Are State Law Tort Claims Against Generic Drug Manufacturers Always Preempted by Federal Law? Why the Fourth Circuit Was Wrong in Saying Yes in Drager v. PLIVA USA, Inc.

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ARE STATE LAW TORT CLAIMS AGAINST GENERIC DRUG MANUFACTURERS ALWAYS PREEMPTED BY FEDERAL LAW?

WHY THE FOURTH CIRCUIT WAS WRONG IN SAYING YES

DRAGER v. PLIVA USA, INC., 741 F.3d 470 (4TH CIR. 2014)

Benjamin A. Hooper

I. INTRODUCTION

Envision yourself going to the emergency room because you are suffering from a bad stomachache and bouts of nausea. Without telling you, the nurse injects you with an anti-nausea drug to alleviate your symptoms. This injection then results in a gangrene infection that ultimately concludes with the necessary amputation of your arm. When you try to bring suit against the drug manufacturer for a faulty warning label, the case is dismissed on federal preemption grounds, leaving you with no recourse. You later discover that you were injected with a generic form of the anti-nausea drug rather than the brand-name version, and this distinction alone resulted in your case’s dismissal. This is the situation that Debbie Schork found herself in after she was injected with promethazine, the generic form of Phenergan.1

Schork’s nurse properly injected the anti-nausea medicine directly into her arm, but accidently inserted the medicine into her artery while doing so.2 This error ultimately resulted in the loss of her arm.3 She brought suit against the manufacturers of the generic drug, but the trial court dismissed her case, reasoning that a recent Supreme Court decision in Wyeth v. Levine4 effectively barred all failure to warn claims brought in state courts against generic manufacturers.5

This result is in stark contrast to the Supreme Court’s decision in Wyeth v. Levine, a case involving almost identical facts. In that case, Diana Levine, like Ms. Schork, was injected with anti-nausea medication and lost her arm.6 However, she was injected with Phenergan, the brand-name medication, rather than the generic equivalent.7 Unlike the trial court’s result in Ms. Schork’s case, the

2. Id.
3. Id.
5. Thomas, supra note 1.
6. Id.
7. Id.
Supreme Court held that Levine’s suit was not barred by federal preemption.\(^8\)

The current outlook for patients who receive generic drugs is bleak. According to many courts, Supreme Court precedent mandates that patients using brand name drugs may recover from manufacturers in failure to warn lawsuits, while those using generic drugs may not.\(^9\) This is especially troubling considering that nearly eight out of every ten prescriptions filled are for generic drugs.\(^10\) Though the FDA classifies generic drugs as the chemical equivalent of brand-name drugs,\(^11\) a person effectively relinquishes his or her legal rights regarding failure to warn when receiving a generic drug, as opposed to its branded version.

This Casenote focuses on the circuit split surrounding federal preemption analysis with regard to failure to warn claims brought against generic drug manufacturers as demonstrated in the Fifth Circuit case, \textit{Morris v. PLIVA, Inc.},\(^12\) and the Sixth Circuit case, \textit{Fulgenzi v. PLIVA, Inc.}.\(^13\) In particular, this Casenote focuses on another recent decision on this issue, coming from the Fourth Circuit in \textit{Drager v. PLIVA USA, Inc.}\(^14\) In \textit{Drager}, the Fourth Circuit held that a plaintiff’s state tort claims for failure to warn were preempted by the Food, Drug, and Cosmetic Act (FDCA).\(^15\) Part II of this Casenote provides an overview of federal preemption standards and FDCA requirements for branded and generic drug manufacturers and discusses two important Supreme Court cases that have directly addressed these issues. Part III examines the circuit split that has arisen regarding this issue and outlines the Fourth Circuit’s decision in \textit{Drager}. Part IV analyzes the Fourth Circuit’s decision and discusses the errors of its rationale. Finally, Part V concludes that state tort law claims brought against drug manufacturers should not be preempted by federal law in all circumstances. Additionally, Part V examines past Supreme Court decisions and discusses their proper interpretation.

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\(^{8}\) \textit{Id.}

\(^{9}\) \textit{A Bizarre Outcome on Generic Drugs}, \textit{N.Y. Times} (Mar. 23, 2012), http://www.nytimes.com/2012/03/24/opinion/a-bizarre-outcome-on-generic-drugs.html?_r=2&scp=1&sq=bizarre%20outcome%20generic%20drugs&st=cse&.


\(^{11}\) \textit{Id.}

\(^{12}\) 713 F.3d 774, 776 (5th Cir. 2013).

\(^{13}\) 711 F.3d 578 (6th Cir. 2013).

\(^{14}\) \textit{Drager v. PLIVA USA, Inc.}, 741 F.3d 470 (4th Cir. 2014).

\(^{15}\) \textit{Id.}
II. BACKGROUND

A. The Standards Behind Federal Preemption

Preemption arguments arise from the Supremacy Clause contained in article VI, clause 2 of the United States Constitution. The Supremacy Clause establishes that “federal law may supersede state law in several different ways.” First, federal law may supersede state law through express terms established by Congress. Of course, Congress must be acting within its constitutional limits when mandating express preemption.

