say in drug labeling and how to say it with FDA oversight, as before.\textsuperscript{125} 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.\textsuperscript{126}

\section*{D. Proposed Preemptive Effect of the New Labeling Regulation}

The FDA favored the concurrent operation of state tort law for almost the entire first century of its existence based on its inability to anticipate every way a consumer could be injured by the products it regulated and on the lack of a federal remedy to provide redress for injured consumers.\textsuperscript{127} In the preamble to the new labeling regulation, however, the FDA now argues that product liability lawsuits have directly threatened the agency’s ability to regulate manufacturer dissemination of risk information for prescription drugs.\textsuperscript{128}

\textsuperscript{123} For a discussion of former labeling regulation, see \textit{supra} note 102 and accompanying text.

\textsuperscript{124} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934, 3969.

\textsuperscript{125} Id. at 3990, 3992.

\textsuperscript{126} Id. at 3993.

\textsuperscript{127} \textit{Motus} Amicus Brief of Public Citizen, \textit{supra} note 46, at 12. The Public Citizen Litigation Group argued that:

\begin{quote}
when 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.
\end{quote}

\textit{Id.} (citing \textit{Hearings Before Subcomm. of Comm. on Commerce on S. 1944}, 73d Cong., 2d Sess. 400, 403 (1933)); \textit{see also} Borden Co. v. Liddy, 200 F. Supp. 221, 225 (S.D. Iowa 1961) (explaining that federal food labeling regulations provided a minimum level of safety that could be supplemented by more stringent state regulations).

\textsuperscript{128} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934. The FDA cites three cases in support of this proposition. \textit{Dowhal v. SmithKline Beecham Consumer Healthcare} found conflict preemption based on a FDA warning on nicotine replacement therapy drugs despite a savings clause in the statute specifically protecting the state requirement. 83 P.3d 1, 15 (Cal. 2004). \textit{Motus v. Pfizer, Inc.} was resolved in favor of the manufacturer on causation. 358 F.3d 659, 661 (9th Cir. 2004). \textit{In re Paxil Products Liability Litigation} is an ongoing multidistrict litigation con-
The FDA has explicitly called for preemption before, in implementing the Medical Device Amendments (the “MDA”) of 1976 to the FDCA, but Congress included an express preemption provision in the MDA that delegated authority to the FDA to assess the preemptive effect that its regulations would have on state laws. By contrast, the FDA does not have express authority to preempt regarding prescription drug labeling, and the agency specifically did not address preemption in the proposed new drug labeling regulation. Rather, the original commentary to the regulation specifically stated that it did not preempt state law and that, therefore, it did not implicate federalism concerns. The final regulation also does not contain a preemption provision, but rather discusses preemption in the “preamble” section. That discussion endorses the litigation positions taken in Motus and other cases and suggests that preemption of state tort law is the FDA’s “long standing view” on preemption. That description is at odds with prior statements of the FDA.

The regulation’s preamble, which is in essence an advisory opinion, argues that state law tort actions may frustrate the agency’s consolidated proceeding. None of these three cases would seem to give cause for alarm.

Supra, F. Supp. 2d at 3934, 3975 (J.P.M.L. 2003). None of these three cases would seem to give cause for alarm.


Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (explaining that labeling rule does not have federalism implications nor does it preempt state law; preemption assessment required by Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999)).

See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3969.

Id. 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.”).

Id.

See supra note 32 and accompanying text. 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 Mike Leavitt, supra note 35.

plementation of federal objectives. The FDA disagrees with the assertion—widely made—that its labeling requirements are minimum safety standards and describes that characterization as a misunderstanding of the Act. The FDA takes the position that its regulations can establish both a floor and a ceiling. Such circumstances include when additional labeling requirements may not be more protective of patients, but rather “erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.” The FDA expresses concern that “[e]xaggeration of risk could discourage appropriate use of a beneficial drug” and thus cause over-warning.

After articulating the arguments in favor of preemption, the FDA identifies those claims that its new labeling regulation would implicitly preempt. It seeks to codify its position in Motus that if a label were proposed to the FDA and ultimately not required by the time the plaintiff claims it should have been, the plaintiff’s claim based on a failure to warn is preempted. The FDA acknowledges that some state common law damages actions will not be preempted. It does

138 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.
139 Id. at 3934–35.
140 Id. at 3935. As will be seen infra notes 278–295 and accompanying text, this argument appears derived from the Supreme Court’s recent implied preemption case, Geier v. American Honda Motor Co., which found a motor vehicle safety standard to be both a floor and a ceiling and thus preemptive of state common law damages actions. 529 U.S. 861, 868 (2000).
141 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935. To illustrate the over-warning concern, the preamble uses a case in which a state court found federal preemption of an inconsistent state regulation, not a product liability action. Id. Ironically, the over-warning concern was raised in Motus and other Zoloft 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 note 46 and accompanying text.
142 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935; see also Horn v. Thoratec Corp., 376 F.3d 163, 178 (3d Cir. 2004) (discussing over-warning concern in context of medical device preemption).
143 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935–36. It protects manufacturers for the discretionary choices they make about what to include in the new “Highlights” section of the regulation. Id.
144 Id.
145 Id. at 3936 (explaining that state common law damages actions based on parallel state requirements will not be preempted). In addition, in a recent amicus brief in Perry v. Novartis Pharmaceuticals Corp., the FDA acknowledged that it does not assert that any failure-to-warn claim premised on a manufacturer’s failure to provide a warning not con-
not address, however, the potentially complementary way in which common law damages actions may operate concurrently with FDA regulations by permitting compensation for injury and thereby creating an additional incentive for public safety.\textsuperscript{146}

The FDA claims that existing preemption principles support its preemption position.\textsuperscript{147} The FDA appears to be attempting to alter its historic position against preemption and apply its new position retroactively. To assess the effect of such an attempt requires a thorough understanding of preemption doctrine, which is explored in the next Part.\textsuperscript{148}

\section*{III. Preemption Under the Federal Food and Drug Laws}

This Part explores the of evolution of express and implied preemption doctrine.\textsuperscript{149} It then distills from the case law principles important in understanding preemption of food and drug regulation.\textsuperscript{150}

\subsection*{A. Early Preemption Doctrine Under the Food and Drug Laws}

Shortly after enactment of the first federal food and drug law in 1906,\textsuperscript{151} questions arose regarding how much state authority it displaced. In 1912, in one of the earliest preemption cases, \textit{Savage v. Jones}, the U.S. Supreme Court was asked to determine whether a state law permitting additional regulation was preempted, even though the federal legislation arguably did not apply to the food additive at issue.\textsuperscript{152} The Court noted that Congress did not expressly declare its intention to prevent the states from regulating within the subject of food and drugs.\textsuperscript{153} The Court then described the applicable implied preemption inquiry:

\begin{itemize}
\item \textsuperscript{146} See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.
\item \textsuperscript{147} \textit{Id.} at 3935–36.
\item \textsuperscript{148} See infra notes 149–348 and accompanying text.
\item \textsuperscript{149} See infra notes 151–339 and accompanying text.
\item \textsuperscript{150} See infra notes 340–348 and accompanying text.
\item \textsuperscript{151} Federal Food and Drugs Act of 1906, Pub. L. No. 59-385, 34 Stat. 768, (repealed 1938).
\item \textsuperscript{152} 225 U.S. 501, 509 (1912). 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. \textit{Id.} at 511. Further, because Congress had regulated in the field, the seller argued that the states were entirely foreclosed from regulating. \textit{Id.} at 512.
\item \textsuperscript{153} \textit{Id.} at 533.
\end{itemize}
If the purpose of the [federal] 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.154

The Court concluded that the state statute was not impliedly preempted because of two corollary principles the Court articulated: (1) Congress’s 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” such that the two acts could not be reconciled.155 The state statute was found not to be in actual conflict with the federal regulation because it did not impose conflicting standards nor oppose federal authority—rather, it added consistent, but more rigorous, regulation.156

Savage was decided decades before the onslaught of post-Depression-era economic regulation and post-World-War-II civil rights and other public interest legislation.157 Preemption doctrine was in its infancy. Nevertheless, Savage is an important foundational case because it articulated a rigorous implied conflict preemption analysis in an early food and drug labeling matter.158 Indeed, the Court continues to refer

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154 Id. (citations omitted) (emphasis added).
155 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. Id. at 536–37. 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 (quoting Mo., K. & T. Ry. Co. v. Haber, 169 U.S. 613, 624 (1898)).
156 Id. at 539.
157 Savage, 225 U.S. at 501.
158 Id. at 535–37.
to Savage’s implied conflict preemption analysis, suggesting its continuing influence.\textsuperscript{159}

Building on its discussion of implied preemption in Savage, the Court, in 1913, decided McDermott v. Wisconsin, in which it found a state food labeling statute impliedly preempted for two reasons.\textsuperscript{160} First, the Wisconsin statute required the defendant food-seller to remove a complying federal label to satisfy the state statute, rendering the product misbranded under federal law.\textsuperscript{161} Second, the U.S. Secretary of Agriculture had decided that the defendant’s label was satisfactory, permitting the conclusion that compliance with the state law would render the product misbranded under federal law.\textsuperscript{162} The Court concluded that the state’s attempt to regulate exclusively was an improper interference with Congress’s authority.\textsuperscript{163} The Court, conceding the state’s authority to regulate consistent with federal law, concluded that the state could not destroy rights arising out of the federal statute nor impair the effect of a federal law.\textsuperscript{164} The impossibility of dual compliance required defeat of the state law.\textsuperscript{165}

Thus, Savage and McDermott contain the seeds of the implied conflict preemption doctrine the Court applies today.\textsuperscript{166} Unlike those cases, however, 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.\textsuperscript{167} During this time, the Supreme Court defined implied preemption doctrine more clearly.\textsuperscript{168} Between the 1940s and 1980s, implied preemption doctrine coalesced

\textsuperscript{159} Crosby v. Nat’l Foreign Trade Council, 550 U.S. 363, 373 (2000) (explaining that foreign affairs power and the congressional Burma Act impliedly preempted Massachusetts’s Burma law); see also Davis, supra note 15, at 1012 (noting the re-emergence of Savage in Court’s modern preemption cases).

\textsuperscript{160} McDermott v. Wisconsin, 228 U.S. 115, 133 (1913).

\textsuperscript{161} Id. 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. Id. at 127.

