Comments

Preemption of State Failure-to-Warn Claims After Wyeth v. Levine: The Regulatory Function of State Tort Law

By Eric S. Almon*

Introduction

IN A RECENT HIGH-PROFILE decision, the Supreme Court determined that federal preemption does not insulate prescription drug manufacturers from state failure-to-warn claims. Wyeth v. Levine was perhaps the culmination of the Court’s recent efforts at establishing a clear preemption analysis in the context of the administrative agency paradigm. Prior to Wyeth, manufacturers of both generic and innovator drugs claimed that Food and Drug Administration (FDA) regulations shielded them from state tort liability. While that argument is now clearly foreclosed for innovators, it remains an open question as to generics.

Generic manufacturers are not, nor should they be, immune from state tort liability for defective labeling practices. To begin with, the generic approval pathway requires manufacturers to comply with the same labeling regulations as their branded competitors. Furthermore, under the principles set forth in Wyeth, FDA statements to the contrary are entitled to little deference. The Court will instead interpret congressional intent, “the touchstone” of its preemption analysis.

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* University of San Francisco, J.D. candidate, 2010. Dartmouth College, B.A., 2000. Thank you to the USF Law Review editorial staff, especially Travis Manfredi, for their work on this Comment, to Professor Brian Budds for his support in the development of this topic, and to my wife, Caroline, for her patience and encouragement.

2. Id.
by construing the statutory language. Finally, the FDA faces significant limitations in its ability to monitor drug safety. State tort law provides an essential complimentary regulatory function and should continue to do so.

Part I of this comment begins by examining the state failure-to-warn cause of action. It then proceeds to review federal statutory requirements pertaining to prescription drug labeling. Finally, it reviews the FDA’s recent comments relating to the preemptive force of those regulations. Part II reviews preemption doctrine in the context of the modern agency paradigm. Part III reviews case law establishing the Supreme Court’s principles with regard to preemption. It then examines *Wyeth* in detail and looks at the effects it has had on the case for generic preemption. Finally, Part IV points out the limitations facing the FDA and details the important role state tort law plays in post-market safety regulation.

I. State Failure-to-Warn Claims & Federal Labelling Requirements

State failure-to-warn claims are at the heart of the debate over the preemptive force of FDA regulations. These claims seek to hold manufacturers responsible for their failure to adequately warn of dangers associated with a product. In the context of drugs approved by the FDA, these claims often implicate labeling modifications which the plaintiff claims should have, and could have, been made. However, both generic and innovator manufacturers rely on a reading of FDA regulations which bars unilateral label modifications. In other words, manufacturers claim it is impossible to comply with both state and federal standards. Preemption would resolve this impasse, effectively foreclosing state claims. In determining whether preemption is appropriate, it is first necessary to understand the role failure-to-warn claims play in drug regulation, as well as the federal statutory requirements that affect labeling practices.

A. State Failure-to-Warn Claims

In a broad sense, products liability is intended to ensure that the costs of injuries from defective or unreasonably dangerous products are borne by the manufacturers that produce them, rather than by the

3. *Id.* at 1194.
injured persons who may not be in a position to protect themselves.\textsuperscript{6} Failure-to-warn is one type of products liability. Failure to warn claims are based on the premise that, armed with superior knowledge, the manufacturer failed to adequately warn of the dangers associated with its product. In order to avoid liability, a manufacturer must therefore consider a number of factors in deciding when and how to warn. Those factors include the extent of the harm, the likelihood that it will arise, and the possibility that too many individual warnings will decrease their effectiveness collectively.\textsuperscript{7}

Drug manufacturers use their label as the primary vehicle to warn of the product’s dangers. For prescription drugs, the label is aimed at providing doctors and other health care professionals with information needed to make informed prescription, dosage, and administration decisions. The labeling must accurately and fairly describe the drug’s intended uses.\textsuperscript{8} It must also address the drug’s known risks, contraindications, warnings, precautions, and adverse reactions.\textsuperscript{9} As discussed further in Part I.B, the FDA regulates the content of such labels to varying degrees. Nevertheless, liability may arise under state failure-to-warn claims where, despite FDA supervision, a manufacturer armed with superior knowledge abdicates its duty to provide adequate warnings to the detriment of the consumer.\textsuperscript{10}

The availability of state failure-to-warn claims is of critical importance to persons injured by FDA-approved drugs. The Federal Food, Drug, and Cosmetic Act (FDCA)\textsuperscript{11} does not contain a cause of action for persons who are injured by unreasonably dangerous drugs. Evidently, Congress “determined that widely available state rights of action provided appropriate relief for injured consumers.”\textsuperscript{12} State claims, then, offer the only chance to recover against a drug manufacturer in a failure-to-warn situation. Should preemption foreclose these claims, injured persons are left without recourse against a drug manufacturer who failed to provide adequate label warnings.

\begin{itemize}
  \item \textsuperscript{6} Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963).
  \item \textsuperscript{7} J\textsc{oseph W. Glannon}, \textsc{The Law of Torts} 352–53 (4th ed. 2010).
  \item \textsuperscript{8} 21 U.S.C. § 355(d) (2006).
  \item \textsuperscript{9} Id. The FDA revised its labeling requirements in 2006. 21 C.F.R. §§ 201.57, 314.50, 314.80 (2006).
  \item \textsuperscript{10} Glannon, supra note 7, at 353.
  \item \textsuperscript{12} See Wyeth v. Levine, 129 S. Ct. 1187, 1199 n.7 (2009) (pointing out that although the first version of the bill would have provided a federal cause of action, witnesses testified that it was unnecessary because common-law claims were already widely available under state law).
\end{itemize}
“[T]here has been a steady stream of failure-to-warn cases brought against pharmaceutical manufacturers by consumers injured by FDA-regulated drugs.”¹³ The trend has implicated manufacturers of both innovator and generic drugs; one question is whether it should. Generic manufacturers, not having access to historical safety databases, have limited knowledge of their drug in comparison to the innovator manufacturer who developed it. If failure-to-warn claims are premised on a manufacturer’s superior knowledge, does this not create an “asymmetrical duty to consumers when compared to their branded competition”?¹⁴ The answer to this question is “no.” Generic manufacturers have the same federal statutory duty as their branded competition to adequately warn consumers of the dangers associated with their drug. A review of the complex FDA regulations pertaining to drug labeling helps shed some light on this conclusion.

