Federal Preemption of State-Law Failure-to-Warn Claims: Has the Presumption Against Preemption Gone Too Far?

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FEDERAL PREEMPTION OF STATE-LAW FAILURE-TO-WARN CLAIMS: HAS THE PRESUMPTION AGAINST PREEMPTION GONE TOO FAR?

AMANDA N. HART


INTRODUCTION

Both state law and products liability tort suits regulate prescription drugs.1 Generally, a prescription drug manufacturer has a duty to warn physicians of any dangerous effects that the manufacturer knows or has reason to know are inherent in the use of the prescription drug.2 A prescription drug manufacturer that fails to warn a physician can be held liable for breach of duty.3 State-law products liability claims based on this failure are commonly referred to as “failure-to-warn claims.”

In addition to state regulation, prescription drugs are strictly regulated by federal law. The Food, Drug, and Cosmetic Act (FDCA) was created to supplement protection already provided by state

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3 Id.
regulation and common-law products liability. The FDCA requires that the Food and Drug Administration (FDA) approve prescription drug labels before the prescription drugs may be distributed for sale. Additionally, the FDCA specifies what information must be included on the label, where it must be placed, and how to change information on the label. Upon a determination that a proposed warning label is false or misleading, the FDA will deny approval and distribution of that prescription drug. Therefore, if the FDA finds that there is insufficient evidence that a prescription drug could have the side effect listed on the warning label, it will withdraw the drug from distribution. Additionally, a Changes Being Effected (CBE) supplement permits a manufacturer to change its warning label “to reflect newly acquired information” without prior FDA approval.

When state and federal regulation of prescription drugs conflict, a determination must be made as to whether federal law preempts state law. This principle of federal preemption derives from the Supremacy Clause of the United States Constitution. A preemption analysis is based on the assumption that the historic police powers of the states are not to be superseded by federal law unless Congress clearly intended it to do so. This presumption is

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4 Levine, 129 S. Ct. at 1195.
5 “The FDA is charged with ‘promot[ing] the public health by promptly and efficiently reviewing [drug manufacturers’] clinical research and taking appropriate action on the marketing of regulated products in a timely manner’ and ‘protect[ing] the public health by ensuring that . . . drugs are safe and effective.’” Colacicco v. Apotex, Inc., 521 F.3d 253, 257 (3d Cir. 2008) (citing 21 U.S.C. §§ 301–397 (2006)).
7 Id. §§ 331, 332, 355.
8 Id. § 352.
9 Id. § 355(e).
10 See 21 C.F.R. 601.12.
11 See U.S. Const. art. VI, cl. 2. (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, 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.”).
particularly applicable where matters related to health and safety are involved. Determining whether a presumption of preemption applies is the first step that a court takes in determining whether state law or federal law prevails. Where the court finds no express presumption of preemption, the court applies a conflict preemption analysis to determine the propriety of preemption. Under the doctrine of conflict preemption, preemption of state law may be inferred where it is impossible to comply with both federal and state law or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

Historically, there has been a presumption against preemption with regard to prescription drugs. Courts have often concluded that, because state-law failure-to-warn claims fall within the states’ police powers over the health and safety of its citizens, the presumption against preemption of state law should apply. This view was reaffirmed with the 1962 FDCA amendment, in which Congress took care to preserve state law by adding a savings clause that indicated that federal law would preempt state law only upon a “direct and positive conflict” with the FDCA. Accordingly, state-law failure-to-

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13 See Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 716 (1985) (in order for federal law to preempt state law, there must be a conflict that is strong enough to overcome the presumption that state and local regulation of health and safety matters can coexist with federal regulation).
14 See Levine, 129 S. Ct. at 1194–95.
17 See e.g., Hillsborough County, 471 U.S. at 715–16.
18 See id.
19 “The intention of Congress in inserting a savings clause is not to preserve common law claims when they conflict with federal regulatory standards, but to prevent a manufacturer from having a complete defense to a common law action not addressed by a standard by merely stating that it is in full compliance with all federal safety standards.” 63B AM. JUR. 2D Products Liability § 1923 (2010).
warn claims continued to evade preemption despite FDA regulations.\footnote{See, e.g., Riegel v. Medtronic, Inc., 552 U.S. 312, 340 (2008) (Ginsburg, J., dissenting) ("By the time Congress enacted the MDA in 1976, state common-law tort claims for drug labeling and design defects had continued unabated despite nearly four decades of FDA regulation.").}

In 2001, the landscape of federal preemption began to change. Many prescription drug manufacturers began filing preemption motions in the district courts, and in many of these cases, the FDA filed amicus briefs in support of these manufacturers.\footnote{Id.} This was the first step in the movement toward federal preemption. The preamble to Congress’s 2006 FDCA amendment strengthened this movement by expressly stating that preemption applies to “claims that a manufacturer breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the manufacturer had an obligation to warn.”\footnote{Mason v. SmithKline Beecham Corp. (Mason I), 546 F. Supp. 2d 618, 625 (C.D. Ill. 2008) (citing Colacicco, 521 F.3d at 269).} This amendment also provided for “changes being effected” supplements, which allowed manufacturers to change labels prior to FDA approval based on newly acquired information.\footnote{Colacicco, 521 F.3d at 259.}

The Third Circuit was the first federal court of appeals to address the issue of preemption in the context of prescription drugs.\footnote{Mason I, 546 F. Supp. 2d at 621.} In \textit{Colacicco v. Apotex, Inc.}, the court considered whether action taken by the FDA and its corresponding regulatory scheme preempted the plaintiffs’ state-law failure-to-warn claims.\footnote{521 F.3d at 256.} Based upon its consideration of the presumption against preemption, Congressional intent, and the FDA’s actions taken pursuant to its statutorily-granted authority, the Third Circuit held that the plaintiffs’ state-law failure-to-warn claims conflicted with federal law, and thus were preempted.\footnote{Id. at 276.}
Because the Seventh Circuit had yet to address the issue of preemption in the context of prescription drugs, the district court in *Mason v. SmithKline Beecham Corporation* relied upon the Third Circuit’s reasoning in *Colacicco*. The court held that, because the FDA had repeatedly rejected the warning label that the plaintiffs contended state law required, the plaintiffs’ state-law failure-to-warn claims were preempted.

