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Preemption: Will Traditional State Authority Survive?

IS THE "PRESUMPTION AGAINST PREEMPTION" STILL VALID?

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Executive Summary

Dean Davis begins her paper with a short review of the origin of the preemption mechanism in the U.S. Constitution, and an example of the questions it poses for courts in the consumer protection field. She also introduces the ***"presumption against preemption"—****a doctrine derived from basic principles of federalism, which has had varying degrees of influence on the decisions of the U.S. Supreme Court in the past half-century.*

In part II, ***"The Basic Preemption Framework,"*** *Dean Davis reviews the several paths through which preemption can work: the* ***express preemption*** *doctrine, employed by courts when Congress has acted to establish, in advance, the degree to which it expects its enactments to displace state law; and* ***implied preemption****, the more complex doctrine employed when Congress has not made its intentions clear and the court must divine on its own what Congress "would have intended" on the facts before it. Implied preemption is divided into two categories:* ***occupation of the field implied preemption,*** *to address situations in which Congress has already "occupied the field" in which it is legislating, and* ***implied conflict preemption****, in which there is actual conflict between federal and state measures. The implied conflict preemption doctrine is further subdivided into the situations in which it is* ***impossible*** *for a regulated entity to comply with both federal and state law, and situations in which compliance with both bodies of law is not impossible, but in which state law is* ***an obstacle*** *to Congress's intentions.*

Part III, ***"The Presumption Against Preemption: A Brief History,"*** *begins with a discussion of the mid-twentieth century decisions of the U.S. Supreme Court in which the Court defined and employed its "presumption against preemption," stating that it would "start with the assumption*

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that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." In the latter half of the twentieth century, defendants (especially in personal injury litigation) frequently argued that federal regulation preempted state tort law in numerous areas. The Court addressed a variety of express preemption provisions that had been written into federal statutes, executive branch regulations, and even preambles to regulations, that dealt with tobacco products, motor vehicles, medical devices, and pharmaceuticals. The Court examined not only the plain language of these express preemption provisions but also other sources like legislative history and the administrative agencies' past and present positions on whether their regulations should trump state law. Although the Court declined in a number of these cases to hold that state law was preempted, it reached its conclusions without relying significantly on the "presumption against preemption," and several leading commentators feared that the presumption was destined for desuetude.

In part IV, ***"Implied Conflict Preemption post-Geier: Wyeth v. Levine,"*** *Dean Davis focuses on the Supreme Court's most recent (2009) foray into preemption doctrine, in which it held that the Food and Drug Administration's regulations on pharmaceutical labeling did not displace state tort remedies in failure-to-warn cases. In* Levine*, the "presumption against preemption" appears to have been resuscitated, and the Court rejected the pharmaceutical manufacturer's arguments that state remedies were impliedly preempted under both the "impossibility" and "obstacle" analyses.*

Part V, ***"A Synthesis of Preemption Analysis,"*** *provides a valuable "road map" for appellate judges to use in deciding preemption questions, whether based on express preemption or on "impossibility," or "obstacle" arguments. For each of those three categories, Dean Davis provides rules of thumb for the judge's analysis and examples of the preemption arguments in action in recent reported court decisions.*

Dean Davis concludes her paper with two final bits of advice for judges dealing with preemption questions: that they keep foremost in mind the matter of congressional intent—the "touchstone" of preemption, which all preemption proponents must establish; and treat seriously the presumption against preemption—"a fundamental backdrop to all preemption analysis."

I. INTRODUCTION

The Supremacy Clause of the United States Constitution declares that federal law is supreme.[1] Preemption doctrine is the complex set of principles that defines the contours of that simple declaration. When Congress has legislated pursuant to one of its enumerated powers,

[1] U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land, and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

there inevitably will be doubt about the extent to which federal law has displaced existing state law that would otherwise govern. Preemption doctrine, therefore, is central to how the spheres of control of our federal and state governments are defined.

The facts of a preemption problem are familiar. An example will help illustrate. Assume Congress has legislated to impose its solution to a perceived problem, for example, consumer product safety. Congress has created an administrative body to implement its solution, in our example, the Consumer Product Safety Commission.[2] Congress charges that agency with promulgating consumer product safety standards to reduce documented unreasonable risks in products. Until Congress entered the field, however, state law, either by direct regulation or common law liability doctrines, had operated to enforce state solutions to the problem of eliminating unreasonable product hazards and compensating consumers for injuries that resulted from those hazards. Under the Supremacy Clause, once Congress has entered the field, is all state law displaced, even law that complements the federal regulatory scheme? May longstanding state tort law doctrines that compensate injured consumers continue to operate once Congress has permitted a federal agency to decide what standards are required to enhance product safety? Where there is overlap, what state law survives and what state law must yield?

To solve such a preemption problem, the Supreme Court has defined a very general framework, albeit one that has been regularly tweaked over the past two decades. This article will identify that framework, explain the variables that exist in its operation, and provide some guidance about how to maneuver around the typical roadblocks to resolving a preemption problem.

One important component of solving a preemption problem is the role of the much-discussed "presumption against preemption." This "presumption" is often stated as follows: "In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"[3] Most commentators favor such a presumption as consistent with federalist notions of limited federal government.[4] The Supreme Court has mentioned such a

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[2] The Consumer Product Safety Act, which is the basis for this example, can be found at 15 U.S.C. §§ 2051-2082 (2009). The CPSA was originally enacted in 1974 and was substantially amended in 2008.

[3] Wyeth v. Levine, 129 S. Ct. 1187, 1195 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996), which quoted Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). This "presumption" has been part of preemption jurisprudence for almost 100 years. *See, e.g.,* N.Y. Cent. R.R. v. Winfield, 244 U.S. 147, 156 (1917). Much has been written on the presumption against preemption including Sandra Zellmer, *Preemption by Stealth*, 45 HOUS. L. REV. 1659, 1666-1673 (2009); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 454 (2008); Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967 (2002); Susan Raeker-Jordan, *The Pre-emption Presumption that Never Was: Pre-emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1380 (1998).

[4] *Compare* Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA,* 48 B.C. L. REV. 1089, 1141-44 (2007); Raeker-Jordan, *supra* note 3, at 1428-29; *and* Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 290 (2000) *with* Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L. J. 2085 (2000) (criticizing the presumption against preemption).

presumption often in the one hundred plus years it has been deciding preemption issues but has treated its value in resolving preemption problems inconsistently. Most recently the Court, in *Wyeth v. Levine*,[5] reaffirmed the existence of the presumption against preemption in a case asking whether a common law failure-to-warn claim involving a prescription pharmaceutical was preempted by the federal Food and Drug Administration's approval of the product's warning label.[6] In the immediately preceding term, however, the Court decided a preemption problem, involving whether a design defect claim based on a federally approved medical device was preempted, without mentioning the presumption at all.[7] How the presumption operates in preemption analysis, what its limitations are, and whether it is a meaningful restriction on the aggressive use of preemption doctrine to restrict state law claims is the subject of the remainder of this article.

II. THE BASIC PREEMPTION FRAMEWORK

The Supreme Court has long held that federal laws preempt state laws, first and foremost, if that is Congress's clear and manifest intent: "The purpose of Congress is the ultimate touchstone in every pre-emption case."[8] Preemption doctrine begins with this understanding that Congress has the power to define the scope of its legislation. Sometimes Congress defines its intent expressly by including in legislation an express provision that addresses the legislation's preemptive scope. When that is the case, the preemption provision must be analyzed to determine Congress's intent. The tools used to determine congressional intent are varied but include an evaluation of the terms of the statute, its structure, and its purpose as discerned through the legislative history.[9]

When Congress has not expressed its preemptive intent, the Supreme Court has identified two basic categories of implied preemption doctrine which act as a substitute for Congress's express intent to preempt. Implied preemption doctrine essentially is a judicial determination of what Congress *would have intended* on the facts before it. The two categories are: (1) "occupation of the field" implied preemption, where Congress has legislated so comprehensively in a field that it must have intended national uniformity of regulation, and, therefore, its legislation displaces all state regulation;[10] and (2) "implied conflict preemption," where the federal and state regulations are in such *actual* conflict that state law must yield to the federal because *either* (a) federal and state provisions directly conflict so that it is impossible for a

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[5] 129 S. Ct. 1187 (2009).

[6] *Id.* at 1191. *Levine* is discussed in more detail *infra* at Section III.

[7] Riegel v. Medtronic, Inc., 552 U.S. ___, 128 S. Ct. 999 (2008).

[8] Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); *see also* Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963) (stating that "the purpose of Congress is the ultimate touchstone" in preemption analysis).

[9] *See, e.g.,* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992); Altria Group, Inc. v. Good, 129 S. Ct. 538 (2008). For further discussion of determining congressional intent to preempt, see infra Section II.D.