B. Federal Label Regulation Under the FDCA

1. The FDA Approval Process

The FDA is charged with ensuring the safety and efficacy of drugs entering the marketplace.¹⁵ The FDCA, which grants the FDA its regulatory power, therefore prohibits the “introduction . . . [of] any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.”¹⁶ These subsections provide two different pathways for obtaining FDA approval.

Subsection (b) authorizes a New Drug Application (NDA). Drug companies seeking to introduce a new or patented innovator drug follow this process.¹⁷ The NDA must contain specific data, including full reports on the clinical trials that support the filing, specifically detailing whether the drug is “safe” and “effective” for use.¹⁸ The application must also include a specimen of the proposed label.¹⁹ Though the manufacturer independently establishes the baseline, the FDA may require modifications to the proposed label at its discretion.²⁰

¹⁵. 21 U.S.C. § 393(b).
²⁰. Murray, supra note 14, at 264.
Subsection (j) offers a more streamlined approach. Added as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), it sets forth the Abbreviated New Drug Application (ANDA) for generic drugs. Manufacturers pursuing this abbreviated application must first show that their drug is the “bioequivalent” of a drug previously approved under an NDA.

In addition, the applicant must submit a labeling specimen that duplicates the listed drug’s label. Exceptions are made to account for the manufacturer’s name, as well as differences in the “route of administration, dosage form, or strength.”

The Hatch-Waxman Amendments were implemented to increase the availability of low-cost generic drugs. Congress sought to relieve generic manufacturers of the increasing costs of the new drug development process (i.e., clinical trials). The amendments provide a generic drug approval pathway that does not demand the rigorous safety and efficacy reporting which would otherwise be required under an NDA. However, as the next section details, post-market safety duties do not vary greatly from duties associated with innovator drugs approved under an NDA.

2. Labeling Revisions Post-Approval

In order to make post-approval label revisions, manufacturers generally must submit, and the FDA must approve, a supplement describing the proposed change. One exception to this rule is the Changes Being Effected (CBE) provision. This longstanding practice was codified in 2004, following the passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The CBE provision allows a manufacturer, upon learning of a clinically significant

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22. See 21 U.S.C. § 355(j)(2)(A)(ii)–(v). Bioequivalence is determined by showing certain characteristics to be the same, including active ingredients, route of administration, dosage and strength. Id.
24. Id.
28. 21 C.F.R. § 314.70(c)(3).
hazard, to modify without prior approval its label to “add or strengthen a contraindication, warning, precaution, or adverse reaction.”30 The manufacturer does not need to wait for FDA approval of the change before distributing the revised label in the marketplace.31 The FDA will ultimately review the CBE change and either approve or reject it.32

The availability of the CBE provision to generic manufacturers is the subject of much debate.33 This debate is largely due to the FDA’s comments on the subject, which have been informal and inconsistent, as will be highlighted in Part I.B.3. The statutory language, however, is clear on the issue despite its complexity. Generic manufacturers may make changes to their label through the CBE process, just as innovators can. Several provisions in the regulations provide clarity.

First, 21 U.S.C. § 356a of the FDAMA expressly authorizes post-approval label changes to applications approved under § 355.34 Section 355 contains both the NDA process under Subsection (b) and the ANDA process under Subsection (j). As one court put it, while Congress requires “ANDA applicants to submit identical labeling to the FDA when seeking ANDA approval . . . it states that generic drug manufacturers are obligated to comply with the same CBE provisions as brand-listed manufacturers” post-approval.35

Second, in the wake of the Hatch-Waxman Amendments, the FDA promulgated 21 C.F.R. § 314.97, entitled “Supplements and other changes to approved abbreviated applications.”36 This rule provides that the holder of an approved ANDA “shall comply with the requirements of [§] 314.70 . . . regarding the submission of supplemental applications and other changes to an approved abbreviated application.”37 The “requirements of [§] 314.70”38 is a direct reference to the CBE provision.39 ANDA holders are, therefore, both au-

30. 21 C.F.R. § 314.70(c)(6)(iii)(A).
31. 21 C.F.R. § 314.70(c)(6).
32. 21 C.F.R. § 314.70(c)(7). In the case of rejection, the FDA may order the manufacturer to cease distribution of the drug with the revised label. Id.
36. 21 C.F.R. § 314.97.
37. Id.
38. Id.
39. 21 C.F.R. § 314.70(c)(3).
In addition to the CBE provision, generic manufacturers must comply with a number of ongoing safety reporting requirements. Under section 314.80, the holder of an approved ANDA must report to the FDA each adverse drug experience that is both serious and unexpected within fifteen days of receipt of that information. It also requires that ANDA holders report every other adverse drug experience at quarterly intervals for three years from the date of approval, and then at annual intervals. Furthermore, an ANDA holder must “develop written procedure for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.”

Finally, Congress addressed the ongoing responsibilities of generic manufacturers in the event the innovator manufacturer exits the market. Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), if the innovator drug approved under an NDA is no longer marketed, the holder of the first approved application under an ANDA becomes the innovator of the drug for purposes of the Act. From that point on, the initial ANDA holder’s label becomes the “model” which other generics must follow. Once again though, Congress took care to include a “rule of construction” which stated that this provision “shall not be construed to affect the responsibility of . . . the holder of the approved [ANDA] application to maintain its label in accordance with existing requirements, including . . . [section] 314.70.” This, of course, is one more explicit reference to a generic manufacturer’s responsibility to comply with the CBE provision.

The statutory requirements promulgated under the FDCA, the Hatch-Waxman Amendments, and the FDAMA are, to be sure, complex. Upon careful analysis, however, it is apparent that Congress has intentionally, and repeatedly, crafted provisions which require generic manufacturers to comply with the CBE provision, as well as numerous other ongoing reporting and surveillance requirements. These requirements have important implications for a preemption analysis. It

41. 21 C.F.R. § 314.80(c)(1)(i).
42. 21 C.F.R. § 314.80(c)(2)(i).
43. 21 C.F.R. § 314.80(b).
45. Id.
is clearly possible for generic manufacturers to modify their label in response to post-market safety information. While there remain policy arguments challenging whether that practice is wise, where the language of a regulation is clear the courts have no warrant to rewrite it in the “guise of ‘interpretation.’”

