Always Ask for a Brand-Name Drug: Trying to Untangle the Holding in PLIVA v. Mensing

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ALWAYS ASK FOR A BRAND-NAME DRUG: TRYING TO UNTANGLE THE HOLDING IN
PLIVA V. MENSING

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I. INTRODUCTION

You walk into the doctor’s office complaining of stomach pains that will not go away, an issue that arises after you eat certain foods. At the same time across town, someone else is experiencing the same pain and conveying the same symptoms to his doctor. Both doctors prescribe metoclopramide tablets, a prescription drug used to treat digestive tract problems. When you order your prescription, the pharmacist fills your prescription with the generic form of the drug. Across town, another pharmacist fills the prescription with the brand-name drug Reglan. After an extended amount of time using the prescription, you develop a serious movement disorder known as tardive dyskinesia. Often irreversible, this disorder has symptoms which include involuntary, repetitive tic-like movements, primarily in the facial muscles or (less commonly) the limbs, fingers, and toes.1 You bring a suit against the drug manufacturers under your state’s regulatory laws; however, you are unable to recover because the generic prescription drug manufacturer is not subject to the more stringent regulations of your state. Your counterpart, the patient across town, also files a claim, but recovers damages from the brand-name manufacturer that is subject to the state regulatory scheme. You cannot recover, despite a majority of the Supreme Court of the United States noting that if your pharmacist had filled your prescription with the brand-name drug, instead of the generic drug, you would have had a claim.2 Further, this claim would have been strong, except for the decision by the Court that your state’s law has been preempted by federal law.3 Because of the dual system of government that has formed in the United States, state versus federal, the Court has held that some state regulation is preempted by federal regulation (i.e. both state and federal cannot regulate the same area).4 The Supreme Court succinctly stated the issue at hand, which mirrored the story above:

Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, [the holding in] Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-

4 Id.
empts these lawsuits. We acknowledge the unfortunate hand
that federal drug regulation has dealt . . . 5

In a controversial decision preceding the above statement in PLIVA v. Mensing, 6 the United States Supreme Court held in Wyeth v. Levine 7 that federal preemption did not apply to a state tort law failure-to-warn claim for a brand-name prescription drug. 8 Two years later in PLIVA, a split five to four
decision, the Court held that the same state standards were preempted as they
to the manufacturers of generic prescription drugs. 9

Gladys Mensing and Julie Demahy were prescribed Reglan, the brand-
name form of metoclopramide tablets (used to treat digestive tract problems) in
2001 and 2002. 10 Before Mensing and Demahy were prescribed Reglan,
however, evidence had accumulated that long-term metoclopramide use could
cause tardive dyskinesia, 11 a “serious movement disorder that is often
irreversible[.]. 12 These findings (sometimes referred to as “events” by the Food
and Drug Administration) strengthened warning labels for the drug several
times over a period of twenty plus years. 13 The final and strongest warning
label was issued in 2009, which stated: “[t]reatment with metoclopramide can
cause tardive dyskinesia, a serious movement disorder that is often
irreversible . . . . Treatment with metoclopramide for longer than 12 weeks
should be avoided in all but rare cases.” 14 Both Mensing and Demahy took the
drug, in its generic form, for several years and developed tardive dyskinesia. 15
Mensing’s and Demahy’s prescriptions were filled with the generic form of
Reglan because many states had “enacted legislation authorizing pharmacists to
substitute generic drugs when filling prescriptions for brand-name drugs” 16 in

5 PLIVA, 131 S. Ct. at 2581 (internal citations omitted).
6 Id.
8 Id. at 555.
9 PLIVA, 131 S. Ct. at 2569.
10 Id. at 2572–73.
11 Id. at 2572 (citing McNeil v. Wyeth, 462 F.3d 364, 370 n.5 (5th Cir. 2006)); Douglas
Shaffer et al., Tardive Dyskinesia Risks and Metoclopramide Use Before and After U.S. Market
cases of metoclopramide-related tardive dyskinesia reported to the FDA’s adverse event
reporting system by mid-2003).
12 Id.
13 PLIVA, 131 S. Ct. at 2572.
14 Id. (citing PHYSICIANS’ DESK REFERENCE 2902 (65th ed. 2011)).
15 Id.
16 Id. at 2583 (citation omitted). The dissent in PLIVA noted the following:

Currently, all States have some form of generic substitution law. Some States
require generic substitution in certain circumstances. Others permit, but do not
the years leading up to the Hatch-Waxman Amendments. Both legislative movements, the substitution legislation in states and the federal action through the Hatch-Waxman Amendments, were meant to “expand consumption of low-cost generic drugs.”