[10] For a discussion of occupation of the field preemption, see DAVID G. OWEN, PRODUCTS LIABILITY LAW §14.4, 942 (2d ed. 2008) and THOMAS O. MCGARITY, THE PREEMPTION WAR 109, 264-65 (2008) ("The Supreme Court has applied field preemption sparingly to state common law claims, and the lower courts have followed suit.").

person to comply with both requirements, *or* (b) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[11]

The Court has rarely found Congress to have occupied a field impliedly and so that category of preemption will not require any further attention in this paper. The most important category of implied conflict preemption is "obstacle," also known as "frustration of purposes," preemption because it is more susceptible of broad application depending on the way federal and state objectives are defined.[12] Defining the scope of congressional intent to preempt in express preemption cases and implementing implied conflict preemption doctrines are the two most difficult features of preemption doctrine. Both often require judges to cut at the joint between competing methods of statutory interpretation and overlapping federal and state objectives. Implied obstacle conflict preemption doctrine has been the most difficult for courts to apply because of the inherent uncertainty in determining Congress's intent to preempt based on an ex post judicial assessment of congressional objectives. The presumption against preemption is an important component of both types of preemption doctrine.

In a prior article, I chronicled 100 years of preemption doctrine history and the application of the presumption against preemption in particular.[13] After reviewing the cases and exploring the twists and turns in the Court's modern preemption cases, it appeared to me that the presumption against preemption was little more than a platitude for the Court to mention before moving with dispatch to find preemption in circumstances in which it traditionally had not.[14] While the Court has recently reaffirmed the presumption against preemption in *Levine*, it is unclear whether my earlier conclusion needs revision. The Court's modern preemption decisions lack the clarity that one would have hoped would be produced by so much opinion writing. Those decisions alternate inconsistently between express and implied preemption analysis.[15] Three cases decided in 2008 and 2009 reiterated some basic tenets of the doctrine, but the preemption landscape continues to be difficult terrain. The recent presidential election has produced a change in the federal government's position on preemption[16] and will certainly have as great an impact on application of the doctrine as any of the Court's recent cases. The following section provides a brief synopsis

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[11] OWEN, *supra* note 10, at § 14.4, 942 (quoting Hines v. Davidowitz, 312 U.S. 52, 61 (1941)).

[12] For a strong criticism of implied obstacle preemption, see Wyeth v. Levine, 129 S. Ct. at 1205 (Thomas, J. concurring) (arguing against any form of obstacle preemption as contrary to federalism principles). *See also* Nelson, *supra* note 4 at 277 (obstacle preemption requires "imaginative reconstruction" of congressional intent).

[13] *See* Davis, *supra* note 3.

[14] *Id.* at 1014-21.

[15] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992); Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996); Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

[16] White House Memorandum on Preemption for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24693 (May 20, 2009), Memorandum for the Heads of Executive Departments and Agencies re: Preemption, May 20, 2009, available at www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/ ("The purpose of this Memorandum is to state the general policy of my Administration that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.").

of the history of the presumption against preemption, describes its modern treatment by the Court, and explains the current state of the presumption.

III. THE PRESUMPTION AGAINST PREEMPTION: A BRIEF HISTORY

A. Foundational Cases Establishing the Presumption Against Preemption

Several cases from the mid-twentieth century set the stage for modern preemption doctrine. In *Rice v. Santa Fe Elevator Corp*.,[17] the Court emphasized the centrality of discerning congressional intent to preempt and defined the presumption against preemption that is quoted today: when Congress has legislated in a field which the States have traditionally occupied, "[w]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[18] *Rice* involved application of the Federal Warehouse Act which, though originally leaving state regulation intact, had been amended to provide the Secretary of Agriculture with "exclusive authority" to license federal warehouses.[19] Plaintiff challenged a variety of Illinois warehousing regulations, most of which did not directly conflict with federal regulations but, rather, were more comprehensive than the federal counterpart.[20]

The Court defined the ways in which Congress's "clear and manifest purpose" might be evidenced. First, the Court noted that, if the federal scheme is pervasive, leaving States no room to supplement it, or the federal legislation involves a field dominated by the federal interest, Congress must have intended to preclude state laws on the same subject, leading to what has been referred to as "field preemption."[21] Finding no dominant federal interest or pervasive federal scheme of regulation, the Court applied a third method of discerning congressional intent: that state policy is inconsistent with federal objectives. To make that assessment, the Court reviewed the statute's terms and its particular history and found that Congress intended to displace state regulation entirely in the field even though many areas had been left unregulated by federal legislation.[22]

Rice relied on statutory interpretation, statutory scope, and legislative history to discern the clear and manifest congressional intent to overcome the presumption against preemption. *Rice* involved implied preemption of a very specific state business regulation—warehouse licensing requirements. In *San Diego Building Trades v. Garmon*,[23] the Court was faced with a different

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[17] 331 U.S. 218 (1947).

[18] *Id.* at 230.

[19] 7 U.S.C. §§ 241-256 (2000) (originally enacted Aug. 11, 1916); *see* Rice, 331 U.S. at 222.

[20] 331 U.S. at 224-29 (including such matters as rates, discrimination, mixing grain, and maintenance of elevators).

[21] *Id*. (citing Hines v. Davidowitz, 312 U.S. 52 (1941) (involving federal immigration laws); N.Y. Cent. R.R. v. Winfield, 244 U.S. 147 (1917) (involving railroad regulations)).

[22] *Id*. at 234-35.

[23] 359 U.S. 236 (1959).

situation: the application of implied preemption doctrine to state common law damages actions and their effect on federal labor laws. In *Garmon*, employers claimed to have been injured by the nonviolent picketing of labor activists. They sued the activists for damages under state tort law, and the activists argued that the National Labor Relations Act preempted the state tort causes of action.[24] The NLRA clearly left room for the states to regulate matters not governed by the federal scheme, so the Court had to determine whether state tort actions survived the federal scheme.[25]

The Court applied an implied obstacle preemption analysis but did not speak directly about a presumption against preemption. In ascertaining congressional intent to impliedly preempt, the *Garmon* Court was sensitive to the nature of the regulatory scheme in place—"new and complicated" and "drawn with broad strokes"— that required the Court to carry out Congress's purposes "by giving application to congressional incompletion."[26] The Court was concerned about the potential conflicts that were posed by "inconsistent standards of substantive law and differing remedial schemes."[27] The Court expressed the opinion, since often repeated, that state common law damages actions have a regulatory effect, albeit indirect, making them a proper subject of preemption analysis: "Such regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[28] The Court concluded that state tort law damages were preempted because "to allow the States to control conduct which is the subject of national regulation would create potential frustration of national purposes."[29] The Court did not discuss the presumption against preemption other than to suggest that the "interests so deeply rooted in local feeling and responsibility" were overcome by a "compelling direction" by Congress that entrusted national labor policy to the NLRB.[30]

After *Garmon,* the potential existed that the Court would broadly apply implied obstacle preemption to common law damages actions. The Court did not return to that subject until twenty-five years later in *Silkwood v. Kerr-McGee Corp*.[31] *Silkwood* involved application of the

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[24] *Id.* at 246.

[25] *Id.* at 240 ("'Congress did not exhaust the full sweep of legislative power over industrial relations given by the Commerce Clause. Congress formulated a code whereby it outlawed some aspects of labor activities and left others free for the operation of economic forces. As to both categories, the areas that have been pre-empted by federal authority and thereby withdrawn from state power are not susceptible of delimitation by fixed metes and bounds. . . . [The Act] 'leaves much to the states, though Congress has refrained from telling us how much.' This penumbral area can be rendered progressively clear only by the course of litigation.'") (quoting Weber v. Anheuser-Busch, Inc., 348 U.S. 468 (1955)).

[26] *Id.*

[27] *Id.* at 244.

[28] *Id.* at 247.

[29] *Id*. at 244.

[30] *Id.* at 242-43.

[31] 464 U.S. 238 (1984).

Atomic Energy Act (AEA) to a tort action for personal injuries and property damage filed by the estate of Karen Silkwood, who had become contaminated with plutonium while working at a nuclear power plant operated by Kerr-McGee Corp.[32] The estate's administrator alleged a variety of irregularities in the operation of the plant that led to Silkwood's contamination. He pled negligence and strict liability claims and sought punitive damages.[33]

The AEA was enacted in 1954 to free the nuclear energy industry from total federal control and to provide for some private involvement in the development of nuclear power.[34] Limited regulatory authority was given to the states, which had never had any authority over nuclear power, but Congress precluded the states from regulating the safety aspects of nuclear material.[35] The preemption provision of the AEA thus defined a limited sphere of state authority carved out of federal authority, unlike the typical circumstance. The Court concluded unanimously that the AEA did not preempt Silkwood's compensatory damages action.[36] The Justices agreed that such an award may have an "indirect" impact on a nuclear facility through its primary purpose to compensate, but because the "Federal Government does not regulate the compensation of victims, and because it is inconceivable that Congress intended to leave victims with no remedy at all,"[37] implied obstacle preemption was not established.