3. Evolving FDA Views on Preemption

The statutory language holding generic manufacturers accountable for the CBE provision has been consistent. On the other hand, the FDA’s views have varied. Historically, the FDA has taken a position that its regulation of drugs did not preempt state failure-to-warn claims. As recently as 1998, the FDA stated that it did not believe that state tort law would cause “the development of standards that would be at odds with the agency’s regulations.” It expressed this position in numerous statements detailing the important role products liability plays in consumer protection.

The tune began to change in 2002, when the FDA intervened on behalf of drug manufacturers in a handful of products liability cases. Then, in 2006, the FDA issued new regulations regarding the content of drug labels. In the preamble to those regulations, the FDA declared that the FDCA establishes both a “floor” and a “ceiling” so that “FDA approval of labeling . . . preempts conflicting or contrary State law.” The preamble further stated that failure-to-warn claims “threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.” Finally, on January 18, 2008, the FDA published another preamble. In a footnote to that preamble, the FDA stated that “CBE changes are not available

48. Id. at 1202.
49. Id. at 1202 n.10 (quoting Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules, 59 Fed. Reg. 3,944, 3,948 (Jan. 27, 1994)); see also Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,437 (Jun. 26, 1979) (“It is not the intent of FDA to influence the civil tort liability of the manufacturer.”).
52. Id. at 3934–35.
53. Id. at 3935.
for generic drugs approved under an abbreviated new drug application.\textsuperscript{54}

None of these statements or actions by the FDA carries the force of law.\textsuperscript{55} They are also “at odds with what evidence we have of Congress’ purposes,” and they reverse “the FDA’s own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA’s regulation of drug labeling . . . .”\textsuperscript{56} As will be discussed further in Part I.B, such unsupported, informal statements are not entitled to judicial deference. Accordingly, the courts have deemed them to have little merit, choosing instead to interpret the clear statutory construction of the FDCA as the proper representation of Congress’s intent.\textsuperscript{57}

II. Preemption and the Agency Paradigm

The past two decades have seen a marked increase in the debate over federal preemption of state tort law. Beginning with \textit{Cipollone v. Liggett Group, Inc.}\textsuperscript{58} in 1992, the Supreme Court has fostered much of the debate with frequent rulings on the subject, especially in the context of products liability and administrative agency law.\textsuperscript{59} As Catherine Sharkey put it, “[p]reemption is the fiercest battle in products liability litigation today.”\textsuperscript{60} Fortunately, \textit{Wyeth} and the cases leading up to it have provided some clarity.\textsuperscript{61} In order to better understand this recent jurisprudence, it is helpful to review the underpinnings of preemption doctrine through the lens of the modern agency paradigm.

\textsuperscript{54}. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 n.1 (Jan. 16, 2008).

\textsuperscript{55}. 21 C.F.R. § 10.85(d)(1) (2009) (stating that preambles to proposed or final regulations are considered advisory opinions and lack the force of law).


\textsuperscript{57}. Why the change in position, then, particularly one veiled in perambulatory statements and footnotes? One intriguing explanation was offered by U.S. Rep. Henry Waxman. David G. Savage, \textit{Memos Shed Light on Drug Lawsuit Dispute}, \textit{L.A. Times}, Oct. 30, 2008, at A18. On Oct. 29, 2008, shortly before oral arguments were to be heard for \textit{Wyeth}, Rep. Waxman released documents detailing a dispute in the FDA’s management between permanent staff and Bush administration appointees over preemption. \textit{Id.} Critics saw this as proof that the Bush administration was behind the recent shift in the FDA’s stance on preemption. \textit{Id.} It is a matter of speculation whether the \textit{Wyeth} Court took this into account in effectively dismissing the 2006 preamble. \textit{Id.}


\textsuperscript{61}. See cases cited supra note 59.
A. Preemption Doctrine

Preemption finds its roots in the Constitution. The Supremacy Clause of Article VI states that:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . 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 . . . Laws of any State to the Contrary notwithstanding.  

Historically, this language has been interpreted to mean that, where conflict arises between federal law and state law, federal law shall prevail. It is also understood to empower Congress to proactively invalidate state law in those areas which it feels should be subject to exclusive federal regulation.

The Court has identified three types of preemption. First, Congress can enact legislation which explicitly articulates that any state law is preempted by the federal law. This type is known as “express” preemption. Second, preemption occurs when Congress legislates so comprehensively in a field that it is reasonable to infer that Congress has left “no room” for state law. This type is known as “field” preemption. Finally, preemption may occur where there is actual conflict between the state and federal law. This type is known as “conflict” preemption.

Conflict preemption can occur in two ways. First, it is implicated when it becomes physically impossible to comply with both federal and state law. This subtype has been called “impossibility” preemption. As the standard suggests, impossibility preemption is a demanding defense. Second, conflict preemption may arise where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” This subtype has been called “obstacle” preemption. Together, field preemption and

62. U.S. CONST., art. VI, cl. 2.
66. Id. at 226–27.
67. Id.
69. Unlike nuclear power, courts have not recognized prescription drug regulation as such a field. Id. at 716.
70. Bhagwat, supra note 64, at 199–200.
72. Bhagwat, supra note 64, at 199–200 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).
these two forms of conflict preemption comprise what is referred to as “implied” preemption. It is this doctrine which is subject to much of the debate over preemption of state tort law in the context of prescription drugs.

The Supreme Court has established two principles which currently guide its interpretation of these preemption doctrines. First, the touchstone of the analysis in every preemption case is congressional intent. In the case of express preemption, this necessarily entails an interpretation of the statutory language.

By contrast, implied preemption demands a more nuanced approach, as Congress has not spelled out its intent. Recognizing the risks inherent in such an analysis, the Court has resolved to interpret congressional intent while maintaining a presumption against preemption. Under this principle, the Court “start[s] 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.” With its thumb firmly on the scale, the Court will then consider the “substance” of the state and federal law to assess whether conflict exists.