In 2009, the United States Supreme Court was given the opportunity to consider the presumption against preemption in the context of prescription drugs. In its landmark decision in *Wyeth v. Levine*, the Supreme Court “restored the landscape of federal preemption to its pre-2001 form.” The Court established a new standard for federal preemption. It held that, absent clear evidence that the FDA would not have approved a prescription drug label that the plaintiffs asserted was required by state law, federal law would not preempt the plaintiffs’ state-law failure-to-warn claims.

The Seventh Circuit recently had the opportunity to reconsider the lower court’s decision in *Mason v. SmithKline Beecham Corporation* in light of the Supreme Court’s decision in *Levine*. The Seventh Circuit adopted the standard set forth in *Levine*—absent clear evidence that the FDA would not have approved a drug labeling change, state-law failure-to-warn claims are not preempted. The court used the facts in *Levine* as a baseline to determine whether the manufacturer effectively demonstrated that the FDA would not have approved the label change that the plaintiffs asserted was required by state law. The court found insufficient facts to establish clear

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28 See Mason I, 546 F. Supp. 2d at 621.
29 Id. at 626.
31 Mason v. SmithKline Beecham Corp. (Mason II), 596 F.3d 387, 391 (7th Cir. 2010).
32 See Levine, 129 S. Ct. at 1198.
33 Id.
34 See Mason II, 596 F.3d at 391.
35 Id.
36 Id. at 392 (stating that if the evidence were less compelling than it was in Levine, the court would not find preemption).
evidence and thus, held that FDA regulations did not preempt the plaintiffs’ state-law failure-to-warn claims. In doing so, the Seventh Circuit overturned the decision of the lower court.

The Seventh Circuit’s adoption of the “clear evidence” standard reflects an apparent shift toward a presumption against preemption. Admittedly, states have an interest in the health and safety of their citizens; however, the shortcomings of the presumption against preemption outweigh this interest. This Note analyzes the presumption against preemption in the context of prescription drugs and argues that Congress should enact an express preemption clause for prescription drugs similar to the Medical Device Amendments of 1976.

I. BACKGROUND

A. Federal and State Regulation of Prescription Drugs

Prescription drugs are regulated by both state law and products liability tort suits. Generally, a prescription drug manufacturer has a duty to warn physicians of any dangerous effects that the manufacturer knows or has reason to know are inherent in the use of the prescription drug. If the manufacturer does not effectively warn the physician, the manufacturer can be held liable for a breach of duty. State products liability actions based on this failure to provide adequate warnings are commonly known as “failure-to-warn” claims. To successfully bring a common law failure-to-warn claim, the consumer bears the burden of proving that the manufacturer failed to adequately warn him of any risks associated with the prescription drug and that

37 Id. at 396 (finding that the manufacturer did not meet its burden of demonstrating by clear evidence that the FDA would have rejected a label change).
38 This statute provides that, after a medical device receives FDA pre-market approval, a state may not establish or enforce any requirement that (1) is different from, or in addition to, any requirement applicable under federal law, and (2) relates to the safety or effectiveness of the device. 21 U.S.C. § 360k(a) (2006).
39 See Levine, 129 S. Ct. at 1195.
40 Rosenhouse, supra note 2.
41 Id.
42 See 63A AM. JUR. 2D Products Liability § 1240 (2010).
the failure to warn was the proximate cause of the consumer’s injury.\textsuperscript{43}

Prescription drugs are also strictly regulated by federal law. The FDCA requires approval of a prescription drug’s warning label before it may be distributed for sale.\textsuperscript{44} The FDCA specifies what risk information must be included in the label, where the information must appear, and how to change information on the label.\textsuperscript{45} Where the FDA finds that a warning label is false or misleading, it will deny approval of the prescription drug.\textsuperscript{46} Additionally, the FDA will withdraw approval of any prescription drug already on the market upon receipt of information that there is a lack of substantial evidence that a prescription drug will have the effect that the warning label suggests.\textsuperscript{47}

When state and federal regulation of prescription drugs conflict, a determination must be made as to whether federal law preempts state law. In these situations, some courts have held that state-law products liability claims based on inadequate warnings were preempted, or supplanted, by FDA regulation.\textsuperscript{48} However, other courts have concluded that state-law failure-to-warn claims fall within the states’ police powers to regulate the health and safety of their citizens, and thus, a presumption against preemption should apply.\textsuperscript{49}

\textsuperscript{43} Rosenhouse, \textit{supra} note 2.
\textsuperscript{44} See Levine, 129 S. Ct. at 1195.
\textsuperscript{46} Id. § 352.
\textsuperscript{47} Id. § 355(e).
\textsuperscript{49} See \textit{supra} text accompanying note 14.
A. Federal Preemption Generally