The presumption against preemption was not directly implicated in *Silkwood* because the area of regulation was federal, nuclear energy production and safety, and not one involving the "historic police powers" of the states. Nevertheless, the Court recognized that Congress would not destroy traditional means of legal recourse without at least acknowledging it openly. Furthermore, Congress's silence on the topic suggested that traditional means of legal recourse indeed would remain. The Court rejected the notion that Congress would implicitly permit the destruction of traditional state tort remedies simply by regulating in a field, even one like nuclear power that requires comprehensive safety standard-setting.[38]

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[32] 42 U.S.C. §§ 2011-2297h-13 (2008). Silkwood later died in an accident that the Court said was unrelated. 464 U.S. at 242.

[33] 464 U.S. at 241, 243, 245.

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

[35] 42 U.S.C. § 2021(c)(4); *see* Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 205 (1983).

[36] 464 U.S. at 251; *id*. at 263 (Blackmun, J., dissenting); *id*. at 275-76 (Powell, J., dissenting).

[37] *Id*. Justice Powell, in dissent, even suggested that "there is no element of regulation when compensatory damages are awarded, especially when liability is imposed without fault as authorized by state law." *Id*. at 276 n.3 (Powell, J., dissenting).

[38] *Id.* at 250.

B. The Rise of Express Preemption and the Changing Role of the Presumption Against Preemption

While federal statutes have always been interpreted to determine congressional intent to preempt, they often either do not contain an express preemption provision or, if one exists, its scope is unclear. Consequently, implied preemption doctrines have been used to determine preemptive scope. When federal statutes and their implementing regulations do contain preemption provisions, courts often found such provisions to be ambiguous and applied implied preemption principles anyway. Consequently, express preemption analysis was rarely applied to preempt state common law damages actions.[39]

In the 1980s, however, more and more defendants in products liability actions sought total protection from liability based on the supremacy of federal regulation. Product manufacturers argued that compliance with governmental safety regulations preempted the operation of state tort laws that might set a higher standard of due care than that set by the federal regulations. Compliance with governmental regulations has always been relevant to the exercise of due care and proof of product defect in tort actions, but it has never strictly been its measure.[40] Regulations that contain standards of conduct have historically been considered to state minimum and not maximum standards. The general consensus by the early 1990s was that "[t]he general approach to tort claims against non-federal actors, . . . is to deny any preemptive or shielding effect unless there is some specific indication of a congressional intent to preempt state tort law."[41]

Also during the mid-1980s, the Supreme Court decided a number of products liability matters, reflecting a general bias in favor of limited tort liability.[42] The Court's preemption doctrine and its restrictive approach to products liability collided in *Cipollone v. Liggett Group, Inc.,* which involved interpretation of the preemptive effect of the federal cigarette labeling and advertising laws on cigarette products liability actions.[43] *Cipollone* was an action against three cigarette manufacturers on behalf of Rose Cipollone, who died of lung cancer after smoking the defendants' cigarettes for 40 years. She pled a number of claims centering on the manufacturers' failure to warn her of the risks of smoking.[44] The Third Circuit Court of Appeals concluded that

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[39] OWEN, *supra* note 10, § 14.4, at 945-47.

[40] *Id.* § 14.3, at 929; s*ee also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b) (1998); RESTATEMENT (SECOND) OF TORTS § 288C (1965).

[41] AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, vol. II, at 91–94 (Reporters' Study 1991).

[42] *See* Mary J. Davis, *The Supreme Court and Our Culture of Irresponsibility,* 31 WAKE FOREST L. REV. 1075 (1996) (discussing the Supreme Court's products liability cases in the 1980s, particularly *East River Steamship v. Delaval Corp.,* and *Boyle v. United Technologies*, both of which limited the reach of tort liability in cases involving federal matters).

[43] 505 U.S. 504 (1992) (applying federal Cigarette Labeling Act of 1965, 15 U.S.C. §§ 1331-1341 (2009); Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331-1341 (2009) (as amended).

[44] 505 U.S. at 508-10.

the express preemption provisions in those statutes did not include common law tort claims, but that the claims were impliedly preempted.[45]

The Supreme Court reversed, concluding that when Congress had expressed the preemptive scope of a statute, and that provision provided a "reliable indicium of congressional intent,"[46] the express preemption provision controlled. The Court recognized the presumption against federal preemption of matters historically within the states' police powers and focused on discerning congressional intent.[47] Perhaps *Cipollone*'s focus on the express preemption provisions was not surprising in light of the turmoil in preemption analysis in the 1980s over the role of implied obstacle preemption.[48] Nevertheless, *Cipollone* represented a dramatic shift in emphasis in preemption analysis from implied conflict preemption to express preemption. It also represented a remarkable extension of express preemption doctrine to include common law damages actions.

All the justices in *Cipollone* agreed that the preemption analysis should proceed by an interpretation of the scope of the express preemption provisions. The federal cigarette labeling laws, from 1965 and 1969, contained express preemption provisions. The 1965 Act stated: "No statement relating to smoking and health, . . . shall be required on any cigarette package. . ." The 1969 Act amended the preemption provision to state: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act."[49] Noting that congressional intent is the "ultimate touchstone" of preemption analysis,[50] the Court described its focus on the express preemption provision: "Such reasoning is a variant of the familiar principle of *expressio unius est exclusio alterius:* Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted. . . . Therefore, we need only identify the domain expressly pre-empted by each of those sections."[51]

The *Cipollone* majority found that the 1965 Act did not preempt any state common law damages actions based on the precise words of the express preemption provision of the Act, read together with the presumption against preemption, which "reinforces the appropriateness of a narrow reading" of the provision.[52] The justices disagreed about the 1969 Act, however, which

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[45] 789 F.2d 181, 187 (3d Cir. 1986). State courts had found otherwise. *See* Dewey v. R.J. Reynolds Tobacco Co., 577 A.2d 1239 (1990) (no implied obstacle preemption by cigarette labeling laws).

[46] 505 U.S. at 517.

[47] *Id.* at 516.

[48] *See* Davis, *supra* note 3 at 995-97.

[49] 505 U.S. at 514-15 (quoting preemption provisions).

[50] *Id.* at 516.

[51] *Id.* at 517 (quoting Malone v. White Motor Corp., 435 U.S. 497, 505 (1978); Cal. Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272, 282 (1987)).

[52] *Id.* at 518. In addition, the Court found that the purposes and the regulatory context of the Act also supported a narrow reading. *Id.* at 519.

prohibited "requirements or prohibitions . . . imposed under State law." The plurality opinion, authored by Justice John Paul Stevens (who has become a prominent author of the Court's preemption opinions) used both the text of the provisions and the legislative history to preempt some, but not all, common law damages actions.[53] Justice Stevens read the language of the preemption provision with particularity to conclude that the statute "plainly reaches beyond such [positive] enactments,"[54] because, as stated in *Garmon,* common law damages actions can have a regulatory effect. Justice Harry Blackmun disagreed vehemently with the conclusion that common law damages actions necessarily were precluded under the statute because they constituted some general "requirement or prohibition."[55] *Cipollone* marked an important shift away from the protective treatment of common law damages actions evidenced by *Silkwood.*

The ensuing 17 years have been extraordinarily active ones for the Court in defining express preemption analysis. The Court twice analyzed the express preemption provision of the National Traffic and Motor Vehicle Safety Act (NTMVSA),[56] which provides that states may not maintain "motor vehicle safety standards" which conflict with federal performance standards on the same topic. In the first NTMVSA case, *Freightliner Corp. v. Myrick*, the Court, in a unanimous opinion by Justice Clarence Thomas, concluded that, because there was no federal standard in issue on the topic of anti-lock brakes for eighteen-wheel trucks, there was neither express nor implied obstacle preemption of state design defect claims based on the absence of such brakes.[57] The Court raised a question about the interaction between express and implied preemption analysis,[58] which it would resolve in the second NTMVSA case, *Geier v. American Honda Motor Co.,* discussed shortly.

The Court's next preemption opinion, *Medtronic, Inc. v. Lohr*, also focused on express preemption, this time under the Medical Device Amendments (MDA) to the Food, Drug and

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[53] *Id*. at 521-24 (discussing change in preemption provision from 1965 Act to 1969 Act).

[54] *Id.* at 521 ("The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.").

[55] *Id.* at 536. "More important, the question whether common-law damages actions exert a regulatory effect on manufacturers analogous to that of positive enactment . . . is significantly more complicated than the plurality's brief quotation from *San Diego Building Trades Council v. Garmon*, [citation omitted], would suggest. The effect of tort law on a manufacturer's behavior is necessarily indirect." Justice Blackmun recognized that the Court's earlier cases assessing preemption of common law damages actions "have declined on several recent occasions to find the regulatory effects of state tort law direct or substantial enough to warrant preemption." *Id.* at 537 (Blackmun, J., concurring in part and dissenting in part) (referring to, among others, Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)).

[56] 15 U.S.C. § 1381 *et seq.*

[57] Freightliner Corp. v. Myrick, 514 U.S. 280, 289 (1995).

[58] *Id.* ("The fact that an express definition of the preemptive reach of a statute 'implies'—i.e., supports a reasonable inference—that Congress did not intend to preempt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption. . . . At best, C*ipollone* supports an inference that an express pre-emption clause forecloses implied pre-emption; it does not establish a rule.").