B. The Agency Paradigm

Preemption doctrine initially developed in a different administrative environment than that which is prevalent today. In the past, federal law was primarily created by Congress; today most federal law is the product of administrative agencies. Congress typically passes a statute with varying degrees of specificity and then empowers an administrative agency such as the FDA to apply the statute through regulations. This paradigm shift implicates both express and implied preemption doctrines, as the “touchstone” of Congressional intent must often be discerned through the words and actions of an agency.

Contributing to the ambiguity, agencies become implicated in the preemption analysis in several ways. For example, when Congress passed the Medical Device Amendments of 1976 (MDA), it included an express preemption clause and charged the FDA with implement-
This form of express preemption is generally afforded great deference, though the Supreme Court has not yet established clear guidance.\(^{79}\) In another scenario, through rulemaking power specifically granted by Congress, an agency may create a substantive regulation that conflicts with a state law.\(^{80}\) The Court has recognized that so long as such regulations are vested with the force of law, they can preempt conflicting state requirements.\(^{81}\)

Finally, agencies may become implicated in the preemption analysis when they express their views on preemption in the absence of express congressional direction. Such informal assertions, often provided in regulatory preambles or in amicus briefs, have been granted different levels of deference by the Court. As Justice Stevens noted in Wyeth, “[t]he weight we accord the agency’s explanation of state law’s impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.”\(^{82}\)

Two primary levels of deference to agency views on preemption have developed. The first, and strongest, level is *Chevron* deference.\(^{83}\) Under this two-pronged analysis, the Court will first determine if the statutory construction is ambiguous.\(^{84}\) If it is, the Court will defer to the agency’s viewpoint so long as that viewpoint is reasonable.\(^{85}\) If the statute is not ambiguous, there can be only one interpretation, and the agency’s viewpoint will be deemed either correct or incorrect based upon that interpretation.\(^{86}\) In the past, the Supreme Court has been willing to grant *Chevron* deference to the FDA’s stated views on

\(^{79}\) Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.); 21 U.S.C. §360k(a) (2006). The subsection states in part: “no State . . . may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device . . . .” *Id.*


\(^{81}\) Bhagwat, *supra* note 64, at 202.


\(^{84}\) *Id.* at 842–43.

\(^{85}\) *Id.*

\(^{86}\) *Id.*

\(^{87}\) *Id.*
preemption. However, as evidenced in *Wyeth*, the Court is clearly leaning towards a more limited standard.

The second level of deference that has developed is *Skidmore* deference. This standard grants an indeterminate amount of deference ranging “anywhere on a sliding scale from very little to practically *Chevron* deference.” The Court considers the “thoroughness evident in [an agency’s] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade . . . .”

Imbedded in the *Skidmore* analysis is the question of whether the agency “[sought] to embody those determinations in lawful specific regulations.” Perambulatory declarations and footnotes, in which the FDA has recently declared its views on preemption, do not carry the force of law. Consequently, the Court will respect the agency’s position expressed in such a manner only to the extent it has the power to persuade.

### III. Case Law: Preemption of State Tort Claims

The preceding two sections frame the issues presented to the Supreme Court in recent preemption cases. Though some preemption cases involve federal regulation of products like cigarettes and medical devices, the reasoning applies equally to prescription drugs. Culminating in *Wyeth*, the Court established several clear principles with regard to federal regulation of health and safety. Using those principles as guideposts, it is apparent that preemption is not currently a viable defense for generic drug manufacturers facing state failure-to-warn claims.

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92. *Skidmore*, 323 U.S. at 140.
93. *Wyeth*, 129 S. Ct. at 1294 (Breyer, J., concurring). In his concurring opinion, Justice Breyer wrote that the Court should be prepared to defer to the FDA’s views on preemption if those views are expressed with the force of law. *Id.*
A. Establishment of Guiding Principles: Cases Leading Up to Wyeth

1. Cipollone v. Liggett Group, Inc. 96

In this landmark case, the Court dealt with products liability claims brought against cigarette manufacturers. Specifically, the Court considered whether an express preemption clause in the Federal Public Health Cigarette Smoking Act of 1969 (FPHCSA) preempted state failure-to-warn claims. 97 Attentive to the historic primacy of state law regarding public health, the Court applied the presumption against preemption despite the FPHCSA’s express language to the contrary. 98 The Court also announced its position that, where express preemption applies to a field of traditional police power, a narrow reading of the preemptory language is appropriate. 99 Despite these presumptions, the Court held that state failure-to-warn claims with respect to cigarette warning labels were preempted by the express language of the FPHCSA. 100

2. Medtronic, Inc. v. Lohr 101

In Lohr, the Court addressed express preemption in the context of the MDA. 102 Unlike the FDCA, the MDA contains an express preemption clause. 103 The plaintiff’s state failure-to-warn claim was based on an injury from a malfunctioning pacemaker. 104 Significantly, the device was approved under the MDA’s “substantial equivalence” provision, a fast-track approval akin to the ANDA. 105 The provision allowed the manufacturer to obtain approval by a showing of substantial similarity to a Class III device already on the market. 106 Much like a generic drug, no evidence-based safety inquiry was performed by the FDA. Claiming a lack of oversight, the Court held that state products

98. Id. at 518-20.
99. Id. at 518.
100. Id. at 524-25.
102. See id.
104. Lohr, 518 U.S. at 480-81.
106. Id.
liability claims were not in conflict with federal regulation, despite an express preemption clause.107

This holding has significant implications for a generic drug preemption defense. The Court was willing to disregard an express preemption clause in the absence of meaningful federal regulation. Extending this logic to the ANDA, which provides no such indication of congressional intent, it is hard to see how the Court would not come to the same conclusion.