Both Mensing and Demahy brought suits in their respective states, Minnesota and Louisiana, claiming that the manufacturers of the generic form of Reglan were liable under state tort law for failing to provide adequate warning labels. The generic manufacturers (“Manufacturers”), on the other hand, claimed that federal law, under the Food and Drug Administration (“FDA”), preempted the state tort claims. The Court agreed with the Manufacturers, reversing both the Fifth and Eighth Circuits’ holdings that the claims were not preempted. The Court decisively distinguished the case from Wyeth, finding that “federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs’ safety labels,” in stark contrast to brand-name prescription drug manufacturers.

Cases addressing federal preemption of state tort lawsuits have been extraordinarily predominate in the Court over the past few decades. Including PLIVA, at least seventeen cases involving the issue have been addressed by the Court since 1992, seven of which were handed down by the Roberts Court.

require, substitution. Some States require patient consent to substitution, and all States “allow the physician to specify that the brand name must be prescribed, although with different levels of effort from the physician.”

Id. (citation omitted).


18 PLIVA, 131 S. Ct. at 2583.

19 Id. at 2572.

20 Id.

21 Id. at 2569, 2573.

22 Id. at 2570.

23 Id. at 2581–82.


25 Wells, supra note 24, at 793 (noting the Roberts Court’s “keen interest in preemption battles”).
The plethora of cases on the matter, however, does not make the outcome of preemption cases any easier to forecast. The question of what analysis of preemption the Court will use, usually based on who the members of the majority are, is still a perplexing part of gauging how the Court will decide.  

For example, United States Supreme Court Justice Clarence Thomas, the majority’s author in PLIVA, has made clear in previous cases his disdain for the “purposes and objectives” of preemption jurisprudence, which is arguably an escape route for courts that want to find that a state law has not been preempted. As Justice Thomas’s stance shows, whether or not a person will actually have a remedy for a tortious injury in certain preemption cases will depend on the make-up of the Court at the time his or her case rises to that level.

The Court’s problematic analysis leads to several questions about how the composition of the Roberts Court affects the outcome of federal preemption cases. Are the members of the Court actually advocating positions in preemption cases that they usually, or previously, had not advocated? Is there a reason that United States Supreme Court Justice Anthony M. Kennedy, usually willing to write why he is or is not concurring, was not compelled to discuss his reasons for not joining the majority in its reasoning of the case based on the arguments surrounding the supposed non obstante provision of the Supremacy Clause? Was the Court’s decision consistent with that held in Wyeth v. Levine? Is it correct, under the current law, to afford generic drug manufacturers more protection from state tort law liability than their brand-name counterparts?

These questions will be answered in this Note. In Part II, this Note discusses the federal preemption backdrop against which PLIVA was decided in, and the generic drug regulation that led to its result. Part III, “The PLIVA Decision,” provides: (1) a brief background of the case; (2) a review of the trends in the Court over the years that have led to inconsistency in federal preemption law and in this case; (3) a summarization of Wyeth and how it is affected by the PLIVA decision; (4) a discussion of the missing concurrence of Justice Kennedy and how it may show a willingness for Kennedy to shift in the future if a practitioner molds their argument in his favor or if the same four Justices insist on using the non obstante provision argument; and (5) an analysis of United States Supreme Court Justice Sonia Sotomayor’s dissent which delves into the other side of the PLIVA argument, and because of the


28 See id.

29 PLIVA, 131 S. Ct. at 2571, 2579–80.
II. BACKGROUND

Part II.A of this Note provides a general overview of federal preemption.\textsuperscript{30} Part II.B describes the state of generic drug regulation as it is now, and how it compares to brand-name drug regulation, with an emphasis on federal regulation.