Cosmetic Act (FDCA).[59] The plaintiff alleged common law product defect claims arising out of his use of defendant's pacemaker, which had been approved under the FDA's pre-market "notification" approval regulations, a grandfathering method of approval without the heightened rigor of the more elaborate pre-market approval process.[60] The Court was divided on whether the MDA preempted the plaintiffs' claims but all justices again agreed that the express preemption provision controlled the analysis.[61]

The justices hewed closely to the language of the express preemption provision, which stated that states may not impose "requirement[s] . . . different from or in addition to" any federal requirement related to safety or effectiveness of the device.[62] The pre-market notification process did not require nor approve specific design features.[63] The majority opinion, again authored by Justice Stevens, applied the presumption against preemption and, in doing so, concluded that common law damages actions alleging design defects did not impose "requirements" in this context.[64] Four justices concluded that nothing in the legislation, its history, or its basic purpose suggested that common law damages actions were intended to be requirements.[65] A majority of justices concluded, however, that, while general common law obligations were not a threat to the non-device specific federal requirements in *Lohr*[66] ―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 products―an entirely different case would exist for preemption under the statute and implementing regulations.[67] The specificity of the federal government's "weighing of competing interests" will become a recurring theme.

The Court also addressed the FDA's position on preemption found in a formally adopted regulation that implemented its statutory preemption authority.[68] Federal agency action regarding

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[59] 21 U.S.C. § 360c(a)(1)(A, B, C).

[60] Medtronic, Inc. v. Lohr, 518 U.S. 470, 476-80 (1996).

[61] *Id*. at 484-85; *id.* at 503 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring and dissenting).

[62] 21 U.S.C. § 360k (2000).

[63] 518 U.S. at 476-80.

[64] *Id.* at 493-94. Justice Stevens stated: "[W]e used a 'presumption against the pre-emption of state police power regulations' to support a narrow interpretation of such an express command in *Cipollone*. That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485.

[65] *Id.* at 487.

[66] *Id.* at 501-02.

[67] *Id.* at 501. Justice Breyer's concurring opinion gave the Court its judgment in the case, and he interpreted the word "requirement" to include common law damages actions in some circumstances, but not in this case. *Id.* at 503-04.

[68] 21 C.F.R. § 808.1(d)(2) (2008) (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").

preemption is central to these cases because it may inform preemptive scope. All three *Lohr* opinions explored the importance of the agency's position on determining the scope of preemption.[69] 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.[70] The FDA did not consider common law damages actions to be preempted by its device approval regulations at this time.[71]

These two disputed features in *Lohr*, the manner of analysis of express preemption provisions (does "requirements" include common law damages actions?) and the treatment of administrative agency opinion on preemptive scope (to defer or not?), are central to the modern debate about preemption analysis. They also foreshadow the Court's return to a focus on implied preemption doctrine in *Geier v. American Honda Motor Co*. one year later.

C. Coordinating Express and Implied Preemption and the Impact of Savings Clauses

Only a few years after *Lohr,* the Court would muddy the preemption waters again. In *Geier v. American Honda Motor Corp*.,[72] the Court was asked to analyze the effect of the express preemption provision in the National Traffic and Motor Vehicle Safety Act (NTMVSA) on a lawsuit alleging that a 1987 Honda was defective in design because it did not have a driver's side air bag.[73] The NTMVSA contains a preemption provision, which states that whenever a federal motor vehicle safety standard, or FMVSS (defined elsewhere in the statute as a minimum safety standard)[74] is in effect, states may not establish or continue any "safety standard applicable to the same aspect of performance" that is not identical to the federal standard.[75] The statute also contains a "savings clause," a provision in a federal statute that does just that—it "saves," or preserves, some category of state law from being overtaken by the federal statute. The NTMVSA savings clause states: "Compliance with any Federal motor vehicle safety standard issued under

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[69] 518 U.S. at 495-96 (agency regulations "substantially inform" interpretation of statute); *id.* at 505-06 (Breyer, J. concurring); *id.* at 511-12 (O'Connor, J. dissenting).

[70] *See* CSX Transp. Inc. v. Easterwood, 507 U.S. 658, 670 (1993); Norfolk & S. Ry. v. Shanklin, 529 U.S. 344 (2000) (preemption under Federal Railroad Safety Act, relevance of agency position debated).

[71] 518 U.S. at 492-94. *But see* Riegel v. Medtronic, Inc., 552 U.S. ___ ,128 S. Ct. 999 (2008), discussed *infra* regarding the FDA's change in position on this issue.

[72] 529 U.S. 861 (2000). *Geier* is a five to four opinion; Justice Breyer writing for the majority, joined by Chief Justice William Rehnquist and Justices Sandra Day O'Connor, Scalia, and Kennedy. Justice Stevens, the author of both the *Cipollone* and *Medtronic* plurality opinions, dissented in an opinion in which Justices Souter, Thomas, and Ginsberg joined.

[73] *Id.* at 865. The National Traffic and Motor Vehicle Safety Act of 1966, 80 Stat. 718, 15 U.S.C. § 1381 et. seq. (1988). The statute was recodified in 1994 at 49 U.S.C. §§ 30101-30169.

[74] 15 U.S.C. § 1391(2): safety standard is a "minimum standard for motor vehicle performance, or motor vehicle equipment performance."

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

this subchapter does not exempt any person from any liability under common law."[76] The clause appeared quite clearly to preserve the operation of "liability under common law."

The Department of Transportation had issued Standard 208 in 1984, after a lengthy administrative process, which permitted automobile manufacturers a choice of passive restraints, culminating in the requirement in 1989 that all cars have a driver's side air bag.[77] Ms. Geier's 1987 Honda did not have a driver's side air bag. Justice Stephen Breyer wrote the majority opinion and articulated a three-part preemption analysis when faced with an express preemption provision. First, does the express preemption provision preempt the lawsuit? If not, then, second, "do ordinary pre-emption principles nonetheless apply?" If so, then, third, does the lawsuit "actually conflict" with the federal statute?[78]

The express preemption provision analysis in *Geier* is quite different from that in both *Cipollone* and *Lohr,* which involved close attention to statutory text. The Court concluded that the express preemption provision did not preempt plaintiff's action but did not discuss the terms of the provision with the particularity it had previously. Nor did the Court assess what the term "standard," as opposed to "requirement," might mean. Instead, the Court concluded, with little fanfare, that the "savings clause" made that exercise unnecessary. The Court said that the savings clause assumed "that there are some significant numbers of common-law liability cases to save."[79] The Court thus concluded that the presence of the savings clause required a narrow reading of the express preemption provision, excluding common law damages actions from its operation, to give actual meaning to the savings clause.[80]

The *Geier* majority opinion never mentioned the presumption against preemption. Indeed, the Court suggested that a broad reading of the preemption provision might be appropriate in some circumstances, but that "[w]e have found no convincing indication that Congress wanted to preempt not only state statutes and regulations, but also common-law tort actions."[81] The Court used the existence of the savings clause to defeat preemption but did not interpret the statute, evaluate its purposes, or consider its legislative history. The Court certainly did not follow the ordinary meaning of the savings clause—to preserve common law liability principles.

After finding no express preemption, the Court concluded that the express preemption provision coupled with the savings clause reflected a neutral congressional policy toward the

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[76] *Id.* § 1397(k).

[77] 49 C.F.R. § 571.208; 49 Fed. Reg. 28999 (1984) (referred to as Standard 208). For a discussion of the tortured administrative history, see 529 U.S. at 875-77; *id*. at 889-92 (Stevens, J., dissenting). *See also* Ralph Nader & Joseph A. Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 GEO. WASH. L. REV. 415 (1996).

[78] 529 U.S. at 864.

[79] *Id.*

[80] *Id.* at 868.

[81] *Id.*

operation of implied preemption doctrine when an actual conflict may exist. The Court, thus, answered its second question in the affirmative: 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."[82] The Court was persuaded to apply implied conflict preemption principles out of concern for the "careful regulatory scheme" established by NTMVSA, despite the arguably plain meaning of the savings clause. The Court did not want to be confined to the traditional categories of implied preemption (obstacle and impossibility), and instead stated that "it has assumed that Congress would not want either kind of conflict."[83] The Court, thus, did not distinguish among types of federal-state conflict. The Court had been badly splintered on how to interpret express preemption provisions so it is not entirely surprising that the Court would revert to application of implied conflict preemption principles to resolve ambiguity over congressional intent to preempt.

In answering the final question, whether an actual conflict existed, the Court clearly perceived that common law tort actions might be detrimental to thoughtfully established federal goals.[84] Because *Geier* represents an important modern application of implied conflict preemption, the following subsections describe that analysis in some detail.