In Geier, the Court dealt with preemption in the context of the agency paradigm. It detailed what some commentators believe to be a path forward for preemption claims based upon robust and calculated FDA decision-making.109 Geier involved the National Traffic and Motor Vehicle Safety Act of 1966,110 which was administered by the federal Department of Transportation (DOT). The plaintiff claimed to have been injured by Honda’s failure to provide a passenger side airbag. Honda, in turn, argued that the DOT’s decision to allow airbags to be phased in over time should have preemptive force.111 The Court agreed, holding that state products liability claims were inconsistent with the DOT’s carefully reasoned decision regarding the introduction of side airbags.112

The case provides a nice counterpoint to Lohr.113 Where Lohr is at one end of the spectrum, representing the Court’s unwillingness to extend preemption in the event of minimal regulatory oversight, Geier is at the other end. That is, when an agency’s decisions with regard to safety are grounded in a thorough risk/benefit analysis, the Court is willing to extend preemption over state claims.114 The FDA’s regulatory oversight of generic drugs currently resides at the Lohr end of the spectrum.115

107. Lohr, 518 U.S. at 500–01.
111. Geier, 529 U.S. at 865.
112. Id. at 874.
114. Id.; Geier, 529 U.S. at 868.
115. Lohr, 518 U.S. 470.
4. **Riegel v. Medtronic, Inc.**

The final preemption case leading up to *Wyeth* is *Riegel*. In that case, the plaintiff’s state products liability claim was based on a ruptured balloon catheter. Unlike the device in *Lohr*, this particular catheter had been approved through the MDA’s stringent Class III approval process. Much like an NDA applicant, the device manufacturer was required to provide extensive safety and efficacy data at the approval stage. This requirement provided for the risk/benefit analysis found wanting in *Lohr* and led the Court to construe the MDA’s preemption clause to foreclose the plaintiff’s claim.

*Riegel* demonstrates that Congress does have the ability and wherewithal to foreclose state products liability claims. Building on the principles of *Cipollone*, the Court will apply a presumption against preemption even in the face of an express preemption clause. It will then interpret congressional intent by weighing the level of regulatory oversight against the requirements of state law. In the event of cursory safety regulation, i.e., the MDA’s substantial equivalence provision, preemption will not apply. However, should the agency regulations provide for extensive risk/benefit analysis, as was the case in *Geier* and *Riegel*, state products liability claims may be found to “disrupt the federal scheme” and thus be foreclosed.

**B. The *Wyeth* Decision: Application of Recent Principles to the FDCA**

Diana Levine, the plaintiff in *Wyeth*, was a professional musician living in Vermont. She suffered from severe migraine headaches that often caused her to feel nauseous. On April 7, 2000, she visited her local clinic requesting treatment. She was initially given an in-

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117. Id. at 320.
118. Id. at 317 (referring to 21 U.S.C. § 360c(a) (1) (C)(ii) (2006)).
119. Id. at 317–18.
120. Id. at 330.
121. That is not to say *all* of Congress agreed that the aim of the MDA’s preemption clause was to foreclose products liability claims. Indeed, the sole Senate sponsor of the legislation in question, the late Edward M. Kennedy, responded to the decision by stating: “Congress never intended that F.D.A. approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices.” Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, N.Y. Times, Feb. 21, 2008, at A1.
124. Id.
125. Id.
tramuscular injection of Phenergan, a drug manufactured by defendant Wyeth. When this treatment didn’t relieve her nausea, she was given a second administration, this time using an “IV-push” method whereby the drug was injected directly into her vein. Unfortunately, the drug was inadvertently injected into Ms. Levine’s artery. When mixed with arterial blood, Phenergan is known to cause gangrene, which Levine developed. Doctors were forced to amputate her right arm up to the elbow in order to save her life.

Levine sued her clinic for malpractice and eventually settled the case. She also brought a state failure-to-warn claim against Wyeth. Wyeth responded with a conflict preemption defense, which the trial judge rejected. The jury found for Levine, awarding her $7,400,000 in damages. The Vermont Supreme Court affirmed the verdict, once again rejecting Wyeth’s preemption defense. Wyeth appealed the decision to the Supreme Court, which granted certiorari on the issue of preemption.

At the heart of Levine’s failure-to-warn claim was the proposition that Wyeth knew of the dangers associated with IV-push administration of Phenergan but failed to adequately update the drug’s label to warn of those dangers. As the Court noted, despite evidence of “at least 20 incidents prior to [Levine’s] injury in which Phenergan injec-

126. Id.
127. Id.
128. Id.
129. Id.
130. Id.
131. Id. Both the physician who administered the injection and the assistant who dismissed Levine’s subsequent complaints of discomfort admitted fault and settled for an undisclosed sum. Id. at 1218 n.3. They each then agreed to testify against Wyeth in the ensuing failure-to-warn action. Id.
132. Wyeth, 129 S. Ct. at 1192.
133. Id. at 1193.
134. Id.
135. Id. at 1194.
136. The jury’s conclusion as to the inadequacy of the label could be questioned. The label read in part:
   Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid . . . inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection . . . suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances.

Id. at 1191 n.1.
tion resulted in gangrene and an amputation,” Wyeth had not sought, nor had the FDA precluded, a stronger warning.\textsuperscript{137}

Wyeth advanced two preemption defenses before the Supreme Court.\textsuperscript{138} First, Wyeth claimed that it was impossible to comply with both the FDCA and the requirements placed on it by Vermont state law.\textsuperscript{139} Second, Wyeth argued that even if it were possible to comply with both laws, doing so would be an obstacle to the accomplishment of the objectives of Congress in enacting the FDCA.\textsuperscript{140}

The majority first rejected Wyeth’s impossibility defense, pointing out that as the holder of an approved NDA, Wyeth had access to the CBE provision of the FDCA.\textsuperscript{141} When the risk of gangrene became apparent, Wyeth acquired a state-law duty to provide a warning that adequately described that risk.\textsuperscript{142} The CBE provision permitted it to provide such a warning without running afoul of the FDCA, thus satisfying both its state and federal requirements.\textsuperscript{143}

The majority then rejected Wyeth’s obstacle defense. The Court began by noting that Congress (i) had never provided a federal cause of action for consumers injured by FDA-approved drugs, and (ii) had never sought to include an express preemption clause during the FDCA’s seventy-year history.\textsuperscript{144} As Justice Stevens pointed out, “[i]f Congress thought state-law tort suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point . . . .”\textsuperscript{145} The majority then turned to the 2006 FDA preamble (discussed supra in Part I.B.3), which Wyeth pointed to as evidence that state law would obstruct the FDA. Applying the \textit{Skidmore} standard, the Court concluded that the FDA’s statements did not merit deference.\textsuperscript{146}