The second avenue of federal preemption is through a finding of implied preemption. The Supreme Court has outlined two categories of implied preemption: (1) “whole field” preemption, where the scheme of a federal regulation is so comprehensive that it is reasonable to infer that “Congress ‘left no room’ for supplementary state law”; and (2) conflict preemption, where state law is nullified because it directly conflicts with federal law. Conflict preemption is found when either (1) “compliance with both federal and state regulations is a physical impossibility”; or (2) state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” Additionally, the Supreme Court has noted that there is a presumption amongst courts against the dismissal of suits on preemption grounds, “particularly in those in which Congress has ‘legislated . . . in a field which the states have traditionally occupied.” The Court has further emphasized the states’ “historic primacy” in the areas of health and safety. According to the Court, Congress’s ultimate purpose and intent of the statute is the main factor against which a preemption claim must be weighed.

One example of state and federal laws that did not conflict under the Supremacy Clause can be seen in Florida Lime & Avocado Growers, Inc. v. Paul. In Paul, Florida avocado growers challenged a California regulation that prohibited the sale or transportation, in California, of avocados containing less than eight percent of oil by weight (a standard

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17. Id. at 713.
18. Id.
19. Id.
20. Id.
21. Id.
22. Hillsborough Cty., 471 U.S. at 713.
24. Id.
25. Id. at 485-86.
used by California to gauge the maturity of avocados). In contrast, federal regulations placed no significance on oil content when gauging the maturity of avocados grown in Florida. Among other claims, the Florida avocado growers challenged the California statute by asserting that it was preempted by federal regulations.

In dismissing the claim, the Court first noted that no “physical impossibility” existed which would prevent Florida growers from complying with both federal and state standards and further concluded that Congress did not intend to “oust or displace state powers to enact the regulation.” Importantly, the Court noted that the areas of consumer protection and safety are typically left to the states and “in the absence of an express command from Congress,” states may impose higher standards for their consumers.

Alternatively, an example of conflicting state and federal laws can be seen in Hines v. Davidowitz. In Hines, the state of Pennsylvania argued that the Alien Registration Act (Pennsylvania Act) it passed was not preempted by a federal act requiring different registration requirements for aliens. The Court held that the Pennsylvania Act was indeed preempted by the federal act because Congress had implemented a comprehensive scheme, “a complete system for alien registration.” Therefore, the Pennsylvania Act was necessarily in conflict with the federal scheme, and as a result, was preempted by the federal act.

B. Requirements for Generic Manufacturers Under the FDCA

Before a drug may be marketed in the United States, the FDA must approve it. The FDCA establishes the approval processes for both branded and generic drug manufacturers. The requirements for branded manufacturers are not the same as those required of generic drug manufacturers. For example, branded manufacturers that wish to introduce a new drug to the marketplace must first submit an

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27. Id. at 134.
28. Id.
29. Id. at 143.
30. Id. at 152.
33. Id. at 60.
34. Id. at 70.
35. Id. at 73-74.
36. FDA.Gov, supra note 10.
This application must include, amongst other requirements, full reports of investigations made into the safety and effectiveness of the proposed drug, a list of components used in the drug, and a full description of the methods used in the drug’s manufacture, processing, and packing. Additionally, the application must provide a label that explains the proper use and possible risks associated with using the drug in accordance with the directions. This application is referred to as a New Drug Application (NDA).

The approval process for generic drug manufacturers differs from the NDA procedure. Rather than filing a NDA, generic drug manufacturers are only required to submit an abbreviated NDA (ANDA) to obtain approval. An ANDA for a drug must include information that the drug contains the same active ingredients as, and for all practical purposes is the same as, a drug that has already been approved (the “listed drug”). Additionally, the ANDA requires that the labeling of the proposed drug be the same as the labeling of the listed drug.

The labeling standards for approved drugs also contain differences depending on whether the drug is being distributed by a branded or generic manufacturer. A branded manufacturer can unilaterally update its labels, although this update is subject to subsequent FDA disapproval. A branded manufacturer may seek to update a label through either a “Prior Approval” supplement, which requires FDA approval, or through a “Changes Being Effected” (CBE) supplement. A CBE supplement can be submitted up to 30 days prior to distribution of the drug and does not require FDA approval.

Generic drug manufacturers, on the other hand, “must maintain labeling consistent with their branded counterpart.” A variation in labeling between the two allows the FDA to withdraw its previous approval of the generic drug. Additionally, generic drug manufacturers may use only the CBE process to update their labels to match their branded counterparts or to follow the FDA’s instructions.
Therefore, generic drug manufacturers cannot unilaterally decide to change the label of a generic drug. They do, however, have a federal duty of "sameness" with regard to their branded counterparts. This duty requires generic manufacturers to update their labels if their branded counterparts have done so.

C. Federal Preemption Applied to Drug Manufacturers

The Supreme Court recently examined the issue of federal preemption in state tort law claims against both branded and generic manufacturers. Though both cases dealt with drug manufacturers, the Court reached two different results on the issue of whether state tort law claims were preempted by the FDCA regulations.