1. Assessing Federal Objectives

To determine whether an actual conflict exists, the federal law and its objectives must be identified. In *Geier*, that law was found in FMVSS 208. The Court discussed at some length the federal objectives behind the regulation.[85] The Court relied extensively on the administrative history of the regulation as well as contemporaneous comments about the regulation's purposes by the Department of Transportation (DOT).[86] The Court was influenced by comments to the original standard and the then-Secretary's position, described in an amicus brief in the case, that the standard "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."[87] The Court noted DOT's effort to balance a variety of concerns and, therefore, concluded that the standard was neither a minimum nor a maximum standard,[88] but one representing a unique balance of considerations.

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[82] *Id.* at 872.

[83] *Id.* at 874. There is no reason to think that field preemption was affected by this discussion.

[84] *Id.* at 881. A similar concern was raised in *Lohr. See supra* text accompanying note 66.

[85] I*d.* at 874-80.

[86] *Id.* at 875-77.

[87] *Id.* at 876.

[88] *Id.*

2. Relevance of the Presumption Against Preemption

The Court did not mention the presumption against preemption.[89] The Court weighed the perceived federal objectives against the general interest the states have in promoting health and welfare and compensating citizens for injuries suffered by defective products.[90] It was somewhat sympathetic to state concerns of compensating victims and enhancing product safety, but concluded that jury-assessed standards would lead to unpredictability and uncertainty in the standard of care.[91] The Court did not describe the burden necessary to establish implied conflict preemption but rejected any "special burden" on the proponent of preemption.[92]

3. Relevance of Agency Position on Preemption

Finally, the Court discussed the role of the federal agency's position on the federal objectives behind the standard and its conclusion that tort suits would stand as an obstacle to those objectives.[93] The Court gave "some weight" to the agency's interpretation because of the technical nature of the subject matter, the complexity of the statutory scheme, and the agency's expertise and "unique" qualification to comprehend the likely impact of state requirements on that scheme.[94] In addition, the Court was influenced by the Secretary's consistent position on preemption.[95] The Court recognized that it should not readily find conflict preemption in the absence of clear evidence of a conflict, but that to require a formal agency statement on preemption was too restrictive.[96]

As mentioned earlier, a federal agency's position on preemption has become increasingly important as a tool for litigants seeking to establish intent to preempt. *Lohr* involved a specific agency rule promulgated to define the scope of the MDA preemption provision prior to litigation and the Court was "substantially informed" by it.[97] The agency's position in *Geier* was found in the history of the regulation and the current Secretary's position in the litigation, which displayed

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[89] *Id.* at 894 (Stevens, J. dissenting).

[90] *Id.* at 882-83.

[91] *Id.* at 871.

[92] *Id.* at 874. The idea of a "special burden" stemmed from Justice Stevens's dissenting opinion in which he criticized the Court's overly broad implied obstacle preemption analysis. *Id.* at 898-99 (Stevens, J., dissenting).

[93] *Id.* at 880. Many scholars have discussed the importance of agency position in preemption analysis. *See generally* Nina Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737 (2004); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007).

[94] 529 U.S. at 881.

[95] *Id.* at 883.

[96] *Id.* at 884-85.

[97] *Lohr,* 518 U.S. at 495-96. Justice Breyer agreed, writing that "the relevant administrative agency possesse[d] a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect." *Id.* at 505-06 (Breyer, J., concurring).

some consistency over time with predecessor opinions.[98] It is clear after *Geier* that agency statements articulating federal objectives and assessing whether those objectives might be thwarted by state tort claims will be very influential in the Court's assessment of implied conflict preemption.

D. Post-*Geier* Express Preemption Analysis: An Emerging Stasis?

In the eight years between *Cipollone* and *Geier,* the Court emphasized express preemption in a wholly new way, resisted discussing the presumption against preemption, and struggled with how to balance the historic role of state tort law with federal regulatory action. After *Geier,* it was unclear what role express preemption analysis would continue to play. Subsequent cases emphasized the search for congressional intent and returned gradually to the presumption against preemption.

1. *Sprietsma*

In *Sprietsma v. Mercury Marine*,[99] the Court followed *Geier* and interpreted an express preemption provision with a savings clause *not* to expressly preempt a products liability claim under the Federal Boat Safety Act.[100] *Sprietsma* involved a Coast Guard assessment of the need for propeller guards on recreational vessels that did not result in any regulation. The Court was faced with whether that failure to regulate preempted common law claims based on a failure to equip with propeller guards, and it found neither express nor implied conflict preemption.[101] The Court was influenced by the Coast Guard regulations, which preserved state authority in the absence of federal action, and the Coast Guard's consistent conclusions that its regulations did not have preemptive effect, though it had no formal rule on the subject.[102] *Sprietsma* was a unanimous opinion.

2. *Bates*

In *Bates v. Dow Agrosciences L.L.C.,*[103] the Court was presented with an express preemption provision, this time from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[104] The Court, speaking through Justice Stevens, described openly the delicate balance that must be achieved in determining the scope of express preemption provisions, and about the effect of shifting agency position on preemption analysis. First, the Court reiterated its adherence to the

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[98] 529 U.S. at 883.

[99] 537 U.S. 51 (2002).

[100] *Id.* at 59-60 (applying 46 U.S.C. §§ 4301-4311 (2000)).

[101] *Id.* at 64-66.

[102] *Id.*

[103] 544 U.S. 431 (2005).

[104] 7 U.S.C. § 136 (2006).

presumption against preemption because tort litigation "provid[es] an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items."[105]

The *Bates* Court employed the narrow express preemption analysis it described in *Cipollone*, specifically rejecting the conclusion that common law jury verdicts are the equivalent of "requirements" simply because they may influence decision-making.[106] 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.[107] The Court concluded that the express preemption provision preempted very few claims.[108] The Court also expressed a sense of frustration at the way the lower courts had broadly read the term "requirements" after *Cipollone* and chastised the "too quick conclusion"[109] that tort claims were also, therefore, preempted under FIFRA.

Bates also addressed the importance of agency position on express preemption. The regulating agency, the Environmental Protection Agency, had shifted its position against preemption to being in favor of it within the previous five years.[110] The Court was not influenced by that shift in position, stating 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."[111] The Court endorsed the parallel operation of common law tort claims, stating they "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, . . . [T]ort suits can serve as a catalyst in this process."[112] The concern expressed by the defendant and the EPA that "tort suits led to a 'crazy-quilt' of FIFRA standards or otherwise created a real hardship for manufacturers" fell on deaf ears, as the Court observed that "for much of this period EPA appears to have welcomed these tort suits."[113] There was remarkable agreement in *Bates*: Justice Breyer concurred and Justices Thomas and Scalia

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[105] 544 U.S. at 449; *see also id.* at 459 (Thomas, J., concurring in part and dissenting in part) ("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.") (citations omitted).

[106] *Id.* at 445.

[107] *Id.*

[108] *Id.* at 451-52.

[109] *Id.* at 446.

[110] *Id.* at 436-37 & n.7, 449.

[111] *Id.*

[112] *Id.* at 451.

[113] *Id.* at 451-52.

concurred in the judgment but dissented over the failure of the majority to focus on the ordinary meaning of the preemption provision.[114]

3. *Riegel*

Riegel v. Medtronic, Inc.[115] also represents remarkable agreement among the Court but in ways contrary to that in *Bates*. The Court in *Riegel* was asked to address for the third time express preemption under the Medical Device Amendments, this time regarding claims involving devices approved under the pre-market approval process.[116] The Court, in an opinion by Justice Scalia, held that the MDA expressly preempts such claims.[117] The Court was quite critical of the role of common law tort claims and expansive in its description of the scope of express preemption, unlike in *Bates*. The Court's express preemption analysis did not emphasize congressional intent to preempt; instead, it reaffirmed its own understanding of the term "requirements."[118] The Court declared that "requirements" includes common law tort claims, stating: "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties."[119] To say that this is contrary to *Bates* is an understatement.

While thus defining the term "requirements" for future Congresses, the Court displayed its distrust over the operation of common law tort actions. According to the *Riegel* Court, tort law as applied by juries is "less deserving of preservation" than other state regulations because juries are incapable of balancing costs and benefits adequately as they "see[] only the costs of a more dangerous design, and [are] not concerned with [the] benefits" consumers reap by the manufacturer's design choices.[120] It is "implausible," according to the Court, that Congress would create the "perverse distinction" that grants greater power to a single state jury than to state officials.[121] There is certainly little, if anything, left of the historic place that state tort law held in regulating public safety in these remarks, and certainly little in common with Justice Stevens's remarks on that score in *Bates*. There is no mention of the "presumption against preemption."

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[114] *Id.* at 454 (Breyer, J. concurring); *id.* at 455 (Thomas, J. & Scalia, J., concurring in judgment and dissenting in part).

[115] 128 S. Ct. 999 (2008).

[116] *Id.* The second time was in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), involving a so-called fraud-on-the-agency theory that the Court found was not expressly preempted by the MDA's express preemption provision but was impliedly preempted because policing fraud on an agency is a uniquely federal matter.

[117] 128 S. Ct. at 1007.

[118] *Id.* at 1007-08.