The principle of federal preemption,\(^{50}\) that federal law can supplant inconsistent state law, derives from the Supremacy Clause of the United States Constitution.\(^{51}\) There are three different types of federal preemption.\(^{52}\) The first type of preemption, known as express preemption, preempts state law where a federal statute unequivocally states that its provisions preemp state law.\(^{53}\) The second and third types of preemption, field preemption and conflict preemption, fall into the category of implied preemption.\(^{54}\) Under implied preemption, state-law claims are preempted where “Congressional intent is inferred from the existence of a pervasive regulatory scheme” or where “state law conflicts with federal law or interferes with the achievement of federal objectives.”\(^{55}\) Specifically, under the doctrine of field preemption, federal preemption may be inferred from Congress’s intent to control an entire regulatory field.\(^{56}\) Under the doctrine of conflict preemption, preemption of state law may be inferred where it

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\(^{50}\) Here, federal preemption refers to ordinary preemption rather than to complete preemption. Ordinary preemption is a federal defense to plaintiff’s state-law claim and may arise either expressly by statute or by a direct conflict between state and federal law. Washington v. Fred’s Stores of Tenn., Inc., 427 F. Supp. 2d 725, 727 (S.D. Miss. 2006). Complete preemption, however, is jurisdictional in nature and authorizes removal to federal court. Id.

\(^{51}\) See U.S. Const. art. VI, cl. 2. (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, 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.”).

\(^{52}\) Washington, 427 F. Supp. 2d at 728.

\(^{53}\) Id. (“Under express preemption, the federal statute must clearly state that its provisions preempt state law.”).

\(^{54}\) Id. (“The second and third categories of ordinary preemption, field preemption and conflict preemption, must be implied from the circumstances.”). Express and implied preemption differ in that, in an implied preemption analysis, it is possible to infer Congressional intent to preempt state law based only on the effect that allowing state law products liability claims would have on the federal scheme established by Congress. 63B AM. JUR. 2D Products Liability § 1923 (2010).

\(^{55}\) Washington, 427 F. Supp. 2d at 728.

\(^{56}\) 63B AM. JUR. 2D Products Liability § 1923.
is impossible to comply with both federal and state law or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

B. Federal Preemption in the Context of Prescription Drugs

All three categories of federal preemption require a court to discern Congressional intent. Where Congress has not explicitly stated that federal law preempts state law, preemption may be implied where there is an actual conflict between state law and the federal regulatory scheme. Courts have traditionally applied a presumption against preemption unless a person or entity that is seeking to have the law preempted demonstrates that there is clear Congressional intent to preclude the states from acting.

The most commonly implicated category of preemption in the context of prescription drugs is conflict preemption, which is implicated when it is impossible for a prescription drug manufacturer to comply with both state and federal prescription drug regulations. Courts have often concluded that, because state-law failure-to-warn claims fall within the states’ police powers over the health and safety of its citizens, the presumption against preemption should apply.

Until 1962, the FDA carried the burden of proving that a prescription drug was unsafe to prevent distribution of that prescription drug. In 1962, however, Congress amended the FDCA to require manufacturers to demonstrate that their prescription drugs were “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling” before they could be distributed. This amendment effectively shifted the burden of proof from the FDA

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57 Washington, 427 F. Supp. 2d at 730.
58 Id.
59 63B AM. JUR. 2D Products Liability § 1923.
61 Washington, 427 F. Supp. 2d at 730.
63 Id.
to the manufacturer. 65 Significantly, Congress took care to preserve state law by adding a savings clause to this amendment,66 which stated that federal law would preempt state law only upon a “direct and positive conflict” with the FDCA.67 Accordingly, plaintiffs continue to successfully bring state-law failure-to-warn claims despite FDA regulations.68

Until the early 2000s, prescription drug manufacturers rarely invoked the defense of federal preemption.69 Notably, when manufacturers asserted this defense, they rarely succeeded.70 However, this began to change in 2001, when many prescription drug manufacturers began filing preemption motions in the district courts, and in many of these cases, the FDA filed amicus briefs in support of these manufacturers.71 This was the first step in the movement away from a presumption against preemption.

This movement toward preemption was bolstered by Congress’s 2007 FDCA amendment. The preamble to this amendment expressly states that preemption applies to “claims that a [manufacturer] breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the [manufacturer] had an obligation to warn.”72 The 2007 amendment also granted the

66 “The intention of Congress in inserting a savings clause is not to preserve common law claims when they conflict with federal regulatory standards, but to prevent a manufacturer from having a complete defense to a common law action not addressed by a standard by merely stating that it is in full compliance with all federal safety standards.” 63B AM. JUR. 2D Products Liability § 1923 (2010).
68 See supra text accompanying note 22.
69 Mason v. SmithKline Beecham Corp. (Mason II), 596 F.3d 387, 391 (7th Cir. 2010).
70 Id.
71 Id.
FDA statutory authority to require manufacturers to alter their prescription drug labels based on safety information discovered after initial FDA approval. By choosing not to enact any provision that would have required FDA preapproval for all label changes, Congress reinforced its position that manufacturers were responsible for updating their own labels.

C. Cases Holding That Failure-to-Warn Claims are Preempted

The Third Circuit was the first appellate court to extensively address the issue of preemption in the context of suicide from prescription drugs, in Colacicco v. Apotex, Inc. There, the court considered whether action taken by the FDA and its corresponding regulatory scheme preempted the plaintiffs’ state-law failure-to-warn claims.