\textit{Wyeth} thus stands for the proposition that state failure-to-warn claims are not implicitly preempted by the FDCA. The holder of an approved NDA can comply with a state duty to warn through the CBE provision without violating federal law. Informal FDA statements to

\begin{itemize}
\item[\textsuperscript{137}] \textit{Id.} at 1197.
\item[\textsuperscript{138}] \textit{Id.} at 1193. Wyeth also raised a field preemption defense in state court but later dropped it. \textit{Id.} at 1192.
\item[\textsuperscript{139}] \textit{Id.} at 1193.
\item[\textsuperscript{140}] \textit{Id.}
\item[\textsuperscript{141}] \textit{Id.} at 1199.
\item[\textsuperscript{142}] \textit{Id.} at 1198.
\item[\textsuperscript{143}] \textit{Id.}
\item[\textsuperscript{144}] \textit{Id.} at 1199–200.
\item[\textsuperscript{145}] \textit{Id.} at 1200.
\item[\textsuperscript{146}] \textit{Id.} at 1201.
\end{itemize}
the contrary lack controlling merit and will not be considered by the Court. Rather, Congress’s decision not to include an express preemption clause in the FDCA throughout its long co-existence with state failure-to-warn law is considered determinative of its intent to retain this important cause of action for consumers.

C. Applying Wyeth to Generic Drug Manufacturers

Would the Court apply the same analysis to the holder of an ANDA? It seems the answer is “yes.” The principles laid out in Wyeth apply equally to claims derived from injuries caused by either innovator or generic drugs.147 This conclusion is well founded, both in the statutory construction of the FDCA, as well as the Supreme Court’s analysis of agency preemption doctrine. It is also supported by a string of recent cases in which lower courts have ruled that state defective labeling claims against generic manufacturers are not preempted by the FDCA.148

One of those cases, Bartlett v. Mutual Pharmaceutical Co.,149 provides a summary of the analysis. In Bartlett, the plaintiff claimed to have suffered serious injuries after taking a nonsteroidal anti-inflammatory drug marketed by Mutual under an approved ANDA.150 Specifically, the plaintiff claimed that Mutual, upon obtaining information suggesting a clinically significant link to its product and toxic epidermal necrolysis, acquired a state-law duty to warn of that danger by updating its label.151

Mutual filed a motion for judgment on the pleadings arguing that the Hatch-Waxman Amendments implicitly preempted the plaintiff’s state law claims.152 Mutual first pointed to the FDA’s “same labeling”153 requirement under 21 C.F.R. § 355(j) as prohibiting the manufacturer from making unilateral label changes.154 It also put forth an obstacle defense, arguing the FDA’s 2008 preamble regard-

147. Phenergan was approved by the FDA in 1955 under the NDA process. Id. at 1191. The drug has lost its patent protection, and many generic forms exist. Ms. Levine received the branded drug by chance.
150. Id. at 282.
151. Id.
152. Id. at 290
ing the unavailability of the CBE process to generic manufacturers was
determinative of Congressional intent.\textsuperscript{155}

In denying Mutual’s motion, the court ruled that the Hatch-Wax-
man Amendments did not explicitly or implicitly preempt the plain-
tiff’s state law claims.\textsuperscript{156} According to the court, the “same labeling”
requirements only apply at the approval stage.\textsuperscript{157} It pointed to 21
U.S.C. § 356a of the FDAMA as expressly authorizing post-approval
label changes to any applications approved under 21 U.S.C. § 355, in-
cluding subsection (j) generics.\textsuperscript{158} Next, the court noted that 21
C.F.R. § 314.97 mandates that holders of an approved ANDA comply
with the requirements of section 314.70, which includes the CBE pro-
vision.\textsuperscript{159} Finally, relying on \textit{Wyeth}, the Court noted that the FDA’s
recent perambulatory statements to the contrary are entitled to little
deferece given their informal venue and lack of persuasiveness.\textsuperscript{160}

The holdings in \textit{Mutual} and many similar cases indicate a grow-
ing consensus in the lower courts. In following the principles of \textit{Wyeth}
to their logical conclusion, courts are finding that state failure-to-warn
claims against generic manufacturers are not impliedly preempted by
the Hatch-Waxman Amendments. If the Supreme Court were to grant
certiorari on the issue, which seems unlikely given this consensus,
there is no reason to believe that the outcome would be different.

\textbf{IV. The Importance of Tort Law: Why Congress Should Not
Expressly Preempt State Failure-to-Warn Claims}

Perhaps recognizing the validity of this judicial posture that state
failure-to-warn claims against generics are not impliedly preempted,
some members of Congress have lobbied to include express preemp-
tion language in the FDCA with regard to generic drugs. During the
debate over the Patient Protection and Affordable Care Act, Senator
John Cornyn (R-TX) filed an amendment that would preempt state
products liability claims against generic drug manufacturers.\textsuperscript{161}

\textsuperscript{155.} \textit{Id.} at 307.
\textsuperscript{156.} \textit{Id.} at 309.
\textsuperscript{157.} \textit{Id.} at 294.
\textsuperscript{158.} \textit{Id.} at 293–94.
\textsuperscript{159.} \textit{Id.} at 298.
\textsuperscript{160.} \textit{Id.} at 303.
\textsuperscript{161.} Kurt R. Karst, \textit{Another Court Rules Against Preemption in Generic Drug Case; Cornyn
Preemption Amendment Would Shield Generic Manufacturers from Liability}, FDA L. Blog (Oct. 5,
2009), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2009/10/another-court-
rules-against-preemption-in-generic-drug-case-cornyn-preemption-amendment-would-
shield.html (blog written by Hyman, Phelps & McNamara, P.C.).
Though the amendment was eventually stricken, President Obama has indicated an openness to tort reform, and the possibility of securing such a change does not seem unlikely.\textsuperscript{162} Indeed, polls at the time indicated that eighty-three percent of Americans wanted tort reform included as part of health care reform.\textsuperscript{163} Modifying the FDCA to protect generic manufacturers from liability in the name of lower drug costs thus might still prove to be a political win-win.