\textsuperscript{162} Id. at 133.

\textsuperscript{163} Id. at 134.

\textsuperscript{164} Id. at 133–34.

\textsuperscript{165} McDermott, 228 U.S. at 133–24. The “impossibility” category of implied preemption, thus, has its roots in cases like McDermott. See id. The Court has rarely found true impossibility, however. See, e.g., Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963) (discussing implied preemption involving impossibility); see also Davis, supra note 15, at 984–85.

\textsuperscript{166} See McDermott, 228 U.S. 133–34; Savage, 225 U.S at 533.

\textsuperscript{167} Davis, supra note 15, at 974–78.

\textsuperscript{168} Id.
into the now-standard categories of occupation of the field preemption and conflict preemption.

Conflict preemption occurs primarily when the state law “stands as an obstacle” to the accomplishment of federal objectives and, therefore, must yield. An early example is the Supreme Court’s 1942 decision *Cloverleaf Butter v. Patterson*, in which Alabama officials seized substantial quantities of packing stock butter, claiming violation of state safety regulations, when the Federal Department of Agriculture would not have permitted seizure. The Court, relying on *Savage* and *McDermott*, concluded that the Alabama law was preempted. The Court stated that for implied preemption to occur, “it must be clear that the federal provisions are inconsistent with those of the state to justify thwarting the state regulation.” Recognizing that the line distinguishing cases of inconsistency was narrow, the Court found the case to be more like *McDermott*, in which the state law prohibited what the federal law permitted. The Court distinguished *Savage* because the state law at issue in that case merely required additional disclosures that the federal law neither required nor prohibited. In *Savage*, federal law was agnostic on the value of the state regulation; in *McDermott* and *Cloverleaf Butter*, federal and state law appeared to operate in opposite directions.

*Direct, positive, actual, clear:* these words describe a substantial showing of conflict that must be made before implied preemption operates based on the Court’s early cases. As applied, the Court’s finding of implied conflict preemption in *Cloverleaf Butter* seemed based on a

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169 Occupation of the field preemption occurs where Congress’s legislation is so comprehensive that it occupies the entire field, displacing all state law. *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941) (finding that the Alien Registration Act of 1940 occupied the field of foreign affairs and national treatment of aliens and was intended to be exclusive). The Court has rejected occupation of the field preemption under the FDCA. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717–18 (1985).

170 See *Davis*, supra note 15, at 983–90.


173 Id. at 158–59, 166.

174 Id. at 156.

175 See id. at 158–59.

176 Id.


178 Id. at 156; *Savage*, 225 U.S. at 533, 537.
minimal conflict\textsuperscript{179} and may reflect an intent to minimize clashes between regulating authorities to free young regulated industries from inconsistencies.\textsuperscript{180} By contrast, the dissenting opinion in \textit{Cloverleaf Butter} 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.\textsuperscript{181}

Sixty years later, similar arguments continue to be made on both sides of the preemption debate.

\textbf{B. Modern Implied Preemption Cases}

The Supreme Court did not address another FDCA preemption case until 1985, in \textit{Hillsborough County v. Automated Medical Laboratories, Inc.}\textsuperscript{182} The Court did, however, decide a number of implied preemption cases in the intervening years that are worth noting.\textsuperscript{183} In 1959, in \textit{San Diego Building Trades Council v. Garmon}, the Court was faced for the first time with an argument for implied preemption of state common law damages actions.\textsuperscript{184} In this case the question was whether the National Labor Relations Act preempted state tort actions by employers allegedly injured in the course of peaceful picketing by labor activists.\textsuperscript{185} 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.\textsuperscript{186} In finding implied preemption based on a conflict with federal legislative objectives, the Court relied on two considerations: (1) the case involved na-

\textsuperscript{179} See 315 U.S. at 172–73 (Stone, C.J., dissenting) (reasoning that there was a “complete want of conflict between the two statutes,” and that the state statute “aids and supplements the federal regulation and policy”).

\textsuperscript{180} See id. at 167–69 (majority opinion).

\textsuperscript{181} Id. at 177 (Stone, C.J., dissenting).

\textsuperscript{182} 471 U.S. at 707.


\textsuperscript{184} 359 U.S. at 237–39.

\textsuperscript{185} Id. at 241–45 (describing NLRA, as amended by the Labor Management Relations Act, 29 U.S.C. §§ 157, 158 (2000)).

\textsuperscript{186} Id. at 239–40.
tional labor policy, about which Congress had legislated “with broad strokes,”187 and (2) state regulation can be exerted through common law damages actions as effectively as through more direct regulatory means.188 To this day, the Court continues to refer to Garmon for these propositions.189 These two fundamental features of implied preemption analysis, defining the federal objectives with which state law arguably conflicts and assessing the regulatory nature of common law damages actions, are central to implied preemption analysis under the FDCA.190

In the 1980s, the Court again addressed the impact of common law damages actions on implied preemption analysis. In its 1984 opinion in Silkwood v. Kerr-McGee Corp., the Court was called upon to determine whether the Atomic Energy Act (the “AEA”),191 which regulated the nuclear energy industry, permitted state common law damages actions as a means of concurrent state regulation.192 The AEA gave states limited regulatory authority, which they had never had before.193 The states were precluded, however, from regulating the safety aspects of nuclear material.194 Thus, the preemption provision of the AEA carved out of federal dominion some small state regulatory authority.195

The Supreme Court concluded unanimously that the AEA did not preempt the plaintiff’s compensatory damages action.196 The Court, after reviewing the legislative history and other congressional actions regarding the AEA,197 found it difficult to believe that Congress would, without comment, remove all means of judicial recourse for those in-

187 Id. at 240.
188 Id. at 246–47. For a more complete discussion of the importance of Garmon, see Davis, supra note 15, at 981–83.
189 See Davis, supra note 15, at 981–83, 1000.
190 See Garmon, 359 U.S. at 240, 246–47.
192 464 U.S. at 241. Karen Silkwood’s estate 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. Id. at 243.
194 42 U.S.C.A § 2021(c) (4).
195 See id.
196 Silkwood, 464 U.S. at 255–56. A majority of the Court held that the AEA similarly did not preempt the plaintiff’s punitive damages claim. Id.
197 Id. at 249–55.
The Court recognized that common law damages actions have regulatory effect, but considered them consistent with federal objectives in the absence of clear congressional intent to prohibit them. Recent decisions confirm the regulatory and remedial importance of common law damages actions.

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 County*, a Florida county sought to regulate the collection of blood plasma from paid donors by requiring further limitations in addition to those required under federal regulations. The defendant blood plasma center argued for preemption under both occupation of the field and conflict preemption. The Supreme Court disagreed on both issues and reversed an appellate court finding of preemption.

The Court 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; and (2) the presumption that state or local regulation of matters related to health and safety can constitutionally coexist with federal regulation. These two impediments to preemption are central to the issue preemption in the drug labeling context and, therefore, must be fully understood.

The Court stated that the prior FDA position against preemption was dispositive on the question of implicit intent to preempt unless either the agency’s position was inconsistent with clearly expressed

\[\text{Id.} \text{ at 251. The Court stated:}\
\text{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.}\
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\[\text{Id.} \text{ at 256.}\
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\[\text{See Davis, supra note 15, at 1001, 1013–14 (discussing the post-*Silkwood* treatment of common law damages actions in preemption analysis).}\
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\[\text{*Hillsborough County*, 471 U.S. at 709.}\
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\[\text{Id. at 709–10.}\
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\[\text{Id. at 714–16.}\
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\[\text{Id. at 716.}\
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\[\text{Id. at 714. Preliminarily, the Court confirmed that preemption of local ordinances is analyzed in the same way as the preemption of statewide laws. Id. at 714 n.1.}\
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\[\text{*Hillsborough County*, 471 U.S. at 714.}\
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\[\text{Id. at 715.}\
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congressional intent, or subsequent developments revealed a change in that position. The FDA’s position against preemption had been made clear in commentary to the blood collection regulations and even though the regulations had since been broadened, the FDA had not indicated that the new regulations affected its disavowal of any intent to preempt. The Court thus rejected occupation of the field preemption even though the regulations were comprehensive, noting that “merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field,” consistent with the historic primacy of state regulation in matters of health and safety.

The Court’s discussion of field preemption and the importance of the FDA’s position against preemption also informed its rejection of implied conflict preemption. The defendant had argued that the local ordinances embodied more stringent requirements than the federal law and, therefore, presented a serious obstacle to the federal goal of ensuring an adequate supply of plasma. The Court found this concern to be too speculative to support preemption. 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. Second, even if there had been evidence of increased costs to plasma collection operators and an in-

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209 Id. at 714.
210 Id. at 716–17. The Court states:

Thus, if an agency does not speak to the question of preemption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to preempt . . . . [W]e will seldom infer, solely from the comprehensiveness of federal regulations, an intent to preempt in its entirety a field related to health and safety.