SmithKline Beecham, doing business as GlaxoSmithKline (GSK), manufactures the antidepressant Paxil, a selective serotonin reuptake inhibitor (SSRI). Lois Colacicco, a fifty-five-year-old woman, was prescribed Paxil on October 6, 2003, to treat depression. Shortly thereafter, Colacicco began taking the generic version of Paxil, manufactured by Apotex, Inc. Less than a month later, Colacicco committed suicide. At the time of her death, the label for the prescription drug included a warning, identical to that of Paxil, which stated that the “possibility of suicide attempt is inherent in major depressive disorder and may persist until significant

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74 Id. (citing S. 1082, 110th Cong. § 208 (2007) (as passed) (proposing new § 506D)).
75 Mason I, 546 F. Supp. 2d at 621.
76 Colacicco, 521 F.3d at 256.
77 Id.
78 Id.
79 Id.
80 Id.
remission occurs.”81 The label failed to warn of any increased risk of suicide.82

After her death, Colacicco’s husband filed suit against Apotex and GSK in the United States District Court for the Eastern District of Pennsylvania.83 Mr. Colacicco alleged that both Apotex and GSK violated state common-law tort rules by selling prescription drugs with labels that failed to warn patients about the increased risk of suicide.84 Both manufacturers moved for dismissal on the ground that federal law preempted the state-law failure-to-warn claim.85 The district court dismissed Colacicco’s claim on the basis of preemption.86

On appeal, Colacicco argued that because CBE supplements allowed manufacturers to strengthen and augment prescription drug warning labels without prior FDA approval, the FDA labeling requirements “constitute[d] mere minimum standards of information that may be required in their labeling.”87 Thus, it was possible for GSK to comply with both state and federal labeling regulations.88 In response, the manufacturers argued that, even though changes made under CBE regulation do not require prior FDA approval, the FDA has the final authority on the legality of those labels, and thus preemption should apply.89 Thus, the court was faced with the issue of whether the plaintiffs’ state-law failure-to-warn claims conflicted with the federal scheme.90

In its analysis, the Third Circuit first considered whether there was an applicable presumption of preemption.91 The court noted that in all preemption cases, the analysis begins with the presumption

81 Id.
82 Id.
83 Id.
84 Id.
85 Id.
87 Id. at 268.
88 Id.
89 Id.
90 Id. at 262.
91 Id.
against preemption, particularly in cases that involve a field traditionally regulated by the states, unless Congress made its intent to preempt state law clear and manifest. Courts that have applied a presumption against preemption tend to premise it on the fact that states have the power to protect the health and safety of their citizens. In this case, the plaintiffs argued that preemption was inappropriate because Congress never expressly stated its intent to preempt state-law tort actions challenging prescription drug labeling. However, the manufacturers contended that a presumption of preemption applied to this case because the federal government, not the states, had traditionally regulated prescription drug labeling.

The Third Circuit looked to the purpose of Congress to determine whether there was any express intent for preemption of state law. In considering the arguments of both sides, the court found a lack of Congressional directive expressly approving or rejecting preemption in the context of prescription drugs. Because Congress did not expressly state its intent to approve or reject preemption in the context of prescription drugs, the court applied a conflict preemption analysis to determine the propriety of preemption. Conflict preemption is applicable when compliance with both federal and state regulations is impossible or when “state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

The plaintiff argued that conflict preemption did not apply because it was possible for GSK to comply with both state and federal law. GSK argued that, because the CBE supplement allowed prescription drug manufacturers to strengthen warning labels without

92 Id. at 268.
93 See supra text accompanying note 14.
94 Colacicco, 521 F.3d at 263.
95 Id.
96 Id. at 264.
97 Id. at 265.
98 Id.
99 Id. (citing Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985)).
100 Id. at 268.
prior FDA approval, the FDA labeling requirements constituted mere minimum standards.101 However, the court looked to the FDA’s past treatment of warning labels for Paxil and found that for over twenty years, the FDA had actively monitored the potential connection between suicide and SSRIs and, in finding no scientific basis for the connection, repeatedly rejected the warning label of increased risk of suicide.102 The FDA determined that the inclusion of such a warning without scientific basis would constitute false and misleading labeling.103

Additionally, in determining whether the plaintiff’s failure-to-warn claim should be preempted, the Third Circuit considered the FDA’s actions taken pursuant to its statutorily-granted authority.104 The FDCA authorizes the FDA to prohibit false or misleading prescription drug labeling.105 The standard for adding a warning to a prescription drug label is the existence of “reasonable evidence of a causal association [of a clinically significant hazard] with a drug.”106 Thus, any state law obligation to include a warning asserting the existence of an association between SSRIs and suicidality when the FDA had determined that the evidence did not support such an association would constitute false labeling.107

Another factor that the court considered was the FDA’s position on federal preemption.108 The court found that the FDA had remained consistent in its position that it had the duty to establish prescription drug warning requirements.109 The court also acknowledged that the FDA had remained consistent in its position that the plaintiff’s claims were preempted as a result of the FDA’s

101 Id.
102 Id.
103 Id.
104 Id.
105 Labeling Requirements for Prescription Drugs and/or Insulin, 21 C.F.R. § 201.56(a)(2) (2006).
106 See Labeling Requirements for Prescription Drugs and/or Insulin, 21 C.F.R. § 201.57(c) (2006).
107 See id.
108 Colacicco, 521 F.3d at 253.
109 Id. at 276.
repeated rejection of warning labels based on insufficient scientific evidence.\textsuperscript{110}

Based on the court’s review of FDA regulations, the FDA’s actions taken pursuant to its statutorily-granted authority, and the FDA’s position on federal preemption, the court found that the plaintiff’s failure-to-warn claims were preempted by FDA regulation.\textsuperscript{111}