A. Federal Preemption Overview

Federal preemption law today is ripe with controversy and has developed a dichotomy of express and implied preemption that must be distinguished in order to fully understand this area of law. The controversy that has arisen can begin to be understood by reviewing the patterns of recent Supreme Court panels, from the Burger Court to the present Court, and how each court has applied federal preemption standards. The following is a foundation for comprehending why the \textit{PLIVA} case was decided incorrectly.

1. An Introduction to the Preemption Dichotomy

Federal preemption is rooted in the tension between state sovereignty and federal supremacy. The United States has chosen a system of dual sovereignty\textsuperscript{31} under which "[t]he principle of federal preemption enables federal law to prevail over conflicting state statutes, local ordinances[,] and

\textsuperscript{30} This overview is not meant to be, and is not, exhaustive of the subject area, but only provides what is needed for this Note.

even state common-law doctrines." The basis of federal preemption is found in the Supremacy Clause of the United States Constitution, which establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." The Supreme Court, however, has applied the "presumption against preemption" in cases where "such traditional areas of state concern as public health and safety" are in question "unless Congress makes its intent to preempt 'clear and manifest.'" Preemption cases are classified under a dichotomy of express and implied preemption. Express preemption occurs where Congress has explicitly provided that federal law controls and excludes state regulation in a certain area. Additionally, a federal agency can make an "express statement that it intends (by federal regulation) to displace state law." This administrative preemption allows federal agencies, when acting under the power given to them by Congress and through federal statute, to supersede state law.

Most cases, however, fall under the implied preemption branch. Implied preemption occurs when an express intention by either Congress or an administrative agency is not present, and the Court must infer Congress's (or the agency's) preemptive intent. Implied preemption is further broken down into two types: occupation of the field and conflict preemption. Occupation of the field occurs when Congress has regulated in a certain field so pervasively as to disallow any other regulation, or where the regulated subject is of "peculiarly federal' interest." Conflict preemption, the second type of implied preemption, is further broken down into two types: obstacle preemption and impossibility preemption. Obstacle preemption permits state law to be displaced where it "stands as an obstacle to the full purposes and objectives of Congress." Impossibility preemption, which was the basis of

32 Ausness, supra note 3, at 248.
33 U.S. CONST. art. VI, cl. 2.
34 Ausness, supra note 3, at 248.
36 Id. at 14–15; Ausness, supra note 3, at 248.
37 STARR ET AL., supra note 35, at 31.
38 Id.
39 Id. at 14.
40 Id. at 18–30; Ashutosh Bhagwat, Wyeth v. Levine and Agency Preemption: More Muddle, or Creeping to Clarity?, 45 TULSA L. REV. 197, 199 (2009).
41 STARR ET AL., supra note 35, at 19.
42 Bhagwat, supra note 40, at 200.
43 STARR ET AL., supra note 35, at 27.
PLIVA, occurs where it is "impossible for a private party to comply with both state and federal requirements."\footnote{PLIVA v. Mensing, 131 S. Ct. 2567, 2577 (2011) (citing Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)).}

A final niche in the federal preemption regime is the non obstante provision argument used by certain members of the Supreme Court.\footnote{Id. at 2579.} The Supreme Court has held that the Supremacy Clause of the United States Constitution is a non obstante provision because it states that "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."\footnote{Id. (citing U.S. CONST. art. VI, cl. 2).} The Court uses this clause to reason that federal law impliedly repeals conflicting state law and that "courts should not strain to find ways to reconcile federal law with seemingly conflicting state law."\footnote{Id. at 2580.} Thus, the Court uses the non obstante provision argument to make the preemption defense\footnote{The author frequently uses the term "preemption defense." This refers to a defendant's use of the argument that the state tort law in question is preempted by federal law, and because of that, preemption the plaintiff does not have a litigious claim.} an easier hurdle for private defendants, such as large generic drug manufacturers, who under this doctrine, no longer need "to attempt to comply with state law before being heard to complain that compliance with both laws was impossible."\footnote{PLIVA, 131 S. Ct. at 2592 (citing Wyeth v. Levine, 555 U.S. 555, 565–66 n.3 (2009)).} The defendants, and the majority, used this same argument in PLIVA.\footnote{Interestingly, Justice Kennedy did not concur and did not give a reason for not concurring. See infra Part III.C.}

2. Application by the Supreme Court

The panels of the Supreme Court spanning from the Burger Court to the now-residing Roberts Court have been inconsistent in applying the federal preemption doctrine. Although each court was generally working with the same legal standards, each court found its own way to manipulate the outcome of preemption cases.