[119] *Id.* at 1008. For a more thorough discussion regarding Congress's intent, see *id.* at 1013 (Ginsburg, J., dissenting). Justice Stevens, the author of *Cipollone*, *Lohr*, *Sprietsma*, and *Bates*, concurred on the scope of "requirements" because it considered it consistent with the result in *Lohr*. *Id.* at 1011-13 (Stevens, J., concurring in part and dissenting in part).

[120] *Id.* at 1008.

[121] *Id.*

The *Riegel* Court also discusses, at some length, the effect of the FDA's changing position on preemption, even though it acknowledged that the position was not relevant to the case because the statutory language was clear.[122] The FDA had recently changed its position on the scope of the MDA preemption provision as it applied to the pre-market approval process.[123] While largely dicta, the Court's statements displayed some sympathy for the proposition that *recent* agency position may be relevant to an assessment of current preemptive scope, despite longstanding agency position to the contrary.[124] These statements are quite different from those made by the Court on this issue in *Geier* and *Bates.*

Some observers have described *Riegel* as a fairly narrow application of the MDA express preemption provision and a logical extension of *Medtronic, Inc. v. Lohr,*[125] but the lack of respect for the traditional longstanding role of state tort law is disturbing. The discussion of agency position on preemption is inconsistent with prior cases and, therefore, curious. The issue is addressed at length in *Levine,* to be discussed shortly, and the new presidential administration has taken a strong anti-preemption position on the matter. The discussion in *Riegel* may now, therefore, be moot.

4. *Altria Group*

The final express preemption case meriting discussion is *Altria Group, Inc. v. Good,*[126] decided after *Riegel*, which involved the continuing validity of *Cipollone* as defining the claims that survived express preemption under the cigarette labeling laws, after the ensuing sixteen years of preemption doctrine.[127] After *Riegel* and its eight-to-one opinion in favor (in dicta, at least) of a more expansive reading of express preemption provisions and the meaning of "requirement," one would have expected that Justice Stevens's plurality opinion in *Cipollone* had been outgrown. But in a stunning turn of events, Justice Stevens, joined by Justices Breyer, Ruth Bader Ginsburg, Anthony Kennedy, and David Souter, held that the plurality opinion of *Cipollone* does, indeed, control the express preemption analysis of that statute.[128] The majority rejected the broader scope of preemption analysis proposed by Justice Scalia in *Cipollone*, and advocated in *Altria Group* by Justice Thomas for the dissent,[129] stating, "Justice Scalia's

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[122] *Id.* at 1009.

[123] *Id.*

[124] *Id.* ("But of course, the agency's earlier position . . . is even more compromised, indeed deprived of all claim to deference, by the fact that it is no longer the agency's position.").

[125] *See* Catherine M. Sharkey, *What* Riegel *Portends for FDA Preemption of State Law Products Liability Claims,* 102 NW. U.L. REV. COLLOQUY 415 nn.3-4 (2008).

[126] 129 S. Ct. 538 (2008).

[127] *Id.* at 541-42.

[128] *Id.* at 549 ("In sum, we conclude now, as the plurality did in *Cipollone*, that 'the phrase "based on smoking and health" fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements.'") (quoting Cipollone v. Liggett Group, 505 U.S. 504, 529 (1992)).

approach was rejected by seven Members of the Court, and in the almost 17 years since *Cipollone* was decided Congress has done nothing to indicate its approval of that approach."[130] Justice Stevens's opinion endorsed the presumption against preemption and a fair but narrow reading of the scope of express preemption.[131]

Sprietsma, Bates, Riegel, and *Altria Group*, as the most recent express preemption opinions, give contrary signals about the role of the presumption against preemption and determining congressional intent to preempt. It appears that, for the time being, the approach to express preemption fashioned by Justice Stevens in *Cipollone* carries the day. A question remains about the continuing validity of the definition of the term "requirements," used in *Riegel*, and the value to be given to common law damages actions in express preemption analysis.

IV. IMPLIED CONFLICT PREEMPTION POST-*GEIER*: *WYETH V. LEVINE*

In March 2009, the Court decided *Wyeth v. Levine,*[132] the much-anticipated implied preemption case involving whether common law tort claims challenging the adequacy of federally approved pharmaceutical labeling are preempted under the federal Food, Drug, and Cosmetic Act. The FDCA does not have an express preemption provision relating to pharmaceutical approvals so the case required an application of implied preemption. The Court had not decided a pure implied preemption case (one not involving any express preemption provision) in recent history. In addition, the FDA, which had for years been in favor of the concurrent operation of state common law damages actions, had changed its position on preemption, first in a series of amicus briefs in cases beginning in 2004 and then in a 2006 preamble to new pharmaceutical labeling regulations.[133] The lower courts had struggled with implied preemption doctrine in these cases and whether to consider the FDA's changed position in the analysis.[134]

Levine involved the anti-nausea drug Phenergan, which had been approved in 1955.[135] Ms. Levine was injected with the drug to alleviate symptoms from a migraine headache. Through inadvertent injection into an artery, gangrene, a known side effect, resulted and much of her right

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[129] *Id.* at 545 n.7; *see id.* at 552-54 (Thomas, J., dissenting).

[130] *Id.* at 545 n.7.

[131] *See id*. at 543.

[132] 129 S. Ct. 1187 (2009).

[133] *See* Davis, *supra* note 4, at 1090 (chronicling the history of the change in FDA preemption policy). The preamble is found in Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 18, 2006). *See also* Sharkey, *supra* note 93.

[134] *See, e.g.,* Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), *vacated in light of Levine*, No. 08-437, 2009 WL 578682 (Mar. 9, 2009); Tucker v. SmithKline Beecham, 596 F. Supp. 2d 1225 (S.D. Ind. 2008); Knipe v. SmithKline Beecham, 583 F. Supp. 2d 553 (E.D. Pa. 2008).

[135] 129 S. Ct. at 1191.

arm eventually had to be amputated.[136] Wyeth knew about the risk of intra-arterial injection, had warned about it in a section of the labeling, and that labeling had been approved over the years by the FDA.[137] Ms. Levine claimed that the labeling inadequately warned of the risk of gangrene, and the jury agreed.[138] The Vermont Supreme Court affirmed a lower court ruling that Ms. Levine's claims were not impliedly preempted by the FDA's labeling approvals.[139]

Wyeth made two separate implied conflict preemption arguments: first, that it would have been impossible for it to comply with the state law duty to warn without violating federal law; and, second, that recognition of the plaintiff's claims would act as an obstacle to the accomplishment of federal objectives because it substitutes a lay jury's decision for the expert judgment of the FDA.[140] The Court, speaking through Justice Stevens with a six-to-three majority, found that the FDA's product labeling approvals did not impliedly preempt Levine's tort claims under either argument.[141]

A. Reaffirming the Presumption Against Preemption

The Court began by reaffirming the "two cornerstones of our pre-emption jurisprudence:" first, that the purpose of Congress is the "ultimate touchstone in every pre-emption case," and, second, "in all pre-emption cases," but particularly those involving fields which the States have traditionally occupied, the analysis begins with the presumption against preemption.[142] The Court rejected Wyeth's argument that the presumption should not apply in implied preemption cases, stating, "The Court has long held to the contrary."[143]

The Court also responded to Wyeth's argument that, because the federal government had long regulated drugs, the presumption should not operate. The Court rejected this argument, stating that it "misunderstands" the presumption which "accounts for the historic presence of state law but does not rely on the absence of federal regulation."[144]

B. Impossibility Conflict Preemption Analysis

The *Wyeth* Court's discussion of impossibility conflict preemption is one of the most thorough it has ever written. Wyeth argued that it would be subject to misbranding liability under

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[136] *Id.* at 1191-92.

[137] *Id.* at 1192.

[138] *Id*. at 1193.

[139] Levine v. Wyeth, 944 A.2d 179 (Vt. 2007).

[140] 129 S. Ct. at 1193-94.

[141] *Id.* at 1191.

[142] *Id.* at 1194-95

[143] *Id.* at 1195 n.3.

[144] *Id.*

FDA regulations if it altered its label, as plaintiff claimed it should have, because the FDA must approve all labeling. The Court disagreed after a thorough exploration of the labeling approval regulations, which permit pharmaceutical manufacturers to alter their warning labels, after initial product approval, to add or strengthen a warning.[145] The Court emphasized that, "through many amendments to the FDCA and to FDA regulation, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[146]

1. "A Demanding Defense"

Implied conflict preemption based on the impossibility of complying with both federal and state law has only rarely been applied, and the Court rejected it in this instance, too.[147] The Court noted that impossibility preemption is "a demanding defense"[148] and that it would require "clear evidence" of impossibility to succeed.[149]

2. Clear Evidence Required

The Court found no "clear evidence" after an intense assessment of the federal regulatory scheme and a searching review of the record. The Court described the type of evidence that might suffice: "[Wyeth] does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA."[150] There was no evidence that the FDA gave more than "passing attention" to the issue, and there was certainly no affirmative decision to prohibit Wyeth from strengthening its warning.[151] Only proof of an affirmative federal prohibition to do what a jury verdict would require would approach satisfying impossibility conflict preemption.