In \textit{Mason v. SmithKline Beecham Corporation}, the United States District Court for the Central District of Illinois was presented with a case strikingly similar to \textit{Colacicco}. In this case the defendant, SmithKline Beecham (SKB), manufactured Paxil.\textsuperscript{112} Two days after the plaintiffs’ daughter, twenty-three-year-old Tricia Mason, began taking Paxil, she committed suicide.\textsuperscript{113} The plaintiffs filed a state-law claim against SKB, alleging that SKB failed to warn consumers about the dangerous side effects of the prescription drug, including an increased risk of self-harm.\textsuperscript{114} SKB moved for summary judgment on the basis of preemption.\textsuperscript{115} The court granted summary judgment and held that the plaintiffs’ state-law tort claims for failure to warn were preempted.\textsuperscript{116}

Like the manufacturer in \textit{Colacicco}, SKB argued that the plaintiffs’ claims were preempted based on proposed warnings that directly conflicted with the FDA-approved labeling for Paxil.\textsuperscript{117} The plaintiffs, however, contended that the court should not find that their state-law failure-to-warn claims were preempted absent clear evidence of a conflict between state and federal regulations.\textsuperscript{118} The plaintiffs further argued that conflict preemption did not apply to this case because it was possible for SKB to comply with both state and federal

\textsuperscript{110} Id. at 274.
\textsuperscript{111} Id. at 275.
\textsuperscript{112} Mason v. SmithKline Beecham Corp. (\textit{Mason I}), 546 F. Supp. 2d 618, 619 (C.D. Ill. 2008).
\textsuperscript{113} Id.
\textsuperscript{114} Id.
\textsuperscript{115} Id. at 620.
\textsuperscript{116} Id. at 627.
\textsuperscript{117} Id. at 620.
\textsuperscript{118} Id. at 619.
This argument was premised on the fact that manufacturers are permitted to strengthen warning labels, without prior FDA approval, through CBE supplements. Thus, the plaintiffs contended that SKB could have strengthened the warning label for Paxil and still have met the minimum FDCA labeling requirements.

To determine whether it was possible for SKB to comply with both state and federal regulations, the district court applied a conflict preemption analysis. Because the Seventh Circuit had yet to address whether state-law claims were preempted in the context of prescription drugs, the district court looked to the Third Circuit’s decision in Colacicco for guidance.

The plaintiffs’ state-law failure-to-warn claims were based on the fact that the prescription drug labeling for Paxil was false or misleading due to its failure to warn consumers of any risk of self-harm. The court rejected the plaintiffs’ claims and followed the Third Circuit’s reasoning that, where a plaintiff’s proposed labeling change conflicts with FDA-approved labeling, state-law failure-to-warn claims are preempted. The court noted that any other outcome would present a direct conflict for SKB. If SKB complied with federal law, it would be exposed to substantial liability from state tort law claims for failing to add a warning that the plaintiffs contended was necessary under state law. If SKB acted to avoid state tort law claims by adding the warning that the plaintiffs contended was necessary, it would expose itself to federal liability, including the possibility that the FDA would withdraw its approval of Paxil for false or misleading labeling.

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119 Id. at 623.
120 Id.
121 Id.
122 Id. at 621.
123 Id.
124 Id. at 626.
125 Id.
126 Id.
127 Id.
128 Id.
D. Wyeth v. Levine: Failure-to-Warn Claim Only Preempted upon “Clear Evidence”

Almost a year after the Third Circuit’s decision in Colacicco, the United States Supreme Court was faced with the issue of preemption in the context of prescription drugs in Wyeth v. Levine.\(^{129}\) This landmark decision restored the federal preemption landscape to its pre-2001 form.\(^{130}\)

Wyeth manufacturers Phenergan, an antihistamine prescribed to treat nausea.\(^{131}\) Phenergan is a corrosive prescription drug that can cause gangrene upon entry into a patient’s artery.\(^{132}\) Phenergan may be injected intravenously through either the “IV-push” method\(^{133}\) or the “IV-drip” method.\(^{134}\) On April 7, 2000, Diana Levine went to her health care clinic, where she was prescribed Phenergan to treat nausea associated with her migraine.\(^{135}\) The physician administered the Phenergan through the IV-push method, as opposed to the IV-drip method.\(^{136}\) The Phenergan accidentally entered Levine’s artery, causing gangrene to develop in her right hand and forearm, both of which had to be amputated as a result.\(^{137}\)

Levine contended that Phenergan’s labeling failed to adequately warn physicians about the risk of IV-push administration, a warning that Levine argued was required by state law.\(^{138}\) Wyeth filed a motion for summary judgment; its argument was premised on the

\(^{129}\) 129 S. Ct. 1187, 1193 (2009).
\(^{130}\) Mason v. SmithKline Beecham Corp. (Mason II), 596 F.3d 387, 391 (7th Cir. 2010).
\(^{131}\) Levine, 129 S. Ct. at 1191.
\(^{132}\) Id.
\(^{133}\) This method of administration involves injecting Phenergan directly into a patient’s vein. Id.
\(^{134}\) This method of administration involves adding Phenergan to a saline solution and allowing the liquid to slowly enter through a catheter inserted into the patient’s vein. Id.
\(^{135}\) Id.
\(^{136}\) Id.
\(^{137}\) Id.
\(^{138}\) Id. at 1191, 1194.
notion that Levine’s failure-to-warn claims were preempted by federal law.  

The trial court found no merit in Wyeth’s conflict preemption argument, stating that there was no evidence that the FDA had “specifically disallowed” stronger language. The Vermont Supreme Court affirmed the trial court’s denial of Wyeth’s motion for summary judgment, holding that Wyeth could have, through the FDA’s CBE regulation, warned against the IV-push administration without prior FDA approval and that the FDA’s requirements are minimal standards that do not create a ceiling for state-law warning label requirements.