Id. at 718.
211 Hillsborough County, 471 U.S. at 716.
212 Id. at 717. The Court was “even more reluctant” to infer field preemption from regulations than from statutes, saying, “To infer preemption 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.” Id.
213 Id. at 719. Prior field preemption cases had involved a “special feature” supporting preemption—the foreign affairs power. Id. (citing Hines, 312 U.S. at 62).
214 Id. at 720.
215 Id.
216 Hillsborough County, 471 U.S. at 720.
217 Id. at 720–21.
increased burden on donors imposed under the local regulation, they
did not necessarily interfere with the federal goal of maintaining an
adequate plasma supply.\textsuperscript{218} According to the Court, neither Congress
nor the FDA had struck a balance between safety and quantity;\textsuperscript{219}
rather, the regulations that contemplated additional state and local
requirements merely established minimum safety standards.\textsuperscript{220}

Finally, the Court noted that the FDA could promulgate preemp-
tion regulations with relative ease, but it had not done so.\textsuperscript{221} The
Court attached significance to the absence of either an FDA position
or formal regulation on preemption and, without such strong evi-
dence, was reluctant to find a threat to the federal goal of ensuring
sufficient plasma.\textsuperscript{222} Because Congress had delegated to the FDA ad-
ministration of the federal program, the Court was strongly influ-
enced by the FDA’s position as reflected in the prior regulatory com-
mentary and the FDA’s silence on the matter in the case before it.\textsuperscript{223}

In summary, until the late 1980s, the Court found preemption
under the FDCA only in two narrow cases, both essentially involving
impossibility.\textsuperscript{224} Those cases arguably now rest on shaky ground be-
cause of the increasingly narrow definition of actual conflict the
Court began to use in subsequent years.\textsuperscript{225} The Court certainly was
influenced by the importance of historic state regulation in the area
of public health and safety in all of these cases.\textsuperscript{226} After \textit{Silkwood}
and \textit{Hillsborough County}, 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 \textit{Hillsborough County} did not create the
kind of obstacle to federal objectives required for preemption, the
more indirect regulation of common law damages actions would likely
not be sufficient, particularly given the long tradition of permitting
such actions.\textsuperscript{227}

\textsuperscript{218} \textit{Id.} at 721.
\textsuperscript{219} \textit{Id.}
\textsuperscript{220} \textit{Id.}
\textsuperscript{221} \textit{Hillsborough County}, 471 U.S. at 721.
\textsuperscript{222} \textit{Id.}
\textsuperscript{223} \textit{Id.}
\textsuperscript{224} \textit{See supra} notes 160–166, 172–177 and accompanying text (discussing \textit{McDermott} and
\textit{Cloverleaf Butter}).
\textsuperscript{225} \textit{See supra} notes 191–199 and accompanying text (discussing \textit{Silkwood}; \textit{see also} Davis,
\textit{supra} note 15, at 983–90 (discussing narrowing of implied preemption doctrine during
1960s and 1970s)).
\textsuperscript{226} \textit{See Hillsborough County}, 471 U.S. at 715–16.
\textsuperscript{227} \textit{See id.} at 716.
C. The Rise of Express Preemption Doctrine and the FDCA: Cipollone and Medtronic

A short seven years after Silkwood, the Supreme Court reevaluated preemption doctrine as it applied to common law damages actions.\footnote{Cipollone v. Liggett Group, Inc., 505 U.S. 504, 508 (1992).} In its 1992 decision in Cipollone v. Liggett Group, Inc., 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.\footnote{Id. at 517. \textit{Cipollone} involved preemption of products liability claims involving cigarettes. \textit{Id.} at 509-10. It required interpretation of the Federal Cigarette Labeling and Advertising Act (the “FCLAA”) of 1965, Pub. L. No. 89-92, 79 Stat 282 (codified as amended at 15 U.S.C. §§ 1331–1340 (2000)), and the Public Health Cigarette Smoking Act (the “PHCSA”) of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331–1340). \textit{Cipollone}, 505 U.S. at 530–31.} In such a case, the Court’s task was only to determine the scope of the provision.\footnote{See \textit{Cipollone}, 505 U.S. at 518, 523. 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.” \textit{Id.} at 514 (quoting the FCLAA § 5(a)). The 1969 act changed the preemption provision slightly to state that “[n]o requirement or prohibition based on smoking and health shall be imposed under State law regarding cigarette labeling or advertising. \textit{Id.} at 515 (quoting the PHCSA § 5(b)). The use of the phrase ”requirement or prohibition” was critical to the Court’s analysis of whether common law damages actions were prohibited. \textit{Id.} at 522–24.} Rarely had the Court given exclusive control to an express preemption provision, particularly as it applied to common law damages actions.\footnote{See Davis, supra note 15, at 1001.}

Because the FDCA does not contain an express preemption provision applicable to prescription drug labeling, Cipollone and subsequent cases involving express preemption are not vital to the required analysis. Cipollone did, however, represent a significant change in the approach to preemption doctrine, and subsequent cases have built on its greater focus on congressional intent and its treatment of the presumption against federal preemption of matters historically within the states’ police powers.\footnote{See \textit{Cipollone}, 505 U.S. at 522. The dissenting Justices recognized that the Court’s preemption cases had declined on several occasions to find the regulatory effects of state tort law.} The plurality opinion acknowledged that common law damages actions can have an indirect regulatory effect,\footnote{\textit{Id.} at 523.} but the dissenting Justices recognized that the Court’s preemption cases had declined on several occasions to find the regulatory effects of state tort law.
law either direct or substantial enough to warrant preemption. In the next several products liability preemption cases, the Court adhered to its focus on interpreting the scope of express preemption provisions and also confirmed the importance of implied preemption principles in the absence of Congress’s explicit intent to preempt.

The Court next decided an FDCA express preemption provision case in 1996, in Medtronic, Inc. v. Lohr. Medtronic involved application of the express preemption provision of the MDA. 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. The express preemption provision in the MDA 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. The defendant in Medtronic sought preemption of the plaintiff’s design and manufacturing defect claims regarding its pacemaker because the device had been approved through a premarket notification process, which permits market approval if a device is substantially equivalent to one already on the market. 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.

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[241] Id. at 484–85, 503 (Breyer, J., concurring); id. at 509 (O’Connor, J., concurring in part and dissenting in part). Justice Stevens’s plurality opinion suggested that actual conflict implied preemption analysis may be appropriate in certain circumstances even when an express preemption provision was at issue. Id. at 503 (plurality opinion) (citing Freightliner Corp, 514 U.S. at 287).
Even though Medtronic involved express preemption analysis, a number of important features of the decision may affect implied conflict preemption under the FDCA. 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. The majority opinion confirmed 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. Consequently, the majority opinion considered the language of the express preemption provision narrowly. The premarket notification process, under which the pacemaker had been approved, did not contain device-specific requirements. Four Justices in the plurality opinion, therefore, concluded that nothing in the legislation, its history, or its basic purpose suggested that common law damages actions were intended to be requirements, noting the singularly odd word choice to accomplish a sweeping immunity. A majority of the Justices, however, concluded 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.

Second, because the FDA had adopted a formal regulation to implement the preemption provision, all three Medtronic opinions explored the importance of the agency’s position on determining the

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242 See id. at 475 (majority opinion); id. at 487–88 (plurality opinion); id. 495–96 (majority opinion).
243 Id. at 475 (majority opinion) (citing Hillsborough County, 471 U.S. at 719).
244 Id. at 485.
245 Medtronic, 518 U.S. at 485.
246 Id.
247 The 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 id. at 476–80 (describing the processes and their differences). See generally Susan Foote, Managing the Medical Arms Race: Innovation and Public Policy in the Medical Device Industry (1992).
248 Medtronic, 518 U.S. at 487 (plurality opinion).
249 Id. at 505 (Breyer, J., concurring); id. at 509 (O’Connor, J., concurring in part and dissenting in part). 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. Id. at 505 (Breyer, J., concurring). If none, courts may infer that the “relevant administrative agency possesses a degree of leeway to prescribe the preemptive effect of its regulation.” Id.
250 21 C.F.R. § 808.1(d)(2) (2007) (no preemption of state or local requirements that are “equal to, or substantially identical to, requirements” imposed under the MDA); id. § 808.1(d)(1) (no preemption of “state or local requirements of general applicability”).
The Justices disagreed on the extent to which they should rely on an agency’s position on preemption, though in earlier cases the Court had noted that agency regulations could be informative on defining the scope of preemption where consistent with statutory language.\textsuperscript{252} The FDA did not consider common law damages actions to be preempted by its device approval regulations.\textsuperscript{253}

The majority opinion’s interpretation of the scope of the preemption provision was substantially informed by the agency’s regulations\textsuperscript{254} because of the unique role\textsuperscript{255} given to the FDA by Congress.\textsuperscript{256} After comparing the state common law requirements to the entirely generic concerns of the federal regulations, the majority concluded that the general common law obligations were 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.\textsuperscript{257} The majority recognized, however, that where the federal government had 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, an entirely different case exists for preemption under the statute and its implementing regulations.\textsuperscript{258}

Justice Breyer concurred, agreeing that the relevant administrative agency possessed a degree of leeway to determine which rules, regulations, or other administrative actions will have preemptive effect.\textsuperscript{259} In particular, the FDA had a special understanding of the likely impact of

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  \item \textsuperscript{251} 518 U.S. at 495–96 ("The FDA regulations interpreting the scope of § 360k’s preemptive effect support the Lohrs’ view, and our interpretation of the preemption statute is substantially informed by those regulations."); \textit{id.} at 505–06 (Breyer, J., concurring); \textit{id.} at 511–12 (O’Connor, J., dissenting).
  \item \textsuperscript{253}\textit{Porter}, supra note 32, at 7–8.
  \item \textsuperscript{254} \textit{Medtronic}, 518 U.S. at 495.
  \item \textsuperscript{255} \textit{id.} at 496.
  \item \textsuperscript{256} \textit{id.} The Court 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. \textit{id.} (quoting \textit{Hines}, 312 U.S. at 67).
  \item \textsuperscript{257} \textit{id.} at 501–02.
  \item \textsuperscript{258} \textit{id.} at 501.
  \item \textsuperscript{259} \textit{Medtronic}, 518 U.S. at 505–06 (Breyer, J., concurring) (citing \textit{Hillsborough County}, 471 U.S. at 721).
\end{itemize}
both state and federal requirements, and also an understanding of whether, or the extent to which, state requirements may interfere with federal objectives, and the agency could translate these understandings into particularized preemptive intentions accompanying its various rules and regulations.\textsuperscript{260} Justice Breyer concluded that the express preemption provision did not fully answer the preemption question.\textsuperscript{261} He therefore applied implied preemption principles, 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 liability-creating premises of state tort law.\textsuperscript{262} Justice Breyer had an opportunity to employ those conflict preemption principles for the majority in the Court’s next case on preemption of common law damages actions.\textsuperscript{263}

D. \textit{Implied Conflict Preemption and the FDCA: Geier and Buckman Co.}

In \textit{Geier v. American Honda Motor Co.}, a 2000 Supreme Court case, Justice Breyer endorsed an implied conflict preemption analysis despite the presence of an express preemption provision and a savings clause.\textsuperscript{264} \textit{Geier} involved allegations that a 1987 Honda was defective in design because it did not have a driver’s side air bag.\textsuperscript{265} The National Traffic and Motor Vehicle Safety Act authorized the Department of Transportation to promulgate Federal Motor Vehicle Safety Standards (“FMVSS”).\textsuperscript{266} The Act’s preemption provision states that whenever an FMVSS is in effect, states may not establish or maintain any safety standard applicable to the same aspect of performance that is not identical to the federal standard.\textsuperscript{267} The “savings clause” stated: “Compliance with any Federal

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\item \textsuperscript{260} Id. at 506.
\item \textsuperscript{261} Id. at 505.
\item \textsuperscript{262} 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. \textit{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, but one pertaining to the clear statute at issue here is surely not.”) (citation omitted).
\item \textsuperscript{264} Id. at 869.
\item \textsuperscript{265} Id. at 865.
\item \textsuperscript{267} Id. § 1392(d) (current version at 49 U.S.C. § 30103(b)(1) (2000)).
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motor vehicle safety standard issued under this sub-chapter does not exempt any person from any liability under common law."