In Wyeth v. Levine, the Supreme Court granted certiorari to determine whether a state tort claim against a branded manufacturer was barred by federal preemption because of the FDA's approval of the drug's labeling. Wyeth was the manufacturer of the drug Phenergan. It had filed a NDA with the FDA in 1955 and subsequently made changes to the drug's labeling, which the FDA approved. The lawsuit arose after a patient was injected with Phenergan and developed gangrene, a condition that ultimately resulted in the amputation of her entire forearm and hand. Because the patient was a professional musician, she also lost her livelihood as a result of the injection.

The main contention in the case concerned the adequacy of the warnings that were located on the injectable form of Phenergan. There are two ways to administer the injectable form of Phenergan according to the label: (1) intravenously, where the drug is injected directly into a patient's vein, or (2) through the "IV-drip" method, where the drug is introduced through a saline bag connected to a patient's vein. Levine argued that, although the Phenargan label warned about the dangers of the intravenous method, the label failed to instruct physicians that they should use the IV-drip method.

At the trial court level, the jury returned a verdict in favor of Levine,

51. Id. at 582.
53. Wyeth, 555 U.S. at 559.
54. Id. at 558.
55. Id. at 559.
56. Id.
57. Id.
58. Wyeth, 555 U.S. at 559.
59. Id. at 560.
which was subsequently affirmed by the Vermont Supreme Court.\textsuperscript{60} The Supreme Court of the United States affirmed these decisions and dismissed Wyeth's preemption claims, finding that it was not impossible for Wyeth to satisfy both federal and state regulations simultaneously.\textsuperscript{61} The Court reasoned that Wyeth had the ability to unilaterally update its labeling for Phenergan without the consent of the FDA through the CBE process, though this change would need to be subsequently approved.\textsuperscript{62} Nonetheless, the Court found that there was no concrete evidence that if Wyeth had updated the label to strengthen its warnings, the FDA would have disapproved of such changes.\textsuperscript{63} Because Wyeth could have updated its warning labels to bring them into compliance with Vermont State law without violating the FDA regulations, the state tort law claim, which rested on the alleged inadequacy of the warning labels under state law, was not preempted by the FDA regulations.\textsuperscript{64}

In addition to rejecting Wyeth's argument of impossibility, the Court also found that Congress, by enacting the FDA regulatory scheme, did not intend for federal law to preempt all state law claims.\textsuperscript{65} Indeed, the Court noted that there has been a "longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies."\textsuperscript{66} The Court found that a state failure-to-warn claim against a branded manufacturer is not preempted by federal regulations concerning pharmaceutical drugs.\textsuperscript{67}

The Court took a different approach when examining federal preemption in the context of generic drug manufacturers. The Court addressed this issue in 2011 with its decision in \textit{PLIVA, Inc. v. Mensing}.\textsuperscript{68} In this case, Mensing and another individual (Respondents), were prescribed the drug Reglan in 2001, but were given the generic form by their pharmacists.\textsuperscript{69} The FDA first approved the distribution and sale of Reglan in 1980 and five years later generic manufacturers began to produce the drug.\textsuperscript{70} Over the years, evidence showed that the drug had a high risk of causing tardive dyskinesia, a severe neurological disorder.\textsuperscript{71} Starting in 1980, the labels for Reglan were modified several
times. First, in 1985, the labels were updated to warn of the risk of tardive dyskinesia and to caution that treatment beyond twelve weeks had not been evaluated and could not be recommended.72 A modification was again submitted and approved by the FDA for Reglan in 2004. This modification stated “therapy should not exceed 12 weeks.”73 Finally, a black box warning was added to Reglan in 2009, which stressed that treatment should not exceed twelve weeks except in rare cases.74 Respondents took the generic form of Reglan in 2001, before Reglan contained the 2004 and 2009 updated warnings.75

The Supreme Court found that federal law preempted Respondents’ state law tort claims, reasoning that it was impossible for the generic manufacturers to satisfy both state and federal regulations simultaneously.76 The Court acknowledged that the FDA requires generic manufacturers to contact the FDA regarding stronger warning labels when they discover information necessitating increased warnings.77 Nonetheless, the Court found that under the FDA regulations, generic manufacturers could not unilaterally strengthen labels, and therefore, it was impossible for a manufacturer to satisfy both its federal duty of “sameness” as well as state law requirements.78

III. THE CIRCUIT SPLIT

A. Morris v. PLIVA, Inc.

1. District Court Decision

In 2009, plaintiffs Penny and John Morris filed a complaint alleging damages that arose from Mrs. Morris’s ingestion of the drug metoclopramide.79 Though the drug was available in both generic and brand formulations, Mrs. Morris received the generic metoclopramide.80 In her complaint, she alleged that she had taken the metoclopramide tablets from early 2006 through July 2008 and had developed tardive

72. Id.
73. Mensing, 131 S. Ct. at 2572.
74. Id.
75. Id.
76. Id. at 2581.
77. Id. at 2578.
78. Mensing, 131 S. Ct. at 2578.
80. Id.
dyskinesia as a result. This neurological condition causes involuntary movements, as well as other symptoms. Morris brought her action against five separate defendants, all of whom manufactured metoclopramide either in its generic or branded form.