For a number of reasons, this path would not be wise. As this Section will illustrate, there are significant limitations with regard to the FDA’s current regulatory paradigm. A comprehensive determination of drug safety is simply not guaranteed and is often avoided by the traditional clinical trial process. Additionally, the FDA lacks the resources to adequately monitor the post-market environment. State tort law, therefore, serves an essential regulatory function: bringing new safety information to light, compelling documentation where the FDA cannot, and providing a remedy for injured patients. As former FDA Commissioner David Kessler put it, “[t]he case for preemption must be examined in light of a clear-eyed appraisal of the FDA’s ability to assure the safety of the drugs being marketed in the United States.”\textsuperscript{164}

\textbf{A. Clinical Trials Do Not Guarantee Safety}

There is growing consensus in the scientific community that clinical trials have intrinsic limitations that restrict their ability to ensure the safety of FDA-approved drugs.\textsuperscript{165} This problem is evidenced in several high-profile drug safety events which have occurred over the past decade.\textsuperscript{166} The widely held belief that FDA regulation at the approval stage was comprehensive and involved a conclusive risk/benefit analysis was incorrect.\textsuperscript{167} As Barbara Evans notes, while clinical trials

\begin{itemize}
  \item \textsuperscript{163} Id.
  \item \textsuperscript{164} Kessler & Vladeck, \textit{supra} note 13, at 483.
  \item \textsuperscript{166} Id. at 429–30 (mentioning Vioxx, fulminant liver failure with troglitazone (Rezulin), suicidal ideation in youngsters taking antidepressants (selective serotonin reuptake inhibitors), rhabdomyolysis and kidney failure in people taking cholesterol-lowering cerivastatin (Baycol), cardiac problems with the antihistamines astemazole (Hismanal) and terfenadine (Seldane), and a suite of health risks for women using hormone replacement therapy).
  \item \textsuperscript{167} Id. at 428.
\end{itemize}
“are correctly regarded as the highest-quality evidence of drug efficacy. . . . the same may not be true with respect to drug safety.”¹⁶⁸

To begin with, pre-market clinical trials, even those that contain several thousand subjects, are too small to detect relatively rare adverse events.¹⁶⁹ This problem masks safety issues which may present themselves only when the drug is marketed to a much larger population. Experts have estimated that a typical Phase III trial, the largest the FDA requires for approval, can detect drug-related injuries that occur at a rate of between one in five hundred and one in one thousand.¹⁷⁰ Thus, an unexpected adverse event occurring at a rate of one in one thousand, extremely serious in the broader population, might be picked up just a few times in the course of a study, if at all. In such a case, there is little chance the risk will be included on the drug’s label, despite the danger it poses.

In addition to being too small, clinical trials are too short to detect long-term risks. While a typical Phase III trial lasts one to four years, only a few hundred subjects receive the investigational new drug for longer than six months.¹⁷¹ Due to high dropout rates related to the physical and mental exertion of the trial, or even subject mortality, drug companies are often powerless to extend this timeframe.¹⁷² As such, only the most profound and overt side-effects that occur immediately after taking a drug are detected.¹⁷³

Finally, clinical trials are not representative of the larger population to which the drug will be marketed. An investigational new drug is tested on subjects who are least likely to suffer adverse events. Drug companies deliberately exclude vulnerable subpopulations such as the elderly, children, and pregnant women.¹⁷⁴ Certainly, this strategy is taken for commercial reasons, i.e., to produce a better safety profile for filing purposes. It is also taken for ethical reasons. If the company suspects that a particular subpopulation may be vulnerable to its drug, exposing those subjects to heightened risk may be unethical.¹⁷⁵

The FDA’s recent statements on the preemptive force of its oversight do not square with these realities. If state products liability claims are to be foreclosed after FDA approval, as suggested, implicit in that

¹⁶⁸. Id. at 435.
¹⁶⁹. Id. at 444–45.
¹⁷¹. Evans, supra note 165, at 446.
¹⁷². Id. at 454.
¹⁷³. Id. at 453–54.
¹⁷⁴. See Schultz, supra note 170.
¹⁷⁵. Evans, supra note 165, at 475.
statement is a declaration that safety has been comprehensively determined. As noted above, that is simply not the case. This issue is especially problematic in the case of generic drugs, whose safety at ANDA approval is premised on the innovator’s clinical trial data.

B. The FDA Does Not Have Resources for Effective Post-Market Surveillance

Recognizing many of these limitations, Congress passed the FDAAA.\textsuperscript{176} The FDAAA transforms the evidentiary basis of drug regulation by the FDA.\textsuperscript{177} Specifically, it envisions a heightened reliance on large observational safety studies and interconnected health databases in the post-market environment.\textsuperscript{178} The FDAAA adds much needed resources and provides the agency with greater authority to oversee drug safety post-approval.\textsuperscript{179}

While the FDAAA is a step forward, the agency faces a difficult and lengthy task in implementing this complex scheme. In the meantime, the fact remains that the FDA’s current ability to monitor safety remains limited. According to testimony at a 2005 Senate hearing, while the FDA had over one thousand employees reviewing NDAs, the group charged with monitoring the safety of the three thousand prescription drugs on the market had only one hundred employees.\textsuperscript{180} Given the limitations of clinical trials to effectively identify risks to patients, the FDA’s limited resources in the post-market environment heighten the chances that those risks will not be discovered until they harm a significant number of patients.

C. State Tort Law Helps Fill the Gap

In light of these shortcomings, state tort law provides an essential regulatory function by indentifying rare and unknown adverse events in the post-market environment. As the Supreme Court has noted, state tort law often informs labeling decisions by aiding in the “exposure of new dangers” that then prompt the FDA to decide that revised labels are required.\textsuperscript{181} Drug manufacturers too, may decide to investi-

\begin{itemize}
\item \textsuperscript{176} Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.
\item \textsuperscript{177} Evans, supra note 165, at 419.
\item \textsuperscript{178} Id.
\item \textsuperscript{179} Kessler & Vladeck, supra note 13, at 484–85.
\item \textsuperscript{180} Id. at 485 (citing Ensuring Drug Safety: Where Do We Go From Here?: Hearing Before the S. Comm. on Health Educ., Labor and Pensions, 109th Cong. 42 (2005) (statement of Dr. Bruce S. Psaty)).
\end{itemize}
gate these new or underreported risks. In order to avoid further liability and to make their product safer, manufacturers may decide to pursue an updated label. Alternatively, the risk/benefit calculus may not merit a change for rare adverse events. In such a case, drug companies will continue to be liable for injuries sustained by this limited population.