The Department of Transportation issued FMVSS 208 regarding Occupant Crash Protection in 1967. After several revisions, the 1984 version, at issue in Geier, permitted manufacturers to choose, with some restrictions, between air bags and seat belt systems. The plaintiff’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.

Justice Breyer, writing for the majority, mirrored his analysis from Medtronic, concluding that the express preemption provision did not preempt the 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. The Court then concluded that implied conflict preemption principles continued to operate to the extent that they prohibited actual conflict, 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 preemption principles, seeks to protect.”

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268 Id. § 1397(k) (repealed 1994).


270 Geier, 529 U.S. at 865.

271 Id.

272 Id.

273 Id. at 868.

274 Id. at 869.

275 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 concluded that the regulatory scheme in Geier deserved such concern. Id. at 870 (quoting United States v. Locke, 529 U.S. 89, 106–07 (2000)). The Court’s failure to rely on the express preemption provision has been widely criticized, given its prior reliance on such provisions in both Cipollone and Medtronic. See Davis, supra note 15, at 1005–13; see also Richard C. Ausness, Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone, 92 Ky. L.J. 913, 967–68 (2003).
The Court found that an actual conflict preempted the plaintiff’s action.\footnote{\textit{Geier}, 529 U.S. at 881–82.} The Court’s determination of actual conflict in \textit{Geier} is important to the prescription drug labeling cases in two important respects. First, the Court rejected as conclusive the statutory definition of federal standards as minimum standards of care.\footnote{\textit{Id.} at 874. The National Traffic and Motor Vehicle Safety Act defined the term “safety standard” as a “minimum standard” for vehicle performance. 15 U.S.C. § 1391(2) (1966) (repealed 1994).} Instead, the Court reviewed carefully the history of the regulation that had been, at one time or another, unpopular with almost everyone.\footnote{\textit{Geier}, 529 U.S. at 875–77.} The views of the various Secretaries of Transportation on the objectives of the standard were very influential.\footnote{See \textit{id.} at 877–85.} Similarly, the comments to the original standard 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,’”\footnote{See \textit{id.} at 881 (citing Brief for United States as Amicus Curiae at 25, \textit{Geier}, 529 U.S. 861 (No. 98–1811)).} were persuasive. The Secretary sought to balance a variety of concerns that impacted the primary objective of consumer safety, including obstacles to consumer acceptance of restraint devices, industry reluctance to adopt restraint devices, and Congress’s responses to public pressures regarding the restraints.\footnote{\textit{Id.}} The Court recognized that the standard deliberately sought variety and was, therefore, neither a minimum nor a maximum standard.\footnote{\textit{Id.}}

Second, in defining the federal objectives at issue, the Court placed some weight upon the Department of Transportation’s own interpretation of those objectives and its conclusion that the tort actions would stand as an obstacle to those objectives.\footnote{\textit{Geier}, 529 U.S. at 877–79.} The Court justified that level of attention—it did not use the word “deference”—to the agency’s position based on the technical subject matter, the complex and extensive nature of the relevant history and background, and the agency’s uniquely qualified position to comprehend the likely impact of state requirements.\footnote{\textit{Id.}}
The Secretary of Transportation’s consistent position on preemption was also influential in supporting the Court’s position.\textsuperscript{285} That position had been articulated in two recent cases, through amicus briefs.\textsuperscript{286} The lack of a formal statement on preemption was, therefore, not determinative.\textsuperscript{287} Relying on \textit{Hillsborough County}, the Court rejected a requirement of a formal agency statement on preemption to support conflict preemption.\textsuperscript{288} Although the Court accepted that it should not find preemption too readily in the absence of clear evidence of a conflict, it reasoned that to insist on a specific expression of an agency’s intent to preempt, made after notice-and-comment rulemaking, in some cases would be to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended.\textsuperscript{289}

The Court weighed the stated federal objectives against the general interest that the states have in promoting the health and welfare of citizens through compensation for injuries suffered from defective products.\textsuperscript{290} The Court did not mention specifically the presumption against preemption\textsuperscript{291} but was clearly sympathetic to the states’ concerns.\textsuperscript{292} Nevertheless, the Court concluded that the state and federal objectives could not be reconciled because such a state law, by its terms, would have required manufacturers of all similar cars to install air bags rather than other passive restraint systems, thereby presenting an obstacle to the variety and mix of objectives sought by federal regulators.\textsuperscript{293} Although the Court acknowledged that Congress intended some nonuniformity in the regulatory system it created, the Court concluded that jury-assessed standards would lead to unpredictability and uncertainty in the standard of due care.\textsuperscript{294} The Court recognized that tort law may be different and that related considerations, such as the ability to pay damages instead of modifying one’s behavior, may be relevant for preemption purposes, but those considerations were not persuasive in this instance.\textsuperscript{295}

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\item[285] Id.
\item[286] Id. (citing \textit{Freightliner Corp.}, 514 U.S. 280; \textit{Wood v. Gen. Motors Corp.}, 865 F.2d 395 (1st Cir. 1988)).
\item[287] Id. at 884.
\item[288] Geier, 529 U.S. at 884.
\item[289] Id. at 884–85.
\item[290] Id. at 888–83.
\item[291] Id. at 894 (Stevens, J., dissenting); see also Davis, supra note 15, at 1008.
\item[292] Geier, 529 U.S. at 882.
\item[293] Id. at 881.
\item[294] Id. at 871.
\item[295] Id. at 882.
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The Court’s next preemption case again involved the Medical Device Amendments of the FDCA. In the 2001 case *Buckman Co. v. Plaintiffs Legal Committee*, the Court was called upon to determine whether the MDA preempted the plaintiffs’ claim based on the defendant’s fraudulent misrepresentations to the FDA to obtain approval of its orthopedic bone screws. 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. Because policing fraud on a federal agency was uniquely federal and not traditionally governed by the states, the Court concluded that the presumption against preemption did not operate.

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

The Court found that, because the state law claim was based on a federal regulation and not on traditional tort principles, there was no

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297 *Id.*
298 *Id.* at 348 n.2 (“[W]e express no view on whether these claims are subject to express preemption.”).
299 *Id.* at 347–48.
300 *Id.* at 348–49.
301 *Buckman*, 531 U.S. at 349–50.
302 *Id.* at 354 n.2 (Stevens, J., concurring). Justice Stevens noted:

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-law tort 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 for fraudulently obtaining its approval.

*Id.* (citation omitted).
corresponding benefit to the operation of state law.\textsuperscript{303} 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 noninterference with medical practice.\textsuperscript{304} The Court noted, however, that a traditional state tort action, not based on a federal regulation, might survive.\textsuperscript{305}

E. Final Words on Implied Preemption Doctrine: Sprietsma and Bates

The Supreme Court’s next two preemption opinions, \textit{Sprietsma v. Mercury Marine} in 2002, and \textit{Bates v. Dow Agrosciences LLC} in 2005, 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.\textsuperscript{306} 

\textit{Sprietsma} involved allegations of design defect against manufacturers of recreational boats that did not have propeller guards.\textsuperscript{307} The Federal Boat Safety Act of 1971\textsuperscript{308} gave the Secretary of Transportation the authority, delegated to the Coast Guard, to establish a coordinated national boating safety program, including safety standards for boating equipment to establish uniform safety regulations.\textsuperscript{309} The Coast Guard, after gathering data and holding public hearings over a several-year period, decided for reasons of safety, feasibility, and economics not to require such guards.\textsuperscript{310} The boat manufacturer argued

\textsuperscript{303} Id. at 352–53 (majority opinion) (federal enactment is critical element of claim, contrasting \textit{Silkwood}, 464 U.S. at 241, and \textit{Medtronic}, 518 U.S. at 481).

\textsuperscript{304} Id. at 350.

\textsuperscript{305} Id. at 353 (“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.”). \textit{Buckman}, therefore, could be said not to involve a conflict at all between federal and state interests because states do not have an interest in protecting the FDA from fraud claims. \textit{See id.} For a further discussion of this “false conflict” analysis in preemption, see generally Mary J. Davis, \textit{On Preemption, Congressional Intent and Conflict of Laws}, 66 U. Pitt. L. Rev. 181 (2004).


\textsuperscript{307} Sprietsma, 537 U.S. at 55. The plaintiff’s wife had been thrown from a boat and was killed when struck by the propeller blades. \textit{Id.} at 54.