The District Court granted summary judgment to two of the named defendants, Wyeth and Schwarz, because Morris did not dispute that she had ingested generic metoclopramide, a product that neither manufacturer distributed. Contesting this finding, the plaintiffs argued that while these manufacturers had not provided the form of metoclopramide that Morris had taken, their position as the branded manufacturers of the drug nonetheless made them liable for damages. Specifically, Morris argued that generic manufacturers are limited in their ability to update warning labels unilaterally and must maintain the same label as the branded counterpart of their drug. Dismissing these arguments, the district court dismissed the plaintiff’s claims against both Wyeth and Schwarz.

On January 27, 2011 the district court stayed proceedings against the remaining defendants, all of whom were generic manufacturers, because the Supreme Court had granted certiorari to PLIVA, Inc. v. Mensing, a lawsuit with a similar fact pattern. Once the decision in Mensing had been reached, the district court relied entirely on the Supreme Court’s reasoning to determine that Morris’s state law claim for failure to warn was preempted by federal law. Specifically, the district court found that it was impossible for generic manufacturers to comply simultaneously with both their federal regulatory duties and state law duties to warn.

2. Fifth Circuit Decision

On appeal, the United States Court of Appeals for the Fifth Circuit reviewed the district court’s dismissal of plaintiff’s case de novo.

81. Id.
82. Id.
83. Id. at *2.
85. Id. at *10.
86. Id. at *11.
87. Id. at *15.
89. Id. at *3.
90. Id. at *4.
91. Morris v. PLIVA, Inc., 713 F.3d 774, 776 (5th Cir. 2013) (dismissing the plaintiff’s case for failure to state a claim).
Based on its review, the Fifth Circuit affirmed the district court’s finding that plaintiff’s state law claims against the generic drug manufacturers were preempted by FDA regulations. The court found that PLIVA, Inc. v. Mensing was controlling and therefore, the plaintiff’s state law claims were preempted. Morris argued that Mensing should not apply with regard to her failure to warn claim because PLIVA failed to update its label on the generic drug to make it consistent with a 2004 label change to its branded counterpart, Reglan. The Fifth Circuit found that Mensing “forecloses such claims because failure to ‘communicate’ extends beyond just a label change.” The Court reasoned that in order to avoid liability under this theory, the generic manufacturers not only would have had to update their labels, but also “take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label.” Therefore, the Court found that because no branded manufacturers had sent out such warnings, generic manufacturers were not at liberty to send out such warnings themselves. The Court reasoned that this triggered preemption because PLIVA was then unable to comply with both its state law duty to warn and the federal law duty of sameness.

The plaintiffs also argued that the generic drug manufacturers failed to test and inspect the drug in accordance with federal law. The Fifth Circuit quickly dismissed this claim, pointing to the FDCA, which “provides no right of action for these violations.” The plaintiffs’ final argument that PLIVA had violated an express warranty by placing a defective product into the stream of commerce was also denied. In so doing, the Court noted that the Fifth Circuit has rejected this type of claim in the past.

**B. Fulgenzi v. PLIVA, Inc.**

1. District Court Decision

Only a month after the Fifth Circuit’s decision in Morris, the Sixth Circuit addressed the same type of failure to warn claim, again brought

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92. Id. at 775.  
93. Id.  
94. Id. at 777.  
95. Id.  
96. Morris, 713 F.3d at 777.  
97. Id.  
98. Id.  
99. Id. at 778.  
100. Id.  
101. Morris, 713 F.3d at 778.
against PLIVA. Similar to the plaintiff in *Morris*, Eleanor Fulgenzi brought a state tort suit against the generic manufacturer PLIVA for failure to adequately warn of the risks of the drug metoclopramide. Fulgenzi had taken the drug for three months in 2004, as well as for a year between 2006 and 2007. Much like the plaintiff in *Morris*, she alleged that as a result of taking the drug she had developed tardive dyskinesia.

Relying on the holding in *Mensing*, the district court granted the defendant’s motion to dismiss, reasoning that the failure-to-warn claims brought by Fulgenzi were “clearly preempted under *Mensing*.” The court also found that there was no exception to preemption of a state law failure to warn claim based on the failure to comply with FDA regulations. The district court concluded that “regardless of how Plaintiff attempts to cast these claims they are at the core, failure-to-warn claims” and are therefore preempted under *Mensing*.

2. Sixth Circuit Decision

On appeal, the Sixth Circuit examined, de novo, the question of whether the FDA regulations preempted the plaintiff’s state law failure to warn claim. Fulgenzi argued that her case was different from *Mensing* because the branded manufacturer of Reglan, Schwarz Pharma, had sought and received approval from the FDA for a labeling change to the drug in 2004. PLIVA never updated its metoclopramide labeling to include the new warning that was present in its branded counterpart, which cautioned against use of the drug for longer than twelve weeks. Fulgenzi argued that this failure to update in accordance with Reglan’s new warnings in 2004 removed the impossibility for PLIVA to comply with federal and state duties.