C. Implied Obstacle Preemption Analysis

Of greater importance, however, is the Court's discussion of implied obstacle conflict preemption principles. It will be helpful to break down the Court's response to Wyeth's arguments of obstacle conflict preemption. Implied obstacle preemption, according to the Court, requires two things: (1) an identification of the congressional purposes or objectives that support the federal law, and (2) an assessment of whether Congress considered state law claims to pose an obstacle to the accomplishment of those objectives.

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[145] *Id.* at 1197.

[146] *Id.* at 1197-98.

[147] *Id.* at 1198-99.

[148] *Id.* at 1199.

[149] *Id.* at 1198 ("But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirement.").

[150] *Id.*

[151] *Id.* at 1198-99.

1. Establishing Federal Purposes

Borrowing from the successful obstacle conflict preemption analysis in *Geier,* Wyeth argued that Levine's tort claims were preempted because "they interfere with 'Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.'"[152] The Court rejected these arguments because they relied on an "untenable interpretation" of congressional intent and "an overbroad view" of an agency's power to preempt state law.[153]

Wyeth contended that once the FDA approves a drug's label, that decision reflects both a floor and a ceiling for regulation and state law may not hold that decision inadequate.[154] The Court summarily rejected this assessment of federal objectives because it was contrary to all evidence of Congress's purposes.[155] The Court explored the history of federal regulation of pharmaceutical approvals and was influenced by Congress's failure to expressly preempt, stating that, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history."[156] The Court found congressional silence, in the face of "awareness" of concurrent state tort litigation, to be "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."[157]

2. Agency Position on Preemption

Wyeth argued that the FDA's position in favor of preemption by its labeling decisions, as set forth in the preamble to its 2006 labeling regulation, was powerful evidence that the agency had precisely balanced the risks and benefits of the labeling and, thus, state tort jury verdicts must not interfere with that balance.[158] The Court acknowledged that an agency regulation "with the force of law" can preempt conflicting state requirements, but that the Court performs its own conflict determination when deciding such cases, as it had in *Geier.*[159]

The Court rejected reliance on the FDA's "mere assertion" that state law poses an obstacle. Instead, it confirmed that "the weight we accord the agency's explanation of state law's impact

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[152] *Id.* at 1199.

[153] *Id.*

[154] *Id.*

[155] *Id.*

[156] *Id.* at 1200. Congress had not expressly preempted state tort law claims as it had in other contexts, such as in the Medical Device Amendments. *Id.*

[157] *Id.* Further, "[Congress] may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.*

[158] *Id.*

[159] *Id.* at 1200-01.

on the federal scheme depends on its thoroughness, consistency, and persuasiveness."[160] The FDA's position did not deserve deference in this instance because (1) the FDA issued its position on preemption after having earlier stated that it would not "have federalism implications;" (2) the agency finalized the rule without giving States an opportunity to comment; and (3) the position was at odds with the available evidence of Congress's purposes and the agency's own longstanding position in favor of the operation of state tort law.[161] The Court explored the many ways that tort law acts as a complement to federal drug regulation.[162]

The Court distinguished *Geier*, upon which Wyeth had relied. First, *Geier* involved formal agency rule-making that embodied the government's policies, not an individualized product approval as in *Levine*. Second, in *Geier,* the Court assessed the preemptive effect of the rule independently, *informed* by the agency's explanation, not *driven* by it.[163] The Court in *Levine* found the FDA's "newfound opinion" to be inconsistent with the "longstanding coexistence of state and federal law and the FDA's traditional recognition of state law remedies"[164] and thus unpersuasive on assessing a current conflict with federal objectives.

The Court recognized that the FDA's drug regulations could potentially impliedly preempt state tort law claims, but this was not such a case.[165] Justice Breyer, in concurrence, reminded readers that "lawful specific regulations" that establish a ceiling and a floor might have preemptive effect.[166] Justice Thomas strongly criticized obstacle conflict preemption, calling for its abandonment as inconsistent with constitutional federalism principles and likely to result in overreaching.[167]

Levine represents a narrower implied obstacle conflict preemption analysis after *Geier*. The Court seems to have settled into a more balanced approach to the value of state common law tort actions within its implied conflict preemption analysis.

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[160] *Id.* at 1201.

[161] *Id.*

[162] *Id.* at 1202 ("State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.").

[163] *Id*. at 1203.

[164] *Id.*

[165] *Id.* at 1204.

[166] *Id.* (Breyer, J. concurring).

[167] *Id.* at 1205 (Thomas, J. concurring). Justice Samuel Alito dissented in an opinion in which the Chief Justice and Justice Scalia joined.

V. A SYNTHESIS OF PREEMPTION ANALYSIS

The Court has made it clear that the presumption against preemption of historic state police powers continues to operate in cases of both express and implied preemption. Only clear and manifest intent of Congress to the contrary will defeat the presumption. The question remaining is what type of evidence will support that conclusion, particularly in implied conflict preemption cases.

A. Express Preemption and the Search for Congressional Intent

When an express preemption provision provides "clear and manifest" evidence of Congress's intent, it will control. Justice Stevens, in *Cipollone, Lohr, Bates, Altria Group,* and to a lesser extent, in his concurrence in *Riegel,* provides the best statement of the current manner of interpreting express preemption provisions to discern congressional intent: narrowly based on the ordinary meaning of the statute's terms, its structure, purposes, and history, with an understanding that Congress would not defeat the operation of traditional, historic police powers of the states without clearly saying so.

1. Rules of Thumb

Rules of thumb that operate to help establish Congress's intent include:

- "Historic police powers" of the states broadly include those subjects that involve public health and safety and do not "rely on the absence of federal regulation;"

- When the text is susceptible of more than one reading, courts should accept the reading that disfavors preemption;

- A statute's provisions should be assessed with particularity to discern whether the terms used, such as "requirements," "statements," or "standards," legitimately include state common law claims under the history of that statute and not with reference to use of the terms in other statutory schemes;

- The structure of the statute, its purposes and history, and the structure and history of an implementing regulatory scheme are relevant to congressional intent; and

- Any "savings clause" should be applied according to its terms to narrow the scope of express preemption and actually preserve the claims included.

2. An Example: National Childhood Vaccine Injury Act

If the Court's analysis of express preemption provisions teaches anything, it is that statutes are unique and so is the search for congressional intent. Relying on the interpretation of language from one statute runs the risk of proving too much in the interpretation of similar language in

another statute. I hesitate to single out any one statute as an example of express preemption analysis, but cases involving the Childhood Vaccine Injury Act[168] may provide a good example.

In two recent cases, courts have disagreed about how to interpret the following provision in the Act which addresses preemption of state common law tort claims: "Except as provided in subsections (b), (c), and (e). . . . State law shall apply to a civil action brought for damages for a vaccine-related injury or death." Subsection (b) states: "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[169] The Act creates a no-fault compensation system for victims of certain vaccine-related injuries while encouraging vaccine manufacturers to continue vaccine production at reasonable cost.[170]

Plaintiffs in *American Home Products Corp. v. Ferrari,*[171] argued that their son suffered neurological damages caused by vaccines made with a mercury-laden preservative for which a substitute was available and, therefore, the injury was avoidable.[172] The Georgia Supreme Court affirmed a finding of no express preemption of the design defect claim, concluding that a case-by-case basis of determining whether a side effect was unavoidable was required.[173] The *Ferrari* court based its decision on a review of the statute's text, its legislative history, and the presumption against preemption.[174]

The Third Circuit Court of Appeals disagreed in *Bruesewitz v. Wyeth Inc*.[175] The Third Circuit found that the statute preempted all design defect claims and that a case-by-case analysis of such claims would defeat Congress's intent in establishing the compensation scheme and promoting the availability of vaccines.[176] The vaccine manufacturers in *Ferrari* have petitioned for certiorari to the Supreme Court.[177]

The statute's terms appear to carve out some design defect claims that are not preempted. The statute is complex and its structure and history seem to admit of different conclusions

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[168] 42 U.S.C. § 300aa-1 et. seq. (2009).

[169] *Id.* § 300aa-22(b)(1).

[170] *Id; see also* Bruesewitz v. Wyeth, Inc., 561 F.3d 233, 235-36 (3d Cir. 2009) (discussing history and structure of the Act).

[171] 668 S.E.2d 236 (Ga. 2008).

[172] *Id.* at 237-38.

[173] *Id.* at 240.

[174] *Id.* at 238-39.

[175] Bruesewitz, 561 F.3d at 245-46.

[176] *Id.* at 246-47.

[177] 77 U.S.L.W. 3531 (Mar. 5, 2009).

regarding preemptive intent. A narrow reading in light of the presumption against preemption is consistent with the result in *Ferrari*. The case presents a unique federal compensation scheme, however, which clearly displaces the operation of a substantial amount of state common law by its very terms.