State tort law also provides attorneys with information-gathering tools to which the FDA does not have access. The most important of these, the power to subpoena information from any source, is not authorized by the FDCA.\textsuperscript{182} Plaintiffs, then, are often in a better position than the FDA to investigate company records with regard to safety information. This is critical, as manufacturers often resist labeling changes due to emerging safety concerns.\textsuperscript{183}

In their essay, David Kessler and David Vladeck identify an example to illustrate this point. During the Vioxx litigation, plaintiffs’ attorneys uncovered internal company memos and emails which showed that Merck was aware of emerging cardiovascular injuries related to Vioxx.\textsuperscript{184} Senior Merck scientists suggested that the data would “kill [the] drug” and that studies should be carefully designed so the problems “would not be evident.”\textsuperscript{185} These memos were not provided to the FDA, nor were they available through the FDCA.\textsuperscript{186} Only the state failure-to-warn claim brought them to light.

A final point on the important regulatory function of state tort claims is the effect they have on industry practices. Without the safety net of preemption, drug manufacturers are encouraged to investigate emerging safety data more thoroughly. Indeed, one of the key holdings coming out of \textit{Wyeth} is that conflict preemption remains a viable defense where the FDA has fully considered a label change and rejected it.\textsuperscript{187} In that case, both Wyeth and the FDA engaged in what could be best described as disinterested efforts to address Phenergan’s

\textsuperscript{182} Kessler & Vladeck, supra note 13, at 492.
\textsuperscript{183} \textit{Id.} at 480.
\textsuperscript{184} \textit{Id.} at 493.
\textsuperscript{185} \textit{Id.} at 493.
\textsuperscript{186} \textit{Id.} at 492–93.
\textsuperscript{187} \textit{Wyeth v. Levine,} 129 S. Ct. 1187, 1198 (2009) (noting that “absent clear evidence that the FDA would not have approved a change to [the] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements,” which suggests that the impossibility defense is viable when clear evidence of FDA rejection is available).
The lesson seems to be that more robust safety surveillance combined with consistent and well-documented communication with the FDA serve drug manufacturer interests in avoiding liability. Such heightened vigilance, of course, ultimately benefits the patient as well.

D. Preemption and the Cost of Generic Drugs

Perhaps the most frequently cited argument for preemption in the context of prescription drugs, and generic drugs in particular, is that state tort liability drives up costs, which are then transferred to the consumer. This effect frustrates the purpose of the Hatch-Waxman Amendments, which were implemented to provide greater access to affordable medicines. As such, obstacle preemption should preclude state liability for generic manufacturers. This argument is flawed.

The underlying premise, that the Hatch-Waxman Amendments were designed to produce inexpensive drugs at all costs, is incorrect. Between 1962 and 1980, the cost to develop a new drug from concept to approval rose from $6.5 million to $70 million. By 2006 that cost had mushroomed to over $1 billion, with the majority of the increase attributed to the costs of pre-approval clinical trials. Recognizing that a showing of bioequivalence in many cases could stand in for these trials, Congress pursued the Hatch-Waxman Amendments as a vehicle of relieving generic manufacturers of that particular burden.

Nothing in the regulatory history suggests that Congress also sought to relieve generic drug manufacturers of post-market safety costs. In fact, as already examined, the FDCA imposes significant ongoing duties, including the establishment of “written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.” All of these requirements

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188. Id. at 1198–99 (noting that Wyeth initially learned of the dangers of administering Phenergan via the IV-push method in 1967, and that both Wyeth and the FDA gave the risk no more than “passing attention”).


191. For skepticism about these empirical assumptions, see Michelle M. Mello & Troyen A. Brennan, Legal Concerns and the Influenza Vaccine Shortage, 294 JAMA 1817 (2005).


193. Evans, supra note 165, at 424.


195. 21 C.F.R. § 314.80(b) (2009).
naturally impose costs on generic drug makers.\textsuperscript{196} In enacting the Hatch-Waxman Amendments, Congress nevertheless chose to retain them for their public safety value.

Correlatively, there is no unavoidable principal that cost efficiencies achieved by preempting generic manufacturers from state failure-to-warn claims should be “borne by injury victims.”\textsuperscript{197} Preemption in the name of reduced generic drug costs would necessarily foreclose an injured patient’s one chance at compensation. If Congress had intended as much, and thought such efficiencies were worth the price, it “surely would have expressed that intent” with express preemption language.\textsuperscript{198} Of course, Congress did no such thing. It chose instead to retain state tort liability as a much-needed avenue of redress for patients injured by the negligence of generic drug manufacturers.

\textbf{Conclusion}

This Comment set out to answer two questions. First: After \textit{Wyeth} can generic drug manufacturers rely on implied conflict preemption to shield them from state failure-to-warn claims? Second: If these manufactures cannot rely on preemption, should Congress act to insulate them from liability in order to maintain cost efficiency? A detailed review of the FDCA and the relevant case law, as well as a realistic assessment of the FDA’s capabilities produces clear answers. Generic manufacturers are not, nor should they be, immune from state tort liability for defective labeling practices.

Congress has been consistent on the issue. The FDCA and the Hatch-Waxman Amendments apply significant safety follow up mechanisms to the generic approval pathway. Post-approval labeling practices essentially mirror that of innovator drugs. At the same time, Congress has chosen not to shield generic manufacturers from state tort law, despite acknowledging its potential to increase drug prices. The Supreme Court has interpreted these actions—and not unsupported FDA statements to the contrary—as the true representations of congressional intent.

Increasing the availability of affordable, effective drugs is an important goal. Just as important is ensuring that mechanisms are in place to ensure the safety of those drugs. Given the limitations in the

\begin{footnotes}
\item[196] Bartlett, 659 F. Supp. 2d at 307.
\item[197] Rabin, supra note 109, at 993.
\item[198] Bartlett, 659 F. Supp. 2d at 309.
\end{footnotes}
FDA’s ability to monitor post-market safety, it is therefore critical to retain functions which bring new safety events to light. State tort law provides that regulatory function and should continue to do so.