In analyzing whether Fulgenzi’s claim was preempted by federal law, the Sixth Circuit noted that two factors need be considered: (1) whether compliance with both the state and federal law was impossible; and (2) whether the state requirement is an obstacle to the purposes and

103. Id. at 579.
104. Id. at 580.
105. Id.
106. Id. at 582.
107. *Fulgenzi*, 711 F.3d at 582.
108. Id.
109. Id. at 583.
110. Id. at 580.
111. Id.
112. *Fulgenzi*, 711 F.3d at 580.
objectives of Congress. The existence of either of these factors would result in a finding that the plaintiff’s case was preempted.

While considering the first factor, the Sixth Circuit emphasized that the key question presented in Mensing was “whether the private party (PLIVA) could independently comply” with its state duty. In Wyeth, the Court held that no impossibility exists when “approval comes after the independent action of the private party.” The court noted that, “not only could PLIVA have independently updated its labeling to match that of the branded manufacturer through the CBE process . . . but it had a federal duty to do so.” The court went on to state that while the FDA had the authority to reject a change made by PLIVA after the fact, this “possibility of impossibility” was found insufficient under Wyeth and, therefore, Fulgenzi’s claim was not preempted for impossibility.

Addressing the second factor of preemption analysis, the Sixth Circuit determined that state tort suits against generic manufacturers would not frustrate the “purposes and objectives” of Congress. The court stressed that “70 years of Congressional failure to enact an express preemption provision for prescription drugs—despite the enactment of an express provision for medical devices—to be ‘powerful evidence’ that Congress did not intend to preempt state remedies.” The court further held that, though there is a legitimate concern that Fulgenzi “is simply attempting to enforce a federal-law violation through state litigation,” her claim is based solely on state tort law principles and therefore the cause of action remained valid. Ultimately, the Sixth Circuit reached the opposite conclusion than the Fifth Circuit in Morris and found that the Supreme Court’s holding in Mensing did not prevent Fulgenzi from bringing her action.

C. Main Case: Drager v. PLIVA USA, Inc.

1. District Court Decision

More recently, a circuit court addressed the issue of federal

113. Id. at 584.
114. Id.
115. Id.
116. Id.
117. Fulgenzi, 711 F.3d at 584.
118. Id. at 586.
119. Id. at 585.
120. Id. at 586.
121. Id. at 589.
preemption in relation to state law tort claims against generic drug manufacturers in the Fourth Circuit in 2014. The plaintiff, Drager, brought a claim against PLIVA as the personal representative of the estate of Shirley Gross. The facts are nearly identical to the previous two cases; Mrs. Gross had taken the generic form of the drug Reglan and used the medication for more than twelve weeks. Like the plaintiffs in Morris and Fulgenzi, Gross also developed permanent injuries, including tardive dyskinesia.

Gross first filed suit against PLIVA in 2010, but the district court stayed further proceedings pending the Supreme Court's ruling in Mensing. After the decision in Mensing, the district court granted a motion for judgment on the pleadings in favor of PLIVA, stating that all of Gross's claims were preempted by the FDCA pursuant to Mensing. Additionally, the court denied the plaintiff's motion to amend her complaint to include allegations that PLIVA had failed to update its label in accordance with the updated labels of Reglan in 2004, stating that such an amendment would be futile under Maryland law.

2. Fourth Circuit Decision

On appeal, the Fourth Circuit reviewed the decision to grant PLIVA's motion for judgment on the pleadings. The court relied on the holding in Mensing to determine that PLIVA could not have unilaterally changed the labels on the generic form of Reglan and therefore, could not satisfy both Maryland and federal law simultaneously. According to the Fourth Circuit this left PLIVA with only one option: to stop selling the drug altogether. The court found that this solution was not tenable and that a manufacturer's ability to leave the marketplace or face liability for state law claims was not a valid means of avoiding a ruling of preemption.

Drager also contended on appeal that the district court had abused its discretion by denying Drager's amended complaint, which would have included a similar claim to that allowed by the Sixth Circuit in Fulgenzi. More specifically, this claim would have alleged liability based on

122. Drager v. PLIVA USA, Inc., 741 F.3d 470 (4th Cir. 2014).
123. Id. at 473.
124. Id.
125. Id.
126. Id.
127. Drager, 741 F.3d at 473.
128. Id. at 474.
129. Id.
130. Id.
131. Id. at 477.
PLIVA’s failure to update its label in 2004 in accordance with the updated Reglan label.\textsuperscript{132} The Fourth Circuit brushed this argument aside, stating that the motion to amend the complaint had not been “properly made” at the district court level and, therefore, it must be treated as having been waived.\textsuperscript{133}

IV. WHERE THE FOURTH CIRCUIT WENT WRONG

The Fourth Circuit erred by finding that Drager’s state tort law claims were preempted by federal law. In reaching this decision, the Court misconstrued the Supreme Court’s holding in \textit{Mensing}. Specifically, the Court failed to complete a full preemption analysis and did not consider the factual differences present in Drager’s case as compared to \textit{Mensing}. Additionally, the Fourth Circuit failed to consider whether allowance of Drager’s state law claim would frustrate the purposes and objectives of Congress. Finally, the Court did not consider the unfairness toward injured plaintiffs that is created by deeming these types of claims preempted by federal law. All of these gaps in the Court’s reasoning suggest that a new outlook may be necessary for how courts should treat failure to warn claims against generic and branded drug manufacturers.