\textsuperscript{310} Sprietsma, 537 U.S. at 59–60. 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). 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
that the Coast Guard’s decision preempted the plaintiff’s claim based on lack of a guard.\footnote{Sprietsma, 537 U.S. at 55.}

The Court, consistent with \textit{Geier}, found no express preemption and engaged in an implied conflict preemption analysis.\footnote{Id. at 64.} In assessing the strength of the federal and state governmental policies at stake, the Court emphasized that the Coast Guard regulations had preserved state authority pending the adoption of specific federal regulations.\footnote{Id. at 64.} The Coast Guard had been in favor of permitting state common law claims.\footnote{Id. at 65–66.} The Court emphasized the government’s consistent position that the regulation did not have any preemptive effect.\footnote{Id. at 66.}

The Court’s most recent preemption decision made some important, general observations about the delicate balance that must be achieved in determining the scope of preemption.\footnote{Bates, 544 U.S. at 445-46.} \textit{Bates} involved whether common law tort actions challenging the labeling of pesticide were preempted under the Federal Insecticide, Fungicide, and Rodenticide Act (the “FIFRA”).\footnote{7 U.S.C. §§ 136–136y (2000); 544 U.S. at 434.} 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.\footnote{Bates, 544 U.S. at 436.} They reasoned that a jury finding under state law would \textit{induce} the defendant to alter its pesticide labeling, which the Environmental Protection Agency (the “EPA”) had approved.\footnote{Etcheverry v. Tri-Ag Serv., Inc., 993 P.2d 366, 374–78 (Cal. 2000).} The EPA had taken inconsistent positions on preemption in the previous five years, first in favor of the operation of state tort law\footnote{Bates, 544 U.S. at 437 n.7.} and then in favor of preemption.\footnote{Id. at 454–36.}
The Court’s discussion of the history of FIFRA regulation reads much like the history of FDCA regulation.\textsuperscript{322} For example, the Court noted that prior to 1910, the states provided the primary and possibly the exclusive source of regulatory control over the distribution of poisonous substances.\textsuperscript{323} The history of the FDCA regarding drugs is virtually identical.\textsuperscript{324} In addition, the Court noted that FIFRA imposes misbranding liability for labels that are false or misleading in any particular,\textsuperscript{325} just as the FDCA does for prescription drugs and devices. The addition to FIFRA, in 1972, of an express preemption provision that governs the continuing role of the states in pesticide regulation is the primary difference between the two statutory schemes.\textsuperscript{326} In addition, the EPA does not determine or endorse the efficacy of pesticides it approves for marketing,\textsuperscript{327} unlike the FDA’s drug approvals, which do review efficacy claims.\textsuperscript{328}

In an interesting nod to preemption opponents generally, the Court noted that tort litigation against pesticide manufacturers had been taking place for decades, before and after the enactment of FIFRA in 1947, and that it was not until after \textit{Cipollone} in 1992, that a groundswell of preemption arguments based on FIFRA were advanced.\textsuperscript{329} The Court concluded that most claims at issue were not preempted but remanded the case for further inquiry regarding the labeling claims.\textsuperscript{330}

The Court rejected the theory, relied on by the lower courts, that simply because a jury verdict might have the effect of inducing a manufacturer to make a labeling change, the damages action was therefore preempted.\textsuperscript{331} The Court reasoned that a requirement is a rule of law that must be obeyed, whereas an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.\textsuperscript{332} Consequently, state law requirements that are equivalent to or consistent with FIFRA regulations survived.\textsuperscript{333} Parallel state requirements imposed on

\textsuperscript{322} \textit{Id.} at 437–38.
\textsuperscript{323} \textit{Id.} at 437.
\textsuperscript{324} See \textit{supra} notes 65–89 and accompanying text.
\textsuperscript{325} Bates, 544 U.S. at 438.
\textsuperscript{326} Id. at 439.
\textsuperscript{327} Id. at 440.
\textsuperscript{328} See \textit{supra} note 73 and accompanying text.
\textsuperscript{329} Bates, 544 U.S. at 441.
\textsuperscript{330} Id. at 452–53.
\textsuperscript{331} Id. at 445–46.
\textsuperscript{332} Id. at 445. The Court stated, “The inducement test is unquestionably overbroad . . . .” Id.
\textsuperscript{333} Id. at 447.
manufacturers will provide an additional incentive to comply with the federal requirements.334

The Court took a dim view of expansively reading Congress’s intent to preempt given the long history of tort litigation against manufacturers of poisonous substances, which adds force to the basic presumption against preemption.335 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.336 Further, private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA, which contemplates that pesticide labels will evolve over time as manufacturers gain more information about their products’ performance in diverse settings.337 Tort suits, the Court reasoned, can act as a catalyst in this effort.338

F. Synthesis of Preemption Doctrine

The Supreme Court’s discussion in Bates of the benefit of tort suits in warning cases and the value of those tort actions historically in regulating warnings serves as an important bridge to the implied preemption issue under the FDCA.339 The following implied preemption principles derived from the Court’s cases will impact how the Court analyzes the prescription drug labeling cases.

The presumption against preemption maintains vitality particularly in cases involving traditional areas of historic state power.340 The

334 Bates, 544 U.S. at 448–49. The Court rejected the notion that FIFRA contained a “nonambiguous command to preempt,” given that the EPA had just five years earlier advocated against preemption. Id. at 449.

335 Id. at 449; see id. at 456, 459 (Thomas, J., concurring) (also endorsing a narrow view of cases in which implied preemption is permitted). Justice Thomas noted:

Today’s decision thus comports with this Court’s increasing reluctance to expand federal statutes beyond their terms through doctrines of implied preemption . . . . This reluctance reflects that preemption analysis is not [a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, . . . but an inquiry into whether the ordinary meanings of state and federal law conflict.

Id. at 459 (citations and internal quotation marks omitted).

336 Id. at 449 (majority opinion).

337 Id. at 451.

338 Id.

339 For a discussion of the effect of Bates on prescription drug labeling preemption, see David G. Owen, Products Liability Law (2d ed. forthcoming 2008).

340 See supra notes 335–338 and accompanying text. The presumption against preemption has also been described as an assumption of nonpreemption that is not triggered in
presumption is especially forceful in implied conflict preemption doctrine because a determination of actual conflict is intended to be a substitute for congressional intent, and, because it is a weak substitute, the Court has been careful to require strong, clear evidence of such conflicts. The Court continues to be sensitive to the role that tort actions play in motivating conduct, and in Geier it even left open the possibility that tort actions might survive preemption if narrowly drawn.341 The Court appeared, after Cipollone and Medtronic, to be distancing itself from the protections its preemption doctrine had long provided to common law damages actions.342 Geier was similarly reluctant to discuss specifically the presumption against preemption.343 Sprietsma and Bates, however, discuss favorably the long-standing role of tort litigation in regulating public health and safety and emphasize the concurrent role of the states in that regulation.344 In addition, the Court has reiterated in Bates that where compensation remedies are not otherwise available, the courts should be very hesitant to deny protection to those injured by regulated conduct.345

Determining whether an actual conflict exists will involve an assessment of the federal objectives at stake, as identified through the legislation; the regulations promulgated pursuant to it; the history of that regulation; and the agency’s views on the scope of the regulatory scheme.346 The consistency of the government agency’s position in defining the objectives and their preemptive reach will be instructive. But the Court has never described the consideration it has given to agency position regarding preemption as deferential; indeed, the Court seems to go out of its way not to speak in terms of deference to the agency on preemptive scope.347 The Court considers carefully the factors that support a finding of actual conflict, and agency position on preemption is one such factor. An agency’s position on preemptive scope may be persuasive, given its expertise regarding the federal ob-

341 See supra notes 294–295 and accompanying text.
342 See generally Buckman, 531 U.S. 341.
343 529 U.S. at 868.
344 See Bates, 544 U.S. at 449; Sprietsma, 537 U.S. at 70.
345 544 U.S. at 449–50.
346 See supra notes 251–256, 283–289, 313–315, 334 and accompanying text (discussing importance of agency position in Medtronic, Geier, Sprietsma, and Bates).
347 See supra notes 251–256, 283–289 and accompanying text (noting differences of opinion over level of consideration to be given to agency position in Medtronic and Geier).
jectives at issue, but not as to the legal conclusion to be drawn from them.

Federal regulatory action necessarily involves a balancing of objectives, sometimes conflicting ones, and requires careful tailoring of the available means to implement those objectives. Does the decision to approve a prescription drug label constitute the kind of particularized balance that will defeat longstanding tort actions which treat such labeling decisions as minimum standards of conduct to be evaluated by the liability-creating premises of state tort law?2348 Whether state tort claims actually conflict with or complement the federal prescription drug labeling scheme requires close attention to the details of the balance struck by that regulatory scheme.

IV. DEFINING ACTUAL CONFLICT IN PRESCRIPTION DRUG LABELING PREEMPTION

This Part applies the analysis of implied preemption doctrine to the prescription drug labeling context.349 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.350 Finally, insights gleaned from the Court’s broader preemption doctrine aid in supporting the ultimate conclusion that implied conflict preemption of products liability claims is not supported by FDA labeling regulations.351

A. The Arguments for Implied Conflict Preemption

Manufacturers who support preemption must define an actual, direct, and clear 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.352 The Court continues to require that traditional state regulation of health and safety not be

348 Both Hillsborough County and Geier emphasized the importance of the particular balance that the federal regulations sought that might support a finding of actual conflict. See supra notes 216–220, 280–289 and accompanying text.
349 See infra notes 352–457 and accompanying text.
350 See infra notes 352–440 and accompanying text.
351 See infra notes 441–457 and accompanying text.
preempted absent strong evidence of an actual, direct, and clear conflict impairing the accomplishment of defined federal objectives.\textsuperscript{353}

General federal objectives to promote health and safety do not suffice to conflict with state tort laws and support implied preemption because of the assumption that state laws must be permitted to operate in traditional areas of public health and safety. An actual conflict that impliedly preempts must be based on particularized federal goals that state-mandated actions directly frustrate. The Court’s early implied preemption cases involving the FDA make this point\textsuperscript{354} as do all the modern implied preemption cases.\textsuperscript{355} Indeed, the FDA has acknowledged that its labeling regulations do not, as a general proposition, preempt all failure-to-warn claims based on approved labeling\textsuperscript{356} and that “preemptive conflict does not exist in every instance in which state tort law seeks to impose liability for the failure to provide a warning not affirmatively mandated by FDA.”\textsuperscript{357} The FDA has articulated three concerns that its labeling regulations seek to address within the primary goal of ensuring that safe and effective drugs are made available to the public; the following Sections explore these concerns.\textsuperscript{358}

1. Defining Federal Objectives: Over-Warning

First, the FDA asserts that permitting jury verdicts based on approved labeling will encourage manufacturers to warn physicians of unsubstantiated risks and thereby negatively impact medical treatment by inducing physicians to make inappropriate medical treatment decisions.\textsuperscript{359} This potential over-warning of risks may thus deter the use of an otherwise beneficial drug in circumstances when it is advised.


\textsuperscript{354}See supra notes 151–181 and accompanying text.

\textsuperscript{355}See supra notes 215–223, 276–295, 310–315 and accompanying text.


\textsuperscript{357}Id.

\textsuperscript{358}See infra notes 359–377 and accompanying text.