The Burger Court, 1969 to 1986, generally upheld state action over federal regulatory power in its application of federal preemption doctrine.\footnote{William W. Bratton, Jr., The Preemption Doctrine: Shifting Perspectives on Federalism and the Burger Court, 75 COLUM. L. REV. 623, 623–24 (1975); see generally TINSLEY E. YARBROUGH, THE BURGER COURT: JUSTICES, RULINGS, AND LEGACY 126 (2000).} Where it was not clear that Congress clearly and expressly preempted state law, the Burger Court was (generally) more willing to allow state law to prevail.\footnote{Bratton, supra note 51, at 653; see, e.g., Pacific Gas & Electric Co. v. State Energy Resources Comm'n, 461 U.S. 190 (1983).}
The Rehnquist Court shifted away from the Burger Court’s analysis, while quoting the Burger Court’s decisions as precedent, and held that state law was preempted in a majority of their cases.\(^5\) Hence, at this time, the Court was still using the presumption against preemption, but weakened it considerably.\(^4\)

The current court, the Roberts Court, has been considerably more active in the federal preemption market.\(^5\) The Court has been somewhat sporadic with its decisions and has swayed back and forth between finding preemption and allowing state law to prevail.\(^5\) The Court has relied on a regulatory paradigm, whereby it views tort lawsuits as regulatory rather than as compensatory, and thus they interfere with federal regulatory administrations.\(^5\)

This argument has been applied, however, in cases that find preemption. Consequently, in those cases that do not find preemption, the Court has been somewhat unclear about how the regulatory paradigm should be applied.\(^5\) This trend has left the federal preemption arena in a state of flux. Accordingly, a clear standard is needed so that (1) injured plaintiffs know if they have any source of recovery, and (2) the sovereign states know where their regulatory place is within our dichotomous government. The Attorney General approach, therefore, could be a clear standard that could be used to fill this void and provide states with more regulatory power.

B. Generic Drug Regulation

The regulation of generic drugs has proven to be quite a task for the FDA. Generic drug manufacturers have become prominent in the marketplace, which can be seen just by watching a string of television commercials at any time of day. The influx of generic drugs on the market, however, is a new

\(^5\) Andrew M. Siegel, *The Court Against the Courts: Hostility to Litigation As an Organizing Theme in the Rehnquist Court’s Jurisprudence*, 84 Tex. L. Rev. 1097, 1166 (2006).

\(^4\) Id.


\(^5\) Id.

development, brought in by the Hatch-Waxman Amendments and more lenient FDA requirements, which are discussed in this section.

The Hatch-Waxman Amendments, as part of the Drug Price Competition and Patent Term Restoration Act of 1984,59 "allow[ ] a generic drug manufacturer to gain FDA approval simply by showing that its drug is equivalent to an already-approved brand-name drug, and that the safety and efficacy labeling proposed for its drug is the same as that approved for the brand-name drug."60 State tort laws, however, generally require that a drug manufacturer must act accordingly if a change arises, such as an increase in the number of consumers that have a severe adverse reaction.61 Such a change would require a more stringent label, treating brand-name and generic drug manufacturers equally.62 This difference, wherein the FDA requires "sameness"63 from the generic drug manufacturers, and the states require any drug manufacturer to change their label64 is where the preemption issue lies.