\textit{A. The Fourth Circuit Applied the Mensing Rationale Too Broadly}

1. The Court Failed to Perform a Complete Preemption Analysis

One of the biggest problems with the Fourth Circuit’s finding of preemption was its failure to perform a complete preemption analysis. The appellate court noted that the district court had failed to complete a “full preemption analysis” and that “\textit{Mensing} contemplates a more complete analysis,” but found that this alone did not constitute reversible error.\textsuperscript{134} Instead of analyzing each of Drager’s claims individually, the Fourth Circuit lumped them all together, generalizing that each cause of action would necessitate PLIVA to either change its labeling, exit the market, or face liability, and therefore, the claims were preempted.\textsuperscript{135} This generalization of all of Drager’s claims does not follow from the holding in \textit{Mensing}.

In \textit{Mensing}, the Court found that the ultimate question of whether a state tort law claim would be preempted centered on whether the

\textsuperscript{132} Drager, 741 F.3d at 474.
\textsuperscript{133} Id.
\textsuperscript{134} Id. at 476.
\textsuperscript{135} Id.
manufacturer could not comply with both state and federal duties simultaneously. In deciding the case, the Supreme Court did not state that failure to warn or failure to update cases will always be preempted by federal law, but instead that it depends on the question of impossibility. The Court noted that this question must be answered on a case-by-case basis and that it did not intend to create a blanket rule. Such a rule would require that all failure to warn claims brought against generic drug manufacturers be considered preempted by federal law.

This type of case by case analysis can be seen in the Sixth Circuit’s holding in Fulgenzi. In that case, which was decided after Mensing, the Court held that federal law did not preempt the plaintiff’s failure to warn claim. Specifically, the Sixth Circuit noted that “the Court’s decision [in Mensing] rested squarely on the impossibility-preemption analysis and did not suggest that all suits against generic-drug manufacturers would be preempted.” The Fourth Circuit neglected to consider this principle and instead determined that if Drager’s claims involved the need to change labels or warnings, then the claims must be preempted, even though the generic manufacturer could have complied with FDA regulations and state law by conforming to the actions of the branded manufacturer.

Instead of taking this blanket approach, the Fourth Circuit should have taken a deeper look into the question of impossibility and how it specifically affected Drager’s failure to warn claim. In particular, the Fourth Circuit should have examined what options PLIVA had in regards to updating its label. While it is true that PLIVA could not unilaterally update its label unless that update would reflect an identical change of its branded counterpart, Schwarz Pharma, the branded manufacturer, had proposed and received FDA approval for such a label change in 2004. PLIVA, however, never updated its metoclopramide labeling to include this new warning and failed to communicate the

137. Id. at 2577.
138. Id. at 2580. The Court discussed the difficulty that can arise in determining whether a party can sufficiently satisfy both federal duties and state duties simultaneously. The Court noted that this particular case does not pose such a challenge but does not go so far as to say that all failure to warn claims against generic manufacturers will be answered so easily.
139. Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 588 (6th Cir. 2013).
140. Id. at 583.
141. See Drager v. PLIVA USA, Inc. 741 F.3d 470, 477 (4th Cir. 2014). The court stated that any duty under Maryland law would have required PLIVA to change its warnings and therefore the claims must be preempted as this would result in impossibility.
142. Fulgenzi, 711 F.3d at 579.
change to any physicians. 143 The Fourth Circuit appeared to overlook this crucial fact in making its determination. Because Schwarz had updated its Reglan label, PLIVA not only had the ability to update its label on metoclopramide, but also had a federal duty of "sameness" to include the new warning. 144 By reading Mensing too broadly, the Fourth Circuit was able to dismiss Drager's claim solely because it was against a generic manufacturer for failure to update its labeling. The Court erred by taking this approach because it failed to consider the fact-specific basis of Drager's claim.

2. The Court Did Not Consider the Factual Differences

The factual differences between the plaintiff in Mensing and Shirley Gross in Drager are easily distinguishable and, accordingly, require a different result. In Mensing, the plaintiffs, Gladys Mensing and Julie Demahy, were both prescribed Reglan in 2001 and 2002, respectively. 145 Each was given the generic equivalent by her pharmacist, and each took the drug for multiple years, leading to the development of tardive dyskinesia. 146 The date on which these plaintiffs were prescribed, and took the drug, is of great importance. As discussed previously, Schwarz Pharma updated the warning labels on Reglan in 2004, after each of the plaintiffs in Mensing had ingested the generic form. This is at odds with the timeframe in which Mrs. Gross ingested the drug in Drager. Specifically, Gross used the generic form of Reglan between the years 2006 to 2007. 147 This factual difference has a large impact upon the impossibility preemption question.