\textsuperscript{359}See supra notes 140–141 and accompanying text; see also Brief of United States as Amicus Curiae Supporting Defendant at 16, Colacicco v. Apotex, Inc., No. 06-3107 (3d Cir. June 23, 2006) [hereinafter Colacicco Amicus Brief of United States] In an amicus brief, the United States argued:

Under-use of a drug based on dissemination of unsubstantiated warnings may deprive patients of efficacious, possibly live-saving treatment . . . . Rather than
The experience with antidepressants documented by the U.S. District Court for the Central District of California in the 2000 case Motus v. Pfizer, Inc. illustrates these concerns. The FDA studied the alleged association between SSRI antidepressants and the risk of suicide on a number of separate occasions, both before and during the approval process for Zoloft. Although the FDA never prohibited SSRI manufacturers from altering the labeling, it is clear that FDA regularly and consistently from 1991 to 2006 denied that labeling revisions were warranted to enhance the available information about the risk of suicidality from the use of SSRIs. The FDA has consistently argued since 2002 in favor of conflict preemption regarding the labeling of SSRIs because it specifically determined that additional warning of the risk of suicidality was not required by the available evidence. Whether such a decision actually conflicts with a common law damages action asserting a need for the warning requires assessment of the remaining asserted federal objectives and their state counterparts.

2. Minimum or Maximum Standards

Second, even though the FDA has long articulated that its regulations establish only minimum standards, the FDA now asserts that in some cases its individual labeling decisions establish more. The FDA considers certain labeling approvals to define optimal standards from which deviation is not permitted absent specific FDA ap-
proval.\textsuperscript{366} This is the case with SSRI warnings. When a federal regulatory agency describes its standard as more than a minimum, as was the case in the 2002 Supreme Court case \textit{Geier v. American Honda Motor Co.}, a finding of actual conflict is more likely because the particular federal balance may reflect a compromise with the very interests that state tort law serves.\textsuperscript{367} In 1996, in \textit{Medtronic, Inc. v. Lohr}, the Court viewed the question as a determination of whether the action was one in which the federal government had 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.\textsuperscript{368} If this is the case, one must ask the next question: what considerations did the federal regulatory scheme balance, and does state tort law directly conflict with that balance? Implied conflict preemption principles require courts to go beyond easy characterizations to assess the actual regulatory action at issue before pre empting traditionally complementary state tort actions.

3. Potential Misbranding Violations and Impossibility of Dual Compliance

The FDA notes a third specific concern that, in some instances, a manufacturer may be subject to a misbranding violation if it satisfies a state common law damages action and alters a label that subsequently does not meet with FDA approval.\textsuperscript{369} In the case of SSRIs, for example, the FDA has expressed the opinion that a manufacturer would be subject to a misbranding violation if it altered its label to comply with a state tort action.\textsuperscript{370} Such a position implies that requiring a manufacturer to comply with a common law tort action’s determination of adequacy would render it subject to federal misbranding liability and thus, make it impossible to satisfy both obligations.\textsuperscript{371}

\textsuperscript{366} See \textit{supra} notes 137–146 and accompanying text.

\textsuperscript{367} 529 U.S. 861, 877–81 (2002).

\textsuperscript{368} See \textit{supra} notes 257–258 and accompanying text.

\textsuperscript{369} See \textit{Motus Amicus Brief for United States, supra} note 37, at 17. 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. \textit{Id.} The brief stated, somewhat self-servingly, that the FDA would not have approved an altered Zoloft label. \textit{Id.}

\textsuperscript{370} See \textit{Colacicco Amicus Brief of United States, supra} note 359, at 19.

\textsuperscript{371} See \textit{id.}
The Court has rarely found conflict preemption based on impossibility because it has always considered it possible for the defendant to comply with both state and federal regulations, for example by paying tort damages and continuing to comply with a federal requirement.\footnote{372 For an example of impossibility, see McDermott v. Wisconsin, 228 U.S. 115, 133–34 (1913), and, see also Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963) (discussing implied preemption involving impossibility).} In addition, the FDA must establish misbranding liability in court.\footnote{373 See supra note 50 and accompanying text.} Misbranding liability does not attach automatically upon mere FDA assertion.\footnote{374 See supra note 50 and accompanying text.} Whether the Supreme Court would find that it is, indeed, impossible to pay tort damages and simultaneously seek FDA regulatory approval of a stronger warning or provide information to medical care providers through other means, given that the regulations permit this very course, is unlikely.\footnote{375 A number of courts have rejected the impossibility component of the implied preemption argument. See, e.g., Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666, 673–76 (E.D. Ky, 2006); Perry, 456 F. Supp. 2d at 684–85; Levine v. Wyeth, No. 2004-384, 2006 WL 3014078, ¶¶ 21–23 (Vt. Oct. 27, 2006).}

Each of these concerns—over-warning resulting in under-utilization of an effective drug and dilution of its otherwise valid warnings, recognition of maximum standard-setting, and the potential misbranding violations that may result from complying with state tort law—are the federal objectives that purportedly require conflict preemption of concurrent state tort laws.\footnote{376 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006); see also Nagareda, supra note 21, at 31–32 (rejecting misbranding concern).} The next Section analyzes how these objectives are assessed under conflict preemption doctrine when compared to the state tort principles with which they are alleged to conflict.\footnote{377 See infra notes 378–440 and accompanying text.}

B. Application of Implied Conflict Preemption

Based on general implied preemption principles and those applicable to the FDCA, prescription drug labeling preemption raises several unresolved questions. First, how are the federal objectives to be defined in the case of prescription drug labeling with which state tort laws arguably 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 mini-
mum or maximum standards is central to defining the objectives in conflict. Second, what effect does the historic presumption against preemption of state regulation in the field of public health and safety have when balanced against those federal objectives? The Court has been hesitant to permit an overly aggressive assessment of federal objectives to swamp the importance of longstanding tort principles. Third, does the indirect regulatory effect of common law damages actions create an actual, direct, and clear conflict with the objectives of the prescription drug labeling regulatory regime?

1. Federal Objectives of the Prescription Drug Labeling Regulations

As early as the Supreme Court cases of *Savage v. Jones* and *McDermott v. Wilson*, decided in 1912 and 1913 respectively, the objective of the food and drug laws has been clear: to protect the public health and safety from adulterated and misbranded drugs. The FDA, as the undisputed expert federal public health agency charged with ensuring the safety and efficacy of the nation’s drug supply, must be given room to satisfy its public health mission substantially unimpeded. The federal objectives of public safety, however, are not inconsistent with the historic primacy of the states in the field of public health and safety. Because Congress has not expressed its intent to preempt state regulation, even though it has done so regarding food and drug laws on other occasions, the states continue to be free to fulfill their historic regulatory role.

Implied conflict preemption doctrine substitutes for explicit congressional intent the assessment of actual conflict because Congress is presumed to want its federal objectives to prevail over contrary state law. Because congressional intent is implied based on a particular set of circumstances, the fact that Congress has not defined a specific preemptive scope supports defining those federal objectives with cau-

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379 See *McDermott*, 228 U.S. at 128; *Savage*, 225 U.S. at 529; supra notes 151–170 and accompanying text.
380 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.
381 See Medical Device Amendments to the FDCA, 21 U.S.C.A § 360k (West 1999 & Supp. 2007); see also supra notes 17–18, 129–131 and accompanying text.
383 See *Hillsborough County*, 471 U.S. at 713.
tion and particularity so as not to displace state law unnecessarily. The Court, therefore, has been restrictive in its definition of what constitutes an actual, direct, and clear conflict with federal objectives. Those seeking to preempt state health and safety regulations consequently face an uphill battle.

The long history of tort litigation in the prescription drug labeling area, in addition to 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 clear, also support the requirement of clear, particularized federal objectives to which implied conflict preemption principles are to be applied in the prescription drug labeling context. Strong evidence is needed to defeat the presumption that state health laws are not impliedly preempted.

The FDA has asserted that, given its objective to ensure each drug’s optimal use through requiring scientifically substantiated warnings, a common law tort action would frustrate this purpose. The FDA expressed concern for the potential under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, which might deprive patients of beneficial, possibly lifesaving treatment. According to the FDA, a common law tort action might encourage the use of a warning that would diminish the impact of valid warnings, creating an unnecessary distraction.

The FDA’s stated objective to prevent over-warning is the kind of general objective that, standing alone, is unpersuasive under this standard. Manufacturers often raise over-warning concerns in warning cases because of the fear that juries too easily impose liability based on the hindsight that a particular warning would have prevented the plaintiff’s injury, putting manufacturers in the position of having to warn about everything. There is no support, however, for the assertion that

384 See id. at 720–21 (defining federal goal narrowly in actual conflict preemption).
385 See supra notes 214–223, 276–289 and accompanying text (discussing actual conflict as assessed in Hillsborough County, and Geier).
386 Hillsborough County, 471 U.S. at 714.
387 See Bates, 544 U.S. at 449.
388 See id. at 450; see also supra notes 329–338 and accompanying text.
390 Hillsborough County, 471 U.S. at 721.
391 See Motus Amicus Brief of Unites States, supra note 37, at 23; see also Colacico Amicus Brief of United States, supra note 359, at 13.
392 Motus Amicus Brief of United States, supra note 37, at 23.
393 Id. at 23–24.
394 See id. at 23.
this phenomenon occurs in the prescription drug labeling context. Pre-
scription drug labeling is directed at a very sophisticated physician audi-
ence. Any over-warning concern must be assessed given the learned inter-
mediary audience, and it is a concern that the FDA substantiates only
with very general statements and no supporting data. When comment-
ing on the new labeling regulation, physicians uniformly responded that they wanted more, clearer information, not less.

Even if one acknowledges a general over-warning concern, the
FDA has recognized that approved labeling should not by itself pre-
empt state damages actions based on that labeling. It would other-
wise be difficult to reconcile the FDA’s objective to prevent over-
warning—that it is beneficial to have less information about a drug’s possible risks rather than more—with its own regulation that requires manufacturers to alter a label unilaterally to add or strengthen a con-
traindication, warning, precaution, or adverse reaction. A physician
who might be inclined to withhold a particular drug treatment be-
cause of disclosed risks may do so for an infinite variety of reasons re-
lated to an individual patient’s medical needs, only one of which may
be sensitivity to over-warning. A more specific regulatory action re-
lated to a particular label should be required as an initial matter be-
fore any over-warning concern can rise to the level necessary to pre-
vent the concurrent operation of state tort laws which seek to
enhance available risk information, not restrict it.

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, weighs heavily in the determina-
tion of whether state law directly and actually conflicts with federal
objectives in the field. As early as Savage and as recently as Bates v. Dow
Agrosciences LLC, decided in 2005, the Supreme Court has acknowled-
ged 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.