There are certain processes and remedies that the FDA will allow drug manufacturers to use when labeling is found insufficient: the "changes being effected" ("CBE") process and "Dear Doctor Letters."65 Both of these avenues were at issue in the PLIVA decision. The CBE process allows a brand-name drug manufacturer to strengthen a warning, precaution, or instruction about such things as dosage or administration without preapproval by the FDA.66 The FDA, however, has read this regulation to allow generic drug manufacturers to change their labels "to match an updated brand-name label or follow the FDA's instructions."67 "Dear doctor" letters, on the other hand, are not as compelling as the CBE process argument. The "Dear Doctor" letters argument basically contends that the generic drug manufacturers can send additional warnings to the persons they are selling to, namely prescribing physicians and healthcare professionals.68 The FDA again argues that this is "labeling" and thus the

60 PLIVA, 131 S. Ct. at 2570.
61 Id.
62 Id. at 2573.
63 Id. at 2574–75. The Court notes that this means "the [generic drug’s] labeling must be the same as the listed [brand-name] drug product’s labeling because the listed drug product is the basis for [generic drug] approval." Id. at 2575.
64 Id. at 2573.
65 Id. at 2570.
66 Id. at 2575.
67 Id.
68 Id. at 2576.
generic drug manufacturer must strive for “sameness” and can only send letters that are consistent with approved drug labeling.\(^{69}\)

The FDA currently maintains that a generic drug manufacturer can change drug labels, but only by proposing changes to the FDA.\(^{70}\) The FDA will then work with the brand-name manufacturer to change the label for both generic and brand-name forms of the drug, if necessary.\(^{71}\) The FDA bases this proposition on the requirement that “labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.”\(^{72}\) As a consequence, the generic drug manufacturers, under the FDA reasoning, only have the duty of asking the agency to work with the brand-name manufacturer to change the label if it becomes aware of safety problems.\(^{73}\) The Supreme Court, however, has not addressed the FDA’s argument, as it was only referenced in the holding in \textit{PLIVA}.\(^{74}\)

\section*{III. THE PLIVA DECISION}

To understand the FDA’s argument, and the argument of the other parties involved in \textit{PLIVA}, the background leading up to the lawsuit is pivotal. This background will also further the understanding of the editor in why an alternative approach is needed, such as the Attorney General scenario which this Note discusses in a later section. Part III.A of this Note gives the background of the \textit{PLIVA} decision and what led up to the lawsuit. Part III.B describes the trends the Supreme Court has followed through the regimes of the Burger Court, the Rehnquist Court, and finally, the Roberts Court. Part III.C discusses the precursor to the \textit{PLIVA} decision, the \textit{Wyeth} case, and why the Court found the two cases distinguishable from one another. Part III.D delves into the implications for the missing concurrence from Supreme Court Justice Kennedy and how it may be the missing link for practitioners and lower courts. Part III.E reviews Justice Sotomayor’s dissenting opinion in \textit{PLIVA}.

\subsection*{A. Background}

As stated previously, \textit{PLIVA} arose from two plaintiffs who developed tardive dyskinesia ("TD") from prolonged use of a generic form of Reglan. TD is characterized “by involuntary movements of the face, trunk, or extremities, and is often associated with the prolonged exposure to dopamine receptor

\footnotesize
\begin{itemize}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.} (quoting 21 C.F.R. § 201.57(e) (2006); 21 U.S.C. § 352(f)(2) (2006) (from which the FDA bases its practice of working indirectly with generic drug manufacturers)).
\item \textit{PLIVA}, 131 S. Ct. at 2576.
\item \textit{Id. at 2577.}
\end{itemize}
drugs . . . ."75 Frowning, blinking, chewing, and rolling of the tongue are some of the involuntary movements that result.76 Additionally, issues with swallowing, dental issues, respiratory interruptions (such as shortness in breath), weight loss, and a shorter life expectancy are physical side effects of TD.77 Further, psychological side effects, such as depression and anxiety, occur because of the social stigma that persons affected by TD feel because of the physical side effects of the disease.78

In PLIVA and Wyeth, the preemption issue arose from the FDA’s CBE process and sending “Dear Doctor” letters.79 The plaintiffs in PLIVA argued that these two processes allowed for the generic drug manufacturers to act in a similar unilateral fashion to how the brand-name drug manufacturers could in Wyeth.80 The plaintiffs further argued that the holding in Wyeth was controlling and that the more stringent state law requirements should be upheld against the generic drug manufacturers.81 Additionally, even if the court held that Wyeth did not extend to the generic drug manufacturers, the state law regulations were not preempted because of other avenues the manufacturers could have taken other than unilateral relabeling, which the FDA forbids for generic drug manufacturers.82