In Mensing, the Court stated that the determination of whether a party can satisfy both federal and state duties "sometimes may be difficult to determine. But this is not such a case." 148 However, the factual differences present in Drager made this determination much more difficult. Mensing was a 5-4 decision accompanied by a strong dissent arguing the majority had extended the preemption doctrine to situations where there was only the "mere possibility of impossibility." 149 The factual differences in the Drager case actually allow for a finding,

143. Id.
144. Id. at 578. The Sixth Circuit concluded that PLIVA's failure to update its label on the generic form of metoclopramide was in violation of its federal duty and presented an even weaker case for impossibility preemption than in Wyeth where a branded manufacturer failed to succeed on an impossibility preemption argument.
146. Id.
147. Drager v. PLIVA USA, Inc., 741 F.3d 470, 473 (4th Cir. 2014).
148. Mensing, 121 S. Ct. at 2580.
149. Id. at 2582. (Sotomayer, J., dissenting).
consistent with *Mensing*, that PLIVA did not suffer from any impossibility at all. Once Schwarz Pharma had updated the Reglan label in 2004, PLIVA was authorized to update its own labels and could have satisfied both its federal and state duties.

The Sixth Circuit came to such a conclusion in *Fulgenzi*, determining that because the plaintiff had taken the generic form of Reglan only after 2004, her claim was not preempted because PLIVA had an avenue, and a duty, to update its labels. The Fourth Circuit erred by not reaching an identical conclusion.

3. The "Purposes and Objectives" Analysis Was Never Considered

When examining conflict preemption, as the Fourth Circuit did in *Drager*, preemption may be found by two methods. The Court examined the first method, but after reaching its conclusion decided not to mention the second—whether compliance with state law would act as an obstacle to the purposes and objectives of Congress. As discussed above, the court relied too greatly on its broad reading of *Mensing* to determine that conflict preemption was present because of impossibility, completely ignoring the second method of analysis. The Supreme Court has stated that there is a presumption against dismissal of suits on preemption grounds, "particularly in those in which Congress has 'legislated ... in a field which the states have traditionally occupied.'" The fields of health and safety have been noted to be of "historic primacy" to the states.

Because Drager's case should not have been preempted based on impossibility, the Court should have determined whether the pursuit of such state claims would hinder the purposes and objectives of Congress. As noted by the Sixth Circuit, Congress has failed to enact any express preemption provision for prescription drugs, despite the fact that such a provision has been enacted for medical devices. The dissent in *Mensing* echoed this reasoning, stating the majority's approach, "threatens to infringe the State's authority over traditional matters of state interest—such as the failure-to-warn claims here—when Congress expressed no intent to pre-empt state law." There is no evidence that Congress intended to preempt the type of claims brought by Drager, nor is there an indication that allowance of such claims would clash with Congress's purposes and objectives. As neither of these are present, it is

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152. *Id.*
clear that this method of preemption would not apply to Drager’s claims.

B. The Court Did Not Consider the Unfairness that Results from Its Ruling

The Fourth Circuit’s determination that generic manufacturers should be treated differently than branded manufacturers has wide ranging implications that most consumers will be unaware of until they suffer an injury and seek legal recourse. Over the past ten years, generic drugs have been dispensed at an increasing rate, rising from sixty-three percent of dispensed prescriptions in 2006 to seventy-eight percent in 2010. This shift toward generic drugs is not surprising considering that many pharmacists recommend them to patients as being just as effective as their branded counterparts and less expensive.

Consumer Reports, a reviewer of consumer products and services, recommends consumers try the generic whenever possible, and also mentions that in most cases, your pharmacist can give you the generic instead of the brand-name, even when the prescription is for the branded drug. Further, some states, such as Kentucky, have passed statutes that require their pharmacists to substitute branded drugs for their generic equivalents unless the prescription specifically states otherwise. It is important to note that none of the previous sources mention that use of a generic drug may limit the legal remedies that might otherwise be available through use of a branded counterpart. This information leads to the shocking realization that many consumers are receiving generic drugs without fully understanding the potential


156. CVS.COM, Switching to a Generic Could Help You Save, http://www.cvs.com/content/generics (last visited Aug. 16, 2016); see also WALGREENS.COM, GENERIC MEDICATIONS, http://www.walgreens.com/topic/faq/questionandanswer.jsp?questionTierld=700006&faqId=6000026 (the Walgreens FAQ section describes generics as equivalent to their brand name counterparts, cheaper, and just as safe) (last visited Aug. 16, 2016); KROGER.COM, DRUG INFORMATION, https://www.kroger.com/topic/drug-information (noting that pharmacists will often recommend generic versions of medications to save customers money).


158. K.R.S. § 217.822(1) (“When a pharmacist receives a prescription for a brand name drug . . . he shall select a lower priced therapeutically equivalent drug . . . unless otherwise instructed by the purchaser or his physician.”); see also OFF. OF THE ASSISTANT SECRETARY FOR PLAN. & EVALUATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS (2010), http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.shtml (stating that as of 2010, fourteen states have these type of mandates while the remaining thirty-six states still allow for substitution though it is not mandated).
consequences of their decisions.

The majority in Mensing noted that allowing a state claim against a branded manufacturer, while finding preemption in state claims against a generic manufacturer, "made little sense."159 This problem is intensified when most consumers will be given a generic form of a drug without even realizing that they are receiving the generic form, rather than its branded counterpart. Though pharmacists continue to stress to consumers that generics are chemically equivalent to their branded counterparts and equally safe, after the holding in Mensing, many courts will undoubtedly allow for plaintiffs to bring claims against branded manufacturers only, thus stripping away much needed consumer protections.