The issue presented to the United States Supreme Court was whether FDA prescription drug labeling requirements preempt state-law failure-to-warn claims premised on the theory that different labeling judgments were necessary to make prescription drugs reasonably safe for use. Wyeth argued that it was impossible for it to comply with both state and federal labeling requirements and that recognition of the plaintiff’s state-law failure-to-warn claim creates an “obstacle to the accomplishment and execution of the full purposes and objectives of Congress” by transferring prescription drug labeling decision-making from the experts of the FDA to a lay jury.

The Supreme Court first considered the purpose expressed by Congress. Traditionally, courts begin with a presumption against preemption, based on the policy that historic police powers are not to be superseded by federal law unless there is clear intent by Congress to do so. Wyeth contended that the presumption against preemption should not apply because the FDA had regulated prescription drug labeling for more than a century, demonstrating clear Congressional intent for federal preemption. Additionally, Wyeth argued that the

139 Id. at 1192.
140 Id.
141 Id. at 1193.
142 Id.
143 Id.
144 Id. at 1195.
145 Id.
146 Id.
plaintiff’s state-law failure-to-warn claim was preempted because it was impossible to comply with state and federal regulations—a classic conflict-preemption case.\textsuperscript{147} It argued that the CBE supplement, which permits a manufacturer to strengthen a warning label without prior FDA approval, was not implicated in this case because the 2006 amendment provides only that a manufacturer may change its label to reflect newly acquired information.\textsuperscript{148} Wyeth asserted that it could only have changed the label in response to new information not yet considered by the FDA, and thus it was impossible for it to strengthen its label to comply with state-law requirements without violating federal law.\textsuperscript{149}

The Court, however, found that Wyeth could have strengthened its claim though a CBE supplement because, in its notice of the final rule, the FDA explained that “newly acquired information” is not limited to new data but also includes new analyses of previously submitted data.\textsuperscript{150} The plaintiff presented evidence of at least twenty incidents prior to her injury in which injection of the prescription drug resulted in gangrene and amputation.\textsuperscript{151} She argued that Wyeth could and should have analyzed the acquired data and, through a CBE supplement, added a stronger warning label about the IV-push administration of the prescription drug.\textsuperscript{152} Ultimately, the Court held that absent clear evidence that the FDA would not have approved a change to Phenergan’s label, it would not conclude that it was impossible for Wyeth to comply with both federal and state requirements.\textsuperscript{153} While the Court found no preemption in \textit{Levine}, it stated that preemption could be found where the manufacturer meets a strict standard of proving that there was clear evidence that the FDA
III. THE SEVENTH CIRCUIT’S RETURN TO A PRESUMPTION AGAINST PREEMPTION

In *Mason v. SmithKline Beecham Corporation*, the Seventh Circuit reconsidered the lower court’s decision in light of *Levine*. The court adopted the standard set forth in *Levine*—absent clear evidence that the FDA would not have approved a drug labeling change, state-law failure-to-warn claims are not preempted. The court found that the Supreme Court failed to clarify what constitutes “clear evidence” and that the only thing that was apparent was that the evidence presented in *Levine* did not constitute “clear evidence” such that preemption would apply. Therefore, the court was faced with the task of interpreting the *Levine* “clear evidence” standard.

The court used *Levine* as a benchmark to determine whether GSK had presented “clear evidence” that the FDA would not have approved the plaintiffs’ proposed labeling change. If the evidence were found to be less compelling than the evidence in *Levine*, the court would reject GSK’s argument that federal law preempted the state-law failure-to-warn claim.

In *Levine*, the Supreme Court first reviewed the administrative history of Phenergan. It found that the record in *Levine* clearly proffered ample evidence that the “FDA specifically considered and reconsidered the strength of Phenergan’s IV-push-related warnings in light of new scientific and medical data.” Additionally, there was evidence that, instead of banning the administration of Phenergan...
through the IV-push method altogether, Wyeth and FDA authorities agreed that there was a need for better warning of the problems of intra-arterial injection.\textsuperscript{162} A year later, the FDA committee recommended a stronger label for Phenergan regarding the IV-push method but decided not to prohibit the administration of the prescription drug through the IV-push method.\textsuperscript{163} Ultimately, the Supreme Court found that it was clear from the administrative history of Phenergan that the FDA had “strongly considered a similar warning to the one that plaintiff proposed and the Court still did not find preemption.”\textsuperscript{164}

Following the Supreme Court’s analysis in \textit{Levine}, the Seventh Circuit examined the administrative history of Paxil.\textsuperscript{165} In 1989, GSK filed a prescription drug application with the FDA seeking market approval of its new prescription drug, Paxil.\textsuperscript{166} At the time of its approval, the FDA did not require any warnings of suicide risk.\textsuperscript{167} From the date of its approval through February 2003, GSK’s analysis of suicides and suicide attempts of patients taking Paxil found no relationship between suicide and Paxil.\textsuperscript{168} Additionally, the FDA had been thoroughly reviewing the available data about prescription drugs such as Paxil and determined that there was no increased risk of suicide resulting from consumption of these prescription drugs.\textsuperscript{169} GSK also pointed to the FDA’s failure to require a warning about the risk of suicide just before the suicide in this case as evidence that the FDA would not have approved the increased warning that the plaintiffs contended state law required.\textsuperscript{170}

However, in a press release in October 2003, the FDA recommended that physicians stop prescribing Paxil to children because it was investigating the increased risk of suicide resulting

\begin{footnotes}
\item[162] Id.
\item[163] Id.
\item[164] Id.
\item[165] Id.
\item[166] Id.
\item[167] Id.
\item[168] Id.
\item[169] Id. at 394.
\item[170] Id. at 395.
\end{footnotes}
The court found that, in light of this evidence, it seemed unlikely that the FDA would have refused to allow GSK to submit a label change to warn Paxil consumers about the potential risk of suicide for young adults. Considering the administrative history of Paxil as a whole, the court concluded that the evidence fell short of demonstrating by “clear evidence” that the FDA would not have approved the label change that the plaintiffs contended was required by state law. Therefore, the Seventh Circuit overturned the decision of the lower court and held that the plaintiffs’ state-law failure-to-warn claims were not preempted by FDA regulations.