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395 See id. at 23–24.
396 See supra notes 120–121 and accompanying text.
397 See supra notes 144–145 and accompanying text (discussing FDA position asserted
in amicus letter brief in Perry).
398 See supra notes 121–124 and accompanying text (discussing 21 C.F.R. § 314.70(c)(6)
(2007)).
399 See Bates, 544 U.S. at 443; Savage, 225 U.S. at 539.
The Court struggled in recent years with the relevance of the presumption against preemption of state police powers in express preemption analysis, but certainly returned to an emphasis on that presumption in 2002, in *Sprietsma v. Mercury Marine* and more recently in *Bates*.\textsuperscript{400} *A fortiori*, the presumption against preemption in the implied preemption context is critical to prevent over-reaching of the traditional state domain. The Court’s opinions generally reflect this understanding.\textsuperscript{401}

For example, in 1985, in *Hillsborough County v. Automated Medical Laboratories, Inc.*, the Court considered the presumption against preemption to apply strongly and defeat implied field preemption.\textsuperscript{402} Regarding conflict preemption, the Court found no evidence of an actual conflict because the stated federal objectives were too speculative to be credited.\textsuperscript{403}

The Court did not mention the presumption by name in *Geier*, though it was keenly aware of the value of state tort law in regulating product safety and, more importantly, providing compensation for injured parties.\textsuperscript{404} The Court was influenced in *Geier* by the particularized nature of the federal objectives—the specific variety and mix of passive restraint systems permitted a choice of design alternatives to achieve a purposeful balance of restraint systems that would be defeated by permitting state tort actions to require only one of those choices.\textsuperscript{405} Permitting a choice of designs to achieve a deliberate balance in the automobile fleet over time was a conscious attempt to delay the accomplishment of maximum safety to enhance other goals of consumer confidence and acceptance.

The objectives behind the FDA’s particular labeling approvals simply do not have the same character that supported the variety and mix of objectives that were present in *Geier*. If specific prescription drug labeling approvals support preemption, drug manufacturers would receive, in essence, a free pass to avoid making the otherwise


\textsuperscript{401} See *Geier*, 529 U.S. at 882; *Hillsborough County*, 471 U.S. at 716–21; supra notes 207, 214–223, 291–292 and accompanying text.

\textsuperscript{402} See *471 U.S. at 716–21; supra notes 207, 214–223 and accompanying text.

\textsuperscript{403} See *Hillsborough County*, 471 U.S. at 720; supra notes 207, 214–223 and accompanying text.

\textsuperscript{404} See *Geier*, 529 U.S. at 882; supra notes 291–295 and accompanying text.

statutorily required label changes with no simultaneous, conscious purpose to enhance safety or availability. Drug manufacturers who have, or could obtain information about increased risk that would otherwise have to be disclosed will be protected from a failure to disclose. What incentive will then exist to explore postapproval risks and obtain otherwise potentially adverse information? To justify the absolute protection from liability for withholding risk information from sophisticated physicians that preemption would provide on the chance that physicians may under-prescribe a dangerous drug requires much stronger support than the generalized concern of over-warning currently articulated.

It is clear 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 counterweight to the stated federal objectives in the balance.\footnote{406} If, as the FDA has asserted, its decision not to require a labeling change, as in the case of SSRIs, reflects such a particularized balancing of risks, does its decision not to regulate then become preemptive? \textit{Geier} held that it did; though \textit{Geier} involved an explicit choice to reject a design alternative that was unambiguously safer to accommodate other objectives such as consumer acceptance and reliance.\footnote{407} In \textit{Sprietsma}, the Court rejected a finding of implied conflict preemption in such a circumstance—when a federal agency had decided \textit{not} to regulate—precisely because the agency’s conclusion was not an affirmative choice as in \textit{Geier}, but a decision not to choose.\footnote{408} In such a circumstance, the Court was right to conclude that federal objectives did not defeat state tort actions, and rather rely on them as the traditional means of increasing, incrementally, incentives toward safety.\footnote{409} The Court refused to permit an expert agency assessment to have greater effect than necessary.\footnote{410}

Arguably, an FDA decision \textit{not} to require a particular warning in prescription drug labeling is more like the decision in \textit{Sprietsma} than it is the decision in \textit{Geier}.\footnote{411} The FDA decisions not to require a particular labeling change in SSRI labels did not prohibit manufacturers from following the labeling change regulations; rather, it reflected the conclusion that at each time, the citizen petitioners had not made a

\footnote{406} See supra notes 226, 243, 290–292 and accompanying text.
\footnote{407} 529 U.S. at 886.
\footnote{408} \textit{Sprietsma}, 537 U.S. at 67; \textit{Geier}, 529 U.S. at 877–78.
\footnote{409} See supra notes 314–315 and accompanying text.
\footnote{410} \textit{Sprietsma}, 537 U.S. at 67–68.
\footnote{411} Contra Nagareda, supra note 21, at 30 (likening FDA decision in SSRI case to \textit{Geier}).
compelling case. At no time did any manufacturer seek permission to alter a label; each FDA decision not to require a label change to SSRIs was supported by manufacturers who, one might rationally conclude, had an incentive to prevent the addition of more stringent warnings. Such an FDA decision is more like a decision simply to permit the regulatory scheme to continue operating and to require manufacturers to continue complying with it by seeking necessary labeling changes consistent with those requirements.

And in any event, does the parallel operation of state tort laws actually conflict with the objectives behind such a labeling decision? The Court was openly hostile toward the proposed rejection of “long-standing” principles of tort compensation in Bates involving pesticide labeling under FIFRA. The Court confirmed its dedication to the presumption against preemption in assessing Congress’s intent and noted that “[p]rivate remedies . . . would seem to aid, rather than hinder,” the functioning of a public health and safety regulatory scheme. Bates involved a labeling approval regime less rigorous than the FDA’s but operating under an express preemption provision. 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 objective behind the prescription drug labeling regulation, to prevent over-warning, does not actually conflict with state common law tort actions. The main general objective, protection of the public health, is certainly not in conflict with state tort actions but operates in a complementary way with them, as it 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 claims, as the Court found in Bates. 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.

\[412\] See Bates, 544 U.S. at 447–49; supra notes 330–335 and accompanying text.
\[413\] Bates, 544 U.S. at 451.
\[414\] Id. at 437–42.
\[415\] See id.
\[417\] 544 U.S. at 451.
3. Effect of the FDA’s Changed 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 undergird that approval. The concern of over-warning and the consequent possible disincentive to physicians to prescribe are at the core of this argument, but over-warning concerns are not new. The FDA’s approval processes continue to be complex and thorough, but appear no more or less capable of assessing warning adequacy today than in years past. To the extent that manufacturers continue to be in control of the data available to substantiate the need for revised warnings, the regulatory process has not changed. The FDA’s regulations still require unilateral change to labeling where necessary to identify an increased or different risk even if a causal association is not established. The only real change in the regulatory process is the revised conclusion of preemption that the FDA and manufacturers seek to draw from labeling decisions. The recent “groundswell” of effort to use preemption based on FDA approved labeling is another example of an overly aggressive application of the Court’s preemption cases.

The Court’s implied conflict preemption doctrine rejects such a change in agency position 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 Buckman Co. v. Plaintiffs’ Legal Committee, decided by the Court in 2001, nor Bates was such a change in agency position credited in the preemption analysis. Bates involved an express preemption provision, for which greater deference to

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418 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.
419 Id. at 3949.
420 Id. at 3933–35.
423 See id.; supra notes 302, 334 and accompanying text; see also discussion of change in agency position as irrelevant in CSX Transportation, Inc. v. Easterwood, 507 U.S. 658 (1993), supra note 235.
agency interpretation might have been appropriate; nevertheless, the Court refused to endorse it.\textsuperscript{424}

The Court was “substantially informed” by the FDA’s position on preemption in Medtronic because Congress had expressly provided authority to the FDA to determine when state regulations would be preempted under the MDA.\textsuperscript{425} 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.\textsuperscript{426} There is no formal preemption provision in the new prescription drug labeling regulation. There is only commentary in the preamble.\textsuperscript{427} There has been no comment from the health care community, either physicians or their organizations, or state public health officials, on the FDA’s position in favor of preemption. The proposed regulation specifically disclaimed any intent to alter the FDA’s formal position on preemption and, rather, asked for comments on the product liability implications of the proposed labeling regulation itself.\textsuperscript{428} The new preemption position is nothing more than an articulation of the FDA’s very recent litigation position—it is not a long-standing, formal policy, and the Court will likely dismiss any description of it as such in an implied conflict preemption analysis.

An agency’s interpretation of its own regulations is ordinarily accorded great deference.\textsuperscript{429} The degree of that deference has been the subject of much discussion in the Court’s preemption opinions, including the opinions involving the FDA.\textsuperscript{430} Generally, though, the degree of deference due to government positions depends on, among

\begin{itemize}
\item \textsuperscript{424} See supra note 334 and accompanying text.
\item \textsuperscript{425} See supra notes and 250–258 and accompanying text.
\item \textsuperscript{426} Medtronic, Inc. v. Lohr, 518 U.S. 470, 512 (O’Connor, J., dissenting).
\item \textsuperscript{427} See supra notes 131–133 and accompanying text. See generally Sharkey, supra note 4.
\item \textsuperscript{428} Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201) (“[T]his proposed rule does not preempt State law.”).
\item \textsuperscript{430} See supra notes 215–223, 251–256, 302 and accompanying text (discussing Hillsborough County, Medtronic, and Buckman Co.).
\end{itemize}
other things, consistency, formality, and thoroughness. Briefs are not accorded great policy deference, particularly when the agency interprets statutes or regulations in a particular case, at such a time and in such a manner so as to provide a convenient litigating position for a particular action. The FDA’s efforts to obtain greater deference in the MDA context have met with limited success 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. 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.

Although the Court has rejected an absolute requirement of notice-and-comment rulemaking to justify giving some weight to an agency position on preemption, the consistency and thoroughness of the preemption position is critical for it to be persuasive. The FDA’s historic position in favor of the concurrent operation of traditional state tort claims is a significant barrier to the recognition of its current preemption position as consistent with federal objectives. The Court has been cautious about the effect of changed agency position, particularly for litigation purposes, as support for preemption. Conflict preemption requires assessment of actual conflict based on a particular regulatory act, not from a statutory or regulatory preemption provision. An agency’s determination of whether an actual conflict exists is not an ex ante determination based on policy but, rather, is an ex post assessment based on reflection regarding prior circumstances. Only in Geier, in which the Court found implied conflict preemption, was

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431 United States v. Mead Corp., 533 U.S. 218, 228 (2001); see also Witczak, 377 F. Supp. 2d at 730 (explaining that Motus Amicus Brief of United States not given deference because there is reason to suspect that brief’s interpretation does not reflect “fair and considered judgment” of agency on issue).