To assume that Congress intended for the FDCA to deprive injured parties of their ability to bring otherwise viable actions under state law ignores common sense. Any rational individual would believe that the FDCA was enacted to protect consumers from inadequate warning labels and to encourage drug manufacturers, both generic and branded, to maintain high quality and safe products. The Fourth Circuit should have taken note of these considerations when determining whether Drager's claim was preempted.

C. Possible Remedies

With the Supreme Court's holding in Mensing, it appears that this issue may need to be resolved outside of the judicial system. The current precedent set forth by the Supreme Court is both difficult to understand and nonsensical. The Court itself has mentioned that the availability of bringing suit against branded manufacturers, while being foreclosed from bringing a similar suit against a generic manufacturer, is strange. There are a few ways in which this issue could be resolved outside of the judiciary. First, Congress itself could pass legislation that explicitly allows for plaintiffs to bring state law claims against generic manufacturers. Second, the FDA could amend the policies governing the labeling process for generic manufacturers. Both of these remedies would resolve the current circuit split and allow for injured parties to recover.

1. Congress Should Pass Legislation Allowing for State Law Claims

The current disagreement on this issue arises solely from lower courts disagreeing on whether a plaintiffs' state law failure to warn tort claims...
are preempted by federal law. Because the FDCA does not explicitly set forth that these types of state law claims are preempted, courts have dismissed plaintiffs' claims based on a version of implied preemption: conflict preemption. This preemption involves either: (1) an inability to comply with both federal and state standards; or (2) a state law that stands as an obstacle to the purposes and objectives of Congress. The increasing dispersal and usage of generic drugs by both pharmacists and consumers indicate that Congress needs to explicitly state whether or not the purpose and objective of the FDCA is to completely occupy this field.

Because of the public importance of drug safety for all citizens, Congress needs to resolve this issue. The Supreme Court noted in Mensing that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre" and that "Congress and the FDA retain the authority to change the law and regulations if they so desire." It is time for Congress to take the initiative and expressly state that the FDCA does not preempt such claims. Without this remedy, many consumers will lose their right to bring suit against manufacturers without having a choice in the matter. This undermines Congress's purpose in enacting the FDCA and weakens safety regulations for the pharmaceuticals that citizens consume. As the dissent in Mensing stressed, the current distinction between branded and generic manufacturers "threatens to reduce demand for generics" and "may pose 'an ethical dilemma for prescribing physicians.'" It is hard to fathom that the intent of Congress was to create such a distinction. Congress should use its power to make an express statement on its intent surrounding this issue.

2. The FDA Should Allow Generic Manufacturers to Unilaterally Update Warning Labels

Aside from Congress's ability to expressly state whether it intended to preempt tort claims against generic manufactures, the FDA has the ability to amend its rules and procedures to allow for generic manufacturers to better satisfy state law duties. Currently, FDA regulations require that warning labels be updated when "there is reasonable evidence of a serious hazard with a drug." At the same time, however, generic manufacturers have a duty under FDA

162. Id. at 2593.
163. 21 C.F.R. § 201.57(e) (2015).
regulations to have the same labels as their branded counterparts. These requirements are the basis of the impossibility that some courts claim preempt state tort claims by plaintiffs.

This purported impossibility on the part of generic manufacturers could be relieved by the FDA by a change to the regulations for updating warning labels. An easy fix the FDA should implement is a mechanism to allow generic manufacturers to unilaterally update labels of generic drugs when relevant safety information is available. This change would allow generic manufacturers to more easily satisfy state law duties and alleviate all concerns of federal preemption. Additionally, this change would place more importance on both branded and generic manufacturers' efforts to continue monitoring the safety of the drugs they produce. This continued effort to maintain quality safety standards benefits society and the public as a whole.

VI. CONCLUSION

As pharmacists and legislatures continue to push for generic drug usage, courts must afford consumers the same legal remedies, regardless of whether consumers use the generic or branded form of a drug. The current circuit split surrounding this issue has already barred multiple victims from recovery, and this trend is certain to continue in the future. Generic drugs are substituted for their branded equivalents every day, while those receiving the drugs are told that they are identical and work just as well. While the effectiveness of the drugs may be identical, the legal rights afforded to consumers are not. Therefore, many people are receiving generic drugs without realizing that, in some jurisdictions, they are relinquishing their ability to recover from the manufacturers.

To solve this issue, Congress should expressly articulate whether state tort claims against generic manufacturers pose an obstacle to Congress' purposes and objectives of current federal law. This solution gives a concrete answer to the federal preemption question and allows for a more logical statutory scheme. The FDA should also change its regulations governing the procedure for updating warning labels. To better promote overall safety, the FDA should amend the current procedures to allow for, and require, generic manufacturers to seek out new complications with drugs. It should also impose a duty upon generic manufacturers to update their labels, even in circumstances where the branded counterparts have failed to do so. This change would promote overall safety for the general public and benefit society as a whole.

164. Id. § 314.150(b)(10).