IV. THE IMPACT OF A PRESUMPTION AGAINST PREEMPTION

Prior to Levine, state-law failure-to-warn claims were preempted where the FDA had rejected warnings that plaintiffs contended should have been included in the warning label. In other words, because imposing state tort liability for failure-to-warn would conflict with FDA-approved labeling, federal law preempted these state-law failure-to-warn claims. However, after Levine, state-law failure-to-warn claims have been preempted only where the manufacturer meets the strict burden of proving that there is clear evidence that the FDA would not have approved the proposed change(s) in the label. Mason v. SmithKline Beecham Corp. reflects the Seventh Circuit’s clear shift toward the presumption against preemption. Admittedly, states have an interest in the health and safety of their citizens; however, the harms resulting from the presumption against preemption outweigh this interest. An adoption of an express preemption clause similar to the Medical Device Amendments of 1976

171 Id.
172 Id.
173 Id.
174 Id. at 396.
175 See generally Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008); see also Mason II, 596 F.3d at 387.
176 Mason II, 596 F.3d at 391.
(MDA) would solve many of the harms of the current standard for prescription drug preemption.

A. Harms Resulting from the Presumption Against Preemption

First, recognition of state-law failure-to-warn claims subjects prescription drug manufacturers to a multitude of state laws. Standards of care for prescription drug labeling vary from state to state.\textsuperscript{177} “Absent a determination that the FDA-approved labeling and the FDA’s refusal to require the warnings suggested by plaintiffs . . . preempt start tort actions, the manufacturers may be subjected to considerable liability based on varying standards, with no benchmark that they should follow.”\textsuperscript{178} A national standard for prescription drug labeling requirements would ease the burden on prescription drug manufacturers of complying with the fifty-one separate regulatory schemes of each state and the federal government.

Additionally, state-law failure-to-warn claims substitute a lay jury’s decision regarding prescription drug labeling for the expert judgment of the FDA.\textsuperscript{179} New prescription drugs must obtain the FDA’s stamp of approval as “safe” and “effective” before being marketed to the public.\textsuperscript{180} Once a product is on the market, the FDCA employs the FDA to monitor new information and authorizes it to withdraw approval in light of new safety concerns.\textsuperscript{181} A state tort regime which allows a lay jury to make important decisions about prescription drug labeling is incompatible with this scheme.

State-law failure-to-warn claims may also lead to unsubstantiated warning labels. A highly probable risk of holding a prescription drug manufacturer strictly liable for failure to warn of any “knowable” risk is the destruction of the viability of any warnings. If every report of a possible risk, no matter how speculative, imposed an affirmative duty to give some warning, a manufacturer would be

\textsuperscript{177} Colacicco, 521 F.3d at 267.
\textsuperscript{178} Id. at 267–68.
\textsuperscript{179} See Wyeth v. Levine, 129 S. Ct. 1187, 1194 (2009).
\textsuperscript{180} See id. at 1195.
required to provide notice to all physicians of even the slightest risks, thereby diluting the force of any specific warning.\footnote{182}{See Carlin v. Super. Ct. of Sutter Cnty., 920 P.2d 1347, 1360–61 (Cal. 1996).}

Lastly, recognition of state law failure-to-warn claims stifles medical research and testing. Courts have noted for many years that prescription drug tort liability could deter manufacturers from developing and marketing prescription drugs.\footnote{183}{Id. at 1357.} Highly beneficial, commonly used drugs are often incapable of being made entirely safe.\footnote{184}{Id. at 1358.} Additionally, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety for many new or experimental drugs.\footnote{185}{Id. (citing RESTATEMENT (SECOND) OF TORTS § 402A (1965)).} However, medical advancement justifies the development, marketing, and use of the drug notwithstanding a medically recognizable risk.

\textbf{B. The Medical Device Amendments of 1976 (MDA)}

Until Congress’s enactment of the MDA, the introduction of new medical devices was left largely to each state to supervise and regulate in any particular manner.\footnote{186}{Riegel v. Medtronic, 552 U.S. 312, 315 (2008).} However, the landscape of medical device regulation began to change in the 1960s and 1970s, when many complex medical devices thrived and some began to fail.\footnote{187}{Id.} The most notable medical device failure was the Dalkon Shield, an intrauterine device that failed in 1970, leading to many serious infections and deaths.\footnote{188}{Id.} Unfortunately, thousands of resulting tort claims also failed.\footnote{189}{Id.} Many believed that this demonstrated the inability of the common law tort regime to manage risks associated
with dangerous medical devices. As a result, Congress stepped in and enacted the MDA.

The MDA created a scheme of federal oversight for medical devices while dramatically reducing state regulation and oversight requirements. This statute provides that, after a medical device receives FDA pre-market approval, a state may not establish or enforce any requirement that (1) is different from, or in addition to, any requirement applicable under federal law, and (2) relates to the safety or effectiveness of the device. Accordingly, while the MDA preempts many state common-law tort claims, it does not preempt those that do not impose requirements different from or in addition to federal requirements. Further, the MDA permits the FDA to exempt certain state and local requirements from preemption.