435 See Ausness, supra note 30, at 767–69.

436 544 U.S. at 449.

437 Geier, 529 U.S. at 885; see supra note 289 and accompanying text.

438 See, e.g., Bates, 544 U.S. at 437 n.7; Buckman, 531 U.S. at 354 n.2 (Stevens, J., concurring).
agency position persuasive, and that was based on the Secretary of Transportation’s unwavering position on the importance of the federal objectives at issue, and not on a position about preemption per se. In the railroad safety regulation cases, 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. Although agency position is given some persuasive treatment, in the case of implied conflict preemption of traditional state tort actions, consistency of position regarding the federal objectives at issue is more important than recency of preemption position in assessing actual conflict.

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

In assessing whether an actual, direct, and clear conflict exists to support implied preemption, the proponent of preemption must establish that conflict with particularized evidence of federal objectives, as explained in Hillsborough County. The best argument for preemption in the prescription drug labeling context will be based on the FDA’s specific consideration, and subsequent rejection of particular labeling proposed by a manufacturer that the FDA finds to be unsubstantiated based on the available data. The Court is unlikely to be persuaded by the speculation and hyperbole that the regulatory sky is falling if a labeling change proposed by tort claimants is permitted, however, and in this context the long-standing characterization of FDA labeling approval decisions as minimum standards will weigh in favor of finding no conflict.

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, regulators, and physicians disfavor preemption. In Bates, which involved pesticide labeling, the Court refused to give broad scope to the preemption provision at issue because doing so would stifle an otherwise dynamic need to continually evaluate risks about which warnings should be provided. Inertia is a powerful force: if preemption is available based on a particular labeling approval, what manufacturer would expend effort and resources to identify the need for any further labeling change? The onus would

439 See supra notes 279–281 and accompanying text.
440 See supra note 235 and accompanying text.
441 See supra notes 205–208 and accompanying text.
442 See 544 U.S. at 451; supra notes 336–337 and accompanying text.
be on the FDA and the public to police the scientific advances regarding each prescription drug approved and then propose and establish the need for labeling changes without the active assistance of the manufacturers, who would have no financial incentive to support a label change. Why would a manufacturer spend any resources on acquiring information about a product’s risks when a label already protects it from liability?

This is, in effect, where the process is now because manufacturers rarely propose labeling changes postmarket and, when they do, it is often too little, too late. To place the postmarket obligation exclusively on the FDA and other public groups would destroy the ability of the FDA to regulate effectively the postmarketing risks stemming from the large number of prescription drugs it oversees. One can only imagine the paralysis that would accompany any labeling approval to which preemption attached under such a scheme.

Indeed, many commentators, and also more recently the Government Accountability Office, have criticized the FDA’s inability to obtain full information from prescription drug manufacturers because the reporting process for postapproval adverse reaction events and clinical trials is too weak. The FDA does not have sufficient 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.

Professor Richard Nagareda has suggested that one of the preconditions for preemption should turn on the provision of information by manufacturers that is the logical predicate for a regime of optimal regulation. This proposal is entirely consistent with the current way tort law operates, sub silentio, under the presumption against preemption in the balance against purported federal objectives. Unless federal objectives can be articulated in a way that ensures, in the labeling context, that manufacturers have a continuing incentive to enhance a product’s safety through acquiring and sharing risk information, actual

443 See supra note 77 and accompanying text.
445 Joe Pickett, Pressure Building for FDA to Mandate Post-Approval Studies After Vioxx Incident, 4 Bioresearch Monitoring Alert, Dec. 1, 2004, at 1 (explaining that 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.”) (citations omitted); Young, supra note 32, at 1.
446 Nagareda, supra note 21, at 40–41.
conflict is not established. Professor Nagareda soundly envisions that preemption doctrine can maximize the flow of information to enhance regulatory decision making and provide manufacturers with protection against the operation of the tort system.\textsuperscript{447}

Professor Richard Epstein asserts, to the contrary, that information about potential risks is available from a wide variety of other sources, so preemption of tort claims will not prevent the availability of adverse risk information.\textsuperscript{448} Professor Epstein proposes a broad sweep for preemption of tort claims under an expanded notion of field preemption, out of a greater concern for enhancing product innovation by streamlining the regulatory processes in general.\textsuperscript{449} The proposal that the entire drug regulatory process needs improvement produces no disagreement and is not inconsistent with permitting tort claims as an oversight mechanism regarding currently approved products and knowledge of their true risks. Such actions ask for assessment of the very information that Professor Epstein suggests is otherwise widely available and that the FDA also seeks: information about risk that may change the very reason the product was approved—to enhance the users’ health safely and effectively.\textsuperscript{450} He acknowledges that the reason for allowing products to stay on the market despite their risks is to permit users the opportunity to self-select.\textsuperscript{451} Self-selection occurs only with full information, in this instance, to the medical care provider. Availability of full information is not possible while the system intended to encourage that full disclosure provides no effective mechanism to ensure its availability.

One example will illustrate the weakness of the FDA regulatory system that should 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.\textsuperscript{452} 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 cardio-

\textsuperscript{447} See id. at 41.

\textsuperscript{448} Epstein, supra note 21, at 30.

\textsuperscript{449} Id. at 26, 30–31.

\textsuperscript{450} See id. at 30.

\textsuperscript{451} See id. at 32.

vascular risks. Merck voluntarily recalled Vioxx from the market in September 2004, because results of another clinical trial vindicated the first and indicated a doubled risk of cardiac events in those who used Vioxx. After Merck withdrew Vioxx from the market Congress held hearings on the FDA’s alleged regulatory failure to require stronger warnings sooner. The FDA spokesman that stated the FDA needed more regulatory authority to require warning labels after safety concerns surface postapproval. The Vioxx warning label change was delayed for one year while the FDA and Merck negotiated over it.

Although 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 statutory scheme imposes on manufacturers a greater obligation to protect the public safety. Tolerating or ignoring a failure to fulfill that obligation is inconsistent with the statutory mandate. The FDA may tolerate, even encourage, the practice of permitting manufacturers to not change labeling until approval is obtained, but permitting common law tort actions to operate concurrently does not conflict with either the statutory or regulatory mandate that requires more. 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. In this way, state tort claims advance, rather than conflict with, federal objectives.

**Conclusion**

To permit preemption based on an FDA-approved label, even one that specifically rejected proposed language as unsubstantiated, will create a disincentive to manufacturers to act promptly based on acquired evidence of risk. Indeed, it creates a disincentive to seek in the first instance evidence of increased risks or adverse side effects which may be available. Knowledge of adverse side effects and evidence of increased risk come to drug manufacturers in a wide variety of ways.

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453 O’Steen & O’Steen, supra note 452, at 68.
454 Id. at 67–68.
455 See Ensuring Drug Safety, supra note 76.
456 See id.
of ways. The FDA approves labels based on information submitted to it by manufacturers, and it relies on manufacturers to provide the information required under its regulations. 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. The tort litigation system is one such avenue of information that would be closed if preemption operated under these conditions; it is an avenue that needs to operate concurrently with the regulatory system that does not have authority to require the regulated industry to engage in efforts to obtain or report all adverse risk information.

The history of SSRI antidepressant labeling used throughout this Article is instructive. 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. The FDA refused to require such a label until 2004, when it issued a public health advisory to that effect. The FDA asked manufacturers for additional information about studies on other antidepressants 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 nonmanufacturers, it might never have. If preemption had been available, and the common law tort system had not been active to bring some of this information to light, the warning might not yet be provided. Indeed, it is wrong to suggest

458 See Motus Amicus Brief of Public Citizen, supra note 46, at 18–19; see also Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation and the Role of Litigation, 5 Yale J. Health Pol’y, L. & Ethics 587, 591 (2005) (preemption removes opportunity for litigation system to aid in effort to monitor product safety).
460 Id. § 314.80 (post-marketing reporting of adverse drug experiences).
461 See Ensuring Drug Safety, supra note 76.
462 See supra notes 358–377 and accompanying text.
463 See supra note 46 and accompanying text.
that the FDA rejected a stronger warning in the case of SSRIs because the manufacturers never sought it.\footnote{See generally Brief of Appellants, Colacicco v. Apotex, Inc., No. 06-3107 (3d Cir. June 23, 2006).}

The FDA's final argument that its regulations provide optimal, not minimum, standards is inconsistent with the regulatory scheme it administers. The unilateral obligation of manufacturers to alter warnings when substantial risk information comes to them and the FDA's inability to require postmarketing trials to obtain risk information substantially undercut any argument that the labeling regulation was intended to provide a maximum standard of care. 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, frozen for all time with only the regulated industry with an incentive to shed additional light.

Implied conflict preemption based on approved drug labeling would be an expansive application of the Court's conflict preemption doctrine. The FDA's new position on preemption, applied not retroactively but prospectively, might one day be characterized as a consistent agency position on preemption for those prescription drugs that fall within it. That day is in the distant future. As to currently produced and marketed prescription drugs, the FDA's long-standing and traditional position against preemption will continue to control.

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 U.S. patients receive proper medical care only fifty-five percent of the time,\footnote{Proper Health Care Put at 55%, Assoc. Press, Mar. 16, 2006 (on file with the Boston College Law Review), available at http://www.bc.edu/schools/law/lawreviews/bclawreview/Past_Issues.html (reporting on a study in the New England Journal of Medicine).} pharmaceutical companies are in control of the research conducted on their products premarketing and postmarketing,\footnote{PhRMA, Pharmaceutical Industry Profile 2005 at 3 fig.1.2 (2005) (industry funds research at almost twice the level of the National Institutes of Health).} pharmaceutical sales representatives have increasing influence on the drugs that physicians prescribe,\footnote{Carl Elliott, The Drug Pushers, Atlantic Monthly, Apr. 2006, at 82–83 (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).} and the pharmaceutical industry is the largest lobbying group in the United States,\footnote{Id. at 88.} the products liabil-
ity litigation system is a critical component to create incentives for greater access to risk information to ensure 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 over implied preemption.