The Supreme Court has asked for an opinion from the Solicitor General on the government's position on preemption in *Ferrari*.[178] The White House's recently announced position restricting agencies to preemption positions "with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis" will apply.[179] The express preemption provision of the Act must be assessed for Congress's intent, but governing agencies assist in determining that intent. The recent White House policy endorses narrow preemption principles which call for "strict adherence to governing law" and "clear evidence" of intent to preempt.[180] *Ferrari*, while inconsistent with other cases on the issue, may have the better analysis.

Finally, the Consumer Product Safety Act, mentioned in the introduction to this paper, has an express preemption provision with a savings clause. After *Geier*, cases interpreting the CPSA found no express intent to preempt but held that implied preemption defeated some claims.[181] The operation of savings clauses should be reexamined in light of a refocus on congressional intent and the presumption against preemption which did not figure prominently in *Geier,* an analysis that rightly has been criticized.

B. Implied Conflict Preemption

Implied conflict preemption similarly incorporates the presumption against preemption, though how the presumption operates in such cases is more uncertain than within express preemption analysis. Conflict preemption requires that the proponent of preemption establish an actual conflict between federal and state law, either because of impossibility of compliance with both or frustration by state law of federal objectives. When the Court applies either kind of implied conflict preemption, it rarely discusses how the presumption operates in the establishment of actual conflict. The Court tends to be very situation-specific and fact-driven in determining what constitutes an actual conflict. It discusses the value of the relevant state law in its determination of actual conflict but it does not otherwise describe how the presumption against preemption operates in these cases.

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[178] Am. Home Prods. Corp. v. Ferrari, No. 08-1120 (U.S.L.W. June 8, 2009).

[179] Memorandum on Preemption, *supra* note 16 (citing Executive Order 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999)).

[180] 64 Fed. Reg. 43257 (Aug. 4, 1999).

[181] *See, e.g.,* Moe v. MTD Prods., Inc., 73 F.3d 179 (8th Cir. 1995) (applying 15 U.S.C. § 2075); BIC Pen Corp. v. Carter, 251 S.W.2d 500 (Tex. 2008) (same).

1. Rules of Thumb: Impossibility Conflict Preemption

Analysis of implied impossibility conflict preemption incorporates the following rules of thumb:

- Analysis starts by acknowledging that it is a "demanding" defense and, thus, unlikely to be established without substantial evidence of actual impossibility;

- Because the Court has so rarely seen a case of impossibility, only a circumstance where federal law affirmatively prohibits what state law affirmatively requires should suffice;

- A common law tort judgment requiring a defendant to pay damages is typically not an affirmative state law obligation that would make it impossible to comply with a contrary federal obligation; and

- Agency position on conflict preemption must be based on consistent, thorough, and persuasive assessment of congressional intent and should be rigorously challenged in light of the presumption against preemption.

2. An Example: Pharmaceutical Labeling of Antidepressants

Another pharmaceutical labeling case may be a test for impossibility conflict preemption. *Colacicco v. Apotex, Inc.*,[182] involved failure-to-warn claims based on the increased risk of suicidality from taking the antidepressant drug Paxil—a "selective seratonin reuptake inhibitor," or SSRI.[183] Mrs. Colacicco had taken Paxil, and she committed suicide, allegedly as a result. Her estate sued both the manufacturer of the generic drug she had taken and the manufacturer of the brand name drug, GlaxoSmithKline.[184] The FDA, according to the Third Circuit Court of Appeals, had "repeatedly rejected the scientific basis for the warnings that Colacicco and [a companion plaintiff] McNellis argue should have been included in the labeling. The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading."[185] The Court of Appeals thus sustained a finding of

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[182] 521 F.3d 253 (3d Cir. 2008), *vacated and remanded in light of Levine,* 129 S. Ct. 1578 (2009).

[183] *Id.* at 258-60; *see also* Davis, *supra* note 4 at 1095-98 (exploring history of warnings on SSRIs, like Paxil).

[184] 521 F.3d at 256. Cases against generic pharmaceutical manufacturers are pending nationwide and involve claims of implied conflict preemption similar to those involving the brand name manufacturers. *See, e.g.,* Kellogg v. Wyeth, 612 F. Supp. 2d 437 (D. Vt. 2009) (analyzing implied conflict preemption post-*Levine* and concluding: "Thus, although the *Levine* decision did not definitively dispose of the issues in this case, its statement that '[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times,' Levine, 129 S. Ct. at 1202, does not appear to permit the caveat, 'except for generic drug manufacturers.'" *See* Stacel v. Teva Pharms., USA, No. 08 C 1143, 2009 WL 703274 at *6 (N.D. Ill. Mar. 16, 2009) (post-*Levine,* finding no preemption of state-law claims against generic drug manufacturer); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1265-66 (W.D. Okla. 2009) (same)).

[185] 521 F.2d at 269.

implied conflict preemption on the narrow ground that the FDA had "clearly and publicly stated its position prior to the prescriptions and deaths at issue."[186] Consequently, a state law duty to warn of such an association would render the label misbranded under federal law based on the FDA's "oft-repeated conclusion that the evidence did not support an association requiring a warning."[187]

The plaintiffs argued that "nothing less than the FDA's explicit rejection of a drug manufacturer's request to add a contested warning to its drug labeling should suffice to establish conflict preemption."[188] The Supreme Court has clearly stated that the manufacturer is responsible for its labeling under the FDCA. One could make the argument, after *Levine,* that only an affirmative decision by the FDA to prohibit a manufacturer's proposed labeling change will support impossibility conflict preemption of a state common law duty. I am not aware of a circumstance when a pharmaceutical manufacturer has asked to enhance a warning and been affirmatively rebuffed by the FDA after full assessment of the data. *Colacicco* does not present that situation, though it is a stronger case than *Levine* because of the history of the FDA's involvement with SSRI labeling. Nevertheless, the manufacturer is in control of the evidence of post-approval risks and until the FDA has sufficient resources to control access to that information, prior FDA determinations of labeling adequacy may not create an impossible conflict with a state law warning obligation under *Levine*.[189]

3. Rules of Thumb: Obstacle Conflict Preemption

Implied obstacle conflict preemption requires an assessment of congressional objectives with which state common law may conflict, and an evaluation of whether the longstanding value of state common law indeed frustrates those objectives. The presumption against preemption has its greatest importance, in my estimation, in obstacle conflict preemption. Rules of thumb to follow in this preemption analysis include:

- Congressional, not agency, intent is central so legislative history and purposes are important when assessing federal objectives;

- Congressional silence on preemption in the face of awareness of the longstanding operation of tort laws is persuasive evidence against finding state common law an obstacle to accomplishing federal objectives;

- Reasoned agency explanations on preemption, as opposed to political or policy shifts in position, may be useful in assessing federal objectives, but the Court must make an

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[186] *Id.*

[187] *Id.*

[188] *Id.* at 272.

[189] *See* Davis, *supra* note 4 at 1148-51.

independent assessment. Shifts in agency position on preemption are inherently suspect and should be met with skepticism;

- Deference to agency pronouncements on preemption is unwarranted, particularly absent formal rule-making on the subject;

- According to the recently issued White House memorandum on preemption, Federal agency preemption positions must be made "with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption"; and

- Agency failure to regulate fails to establish federal objectives sufficient to preempt state common law.

4. An Example: Food Safety Regulations

Recent cases involving FDA rules regarding food safety are good examples of implied obstacle conflict preemption. In *Fellner v. Tri-Union Seafoods, LLC.,*[190] plaintiff argued that defendant should have warned of the risk of mercury poisoning from eating its canned tuna. Defendant sought preemption based on various FDA actions amounting to a decision not to regulate and an FDA letter opining about preemptive effect of its prior actions.[191] The Court of Appeals reminded us that it is federal *law* that preempts, not any federal *action*. While formal rule-making is not required, the informal agency positions taken regarding mercury in tuna did not suffice.[192] *Fellner* is an excellent example of a court aggressively challenging whether the proposed federal objectives that supposedly preempt state law reflect congressional intent.[193] The Supreme Court declined to review *Fellner.*

VI. CONCLUSION

The presumption against preemption is part of the landscape of preemption jurisprudence, perhaps now more than at any time in recent memory. The Court has reaffirmed the presumption in several recent cases, but uncertainty remains about how it operates. A court must be always mindful of the "touchstone" of preemption: congressional intent. If a proponent of preemption has not established the "clear and manifest" intent to preempt in areas involving the historic police powers of the states, a case for preemption has not been made.

That intent can be established, first, through an express preemption provision. Such a provision should be narrowly interpreted in light of the presumption against preemption. A court should be attentive to the legislative scheme, its structure, and purpose. Implied conflict

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[190] 539 F.3d 237 (3d Cir. 2008).

[191] *Id.* at 241-42.

[192] *Id.* at 251-55.

[193] *Id.* at 245.

preemption is a substitute for express congressional intent and, therefore, should be met with suspicion. The presumption against preemption should be taken seriously as a fundamental backdrop to all preemption analysis and particularly in implied conflict preemption cases to ensure that traditionally operating state law is appropriately preserved.