The MDA maintained the FDA requirement of pre-market approval prior to distribution of any medical device. Pre-market approval imposes certain specific requirements applicable to all medical devices, including a review of the device’s proposed labeling. Once a device has received FDA pre-market approval, it must be marketed without any significant differences from the specifications in the approval application because the FDA has deemed that these specifications provide a reasonable assurance of safety and effectiveness. Notably, a new medical device is not required to undergo pre-market approval if the FDA finds that it is a substantial equivalent of another device exempt from pre-market approval.

After pre-market approval, medical devices are subject to reporting requirements, which include the obligation to inform the FDA of any new clinical investigations or scientific studies concerning

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190 Id.
191 Id. at 316.
192 Id. at 312.
194 Id. § 360k(b).
195 Medtronic, 552 U.S. at 313.
196 Id.
197 Id.
the device that the applicant knows or reasonably should know of and to report incidents in which the device has contributed to death or serious injury. The FDA may withdraw pre-market approval of any medical device based on newly acquired data and must withdraw approval if it determines that the device is unsafe or ineffective under its labeling conditions.

The MDA imposes three different class levels of continuing oversight for medical devices depending on the risks presented by the device. Class I medical devices include elastic bandages and examination gloves and are subject to the lowest level of oversight, known as “general controls,” such as labeling requirements. Class II medical devices include powered wheelchairs and surgical drapes and are subject to general controls and “special controls,” including performance standards and post-market surveillance measures. Class III oversight applies to medical devices that are purported to be for a use in supporting or sustaining human life or for a use that is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. Because of the nature of this class of medical devices, it receives the strictest federal oversight of the three.

C. Proposed Prescription Drug Preemption Clause

Congress should enact an express preemption clause similar to the MDA for prescription drugs. A similar statute would provide that, after a prescription drug manufacturer has received FDA pre-market approval, the states may not promulgate any regulations that differ from or impose greater restrictions than federal regulations. While this statute would preempt most state common-law tort claims, it would

199 Id. § 814.84(b)(2).
200 Id. § 803.50(a).
201 Id. § 360e(e)(1).
202 See Medtronic, 552 U.S. at 316–17.
203 Id. at 316.
204 Id. at 316.
206 Medtronic, 552 U.S. at 317.
not preempt those that do not impose requirements different from or in addition to federal requirements. Further, Congress could grant the FDA the power to exempt certain state and local requirements from preemption.  

A prescription drug preemption statute should maintain the current FDA pre-market approval regulations, which are nearly identical to those for medical devices. However, unlike the MDA, which permits a new medical device to forego pre-market approval if the FDA finds that it is a substantial equivalent of another device exempt from pre-market approval, all prescription drugs should be subject to pre-market approval because of the risk of resulting injuries or illnesses.

This proposed statute should maintain the FDA oversight currently in place for prescription drugs. Congress need not establish differing class levels for continuing oversight for prescription drugs as it has done in the MDA because all prescription drugs present a “potential unreasonable risk of illness or injury,” as is characteristic of Class III medical devices. Thus, all prescription drugs should be subject to the most extensive federal oversight.

D. Effects of the Proposed Prescription Drug Preemption Clause

Congress’s enactment of a preemption clause for prescription drugs similar to the MDA would address many of the harms of the current preemption standard. First, an express preemption clause would create a uniform standard of care for manufacturers to observe. Manufacturers would no longer be subject to the fifty-one different standards of care currently in place. A uniform standard would inevitably lead to less tort liability for manufacturers, as it is much easier to comply with a single standard of care and would result in lower operating costs to the manufacturer.

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207 See 21 U.S.C. § 360k(b).
208 See id. § 360c(f)(1)(A).
209 See Medtronic, 552 U.S. at 316–17.
An express preemption clause would also return the decision of prescription drug labeling requirements to the expert judgment of the FDA rather than the lay jury because most state-law failure-to-warn claims will be preempted. This is important because FDA scientists thoroughly test the safety and effectiveness of prescription drugs before approving them for distribution\(^{211}\) and continue to monitor the safety and effectiveness of the prescription drugs throughout their distribution.\(^{212}\) Lay juries do not have the proper experience with prescription drug labeling to compete with the expertise of the FDA.

Next, an express preemption clause would reduce unsubstantiated warning labels. Once the FDA has approved a prescription drug for distribution, the manufacturer knows exactly what information must be included in the label. Additionally, upon receipt of new information, the FDA would inform the manufacturer of any necessary labeling changes. Accordingly, manufacturers would no longer have to concern themselves with providing notice to physicians of every possible risk, no matter how minute.

Lastly, an express preemption clause would help reduce the negative effect that the current standard of preemption has on medical research and testing. A national standard of care will undoubtedly reduce manufacturers’ tort liability, which courts have found deters manufacturers from developing and marketing prescription drugs.\(^{213}\) As a result, manufacturers will be able to research, develop, and market highly beneficial prescription drugs that they may not have otherwise considered researching and developing under the current standard.

CONCLUSION

The Seventh Circuit’s adoption of the Supreme Court’s strict “clear evidence” standard reflects a clear shift to a presumption against preemption. This new standard has subjected manufacturers to increased tort liability, which has negatively impacted the prescription


\(^{212}\) See 21 U.S.C. § 355(e).

drug market. Accordingly, in order to decrease manufacturers’ tort liability and resolve many of the resulting harms, Congress should enact an express preemption clause similar to the Medical Device Amendments of 1976.