The defendants, on the other hand, argued that unlike Wyeth, where the brand-name manufacturers could act unilaterally to change their labels, the fact that the defendants could only act if the brand-name manufacturers acted first made Wyeth inapplicable.83 The defendants contended that the state regulations made it impossible for them, as generic drug manufacturers, to act under state law while obeying federal regulation under the FDA.84 They further maintained that there was not a duty for generic drug manufacturers to request a strengthened label, although the FDA maintained that there was under 21 U.S.C. § 352(f)(2).85

76 Id.
77 Id. at 806.
78 Id.
79 PLIVA, 131 S. Ct. at 2570.
80 Id.
81 Id. at 2573–74.
82 Id. at 2570. These avenues were addressed above, in section II.B: the CBE process and the “Dear Doctor” letters. Id.
83 Id. at 2573.
84 Id.
85 Id. at 2576–77.
The FDA bases its proposition that a generic drug manufacturer can only change drug labels by proposing changes to the FDA\textsuperscript{86} on 21 U.S.C. § 352(f)(2), which it interprets to require that “labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.”\textsuperscript{87} Thus, the only duty that a generic drug manufacturer has, under the FDA’s reasoning, is to ask the agency to work with the brand-name manufacturer to change the label if it becomes aware of safety problems.\textsuperscript{88} The FDA’s argument, however, has not been addressed by the Supreme Court, and was only referenced in the holding in \textit{PLIVA}.\textsuperscript{89} The Court did not address this argument because it found the federal regulation preempted the state tort law, even assuming a duty existed.\textsuperscript{90}

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\textbf{B. Counter-Trends: The Justices’ Change in Direction}
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This section analyzes the change over time in preemption jurisprudence, starting with an overview of the trends of the Burger Court, then moving onto the Rehnquist Court, and finally the Roberts Court. These trends are important to understanding where the Court now stands and how the preemption landscape has been formed.

1. The Burger Court

The Burger Court spanned 1969 to 1986 and was supposed to be a conservative backlash against the liberal policies implemented by the Warren Court.\textsuperscript{91} The Burger Court did not follow the trend of the Warren Court and traditionally favored state and federal agencies working side-by-side, however, it was a conservative court that took an inconsistent liberal approach to the preemption issue.\textsuperscript{92} The Burger Court upheld state action in areas in which the Warren Court had vigorously applied federal policies.\textsuperscript{93}

\textsuperscript{86} \textit{Id.}
\textsuperscript{87} \textit{Id.} (quoting 21 C.F.R. § 201.57(e) (2006)).
\textsuperscript{88} \textit{Id.}
\textsuperscript{89} \textit{Id. at 2577.}
\textsuperscript{90} \textit{Id.}
\textsuperscript{91} \textit{Tinsley E. Yarbrough, The Burger Court: Justices, Rulings, and Legacy} (2000).
\textsuperscript{92} Bratton, \textit{supra} note 51, at 623–24; \textit{see generally} YARBROUGH, \textit{supra} note 91, at 126.
\textsuperscript{93} Bratton, \textit{supra} note 51, at 623–24.
Pacific Gas & Electric Co. v. State Energy Resources Comm’n94 is an example of the Burger Court’s views on federal preemption. In this case, the Court held that a California statute conditioning the construction of additional nuclear plants on the development of an adequate storage and disposal facilities was constitutional, despite utility companies’ challenges.95 The Court cited the long history of dual federal-state regulation in the field of nuclear-power electrical generation, and the limited conflict between federal and state regulatory efforts, thus upholding the state’s regulatory laws in that area.96 This case is indicative of the Court’s numerous holdings that “where Congress has not made clear its intention to preempt, or where a conflict is unripe or peripheral to the purpose of the federal statute, state legislation will be allowed to stand.”97

2. The Rehnquist Court

The Rehnquist Court was commissioned from 1986 until 2005, when the late William Rehnquist passed away.98 The Rehnquist Court, a more “right” court, tended to say it was going one way, usually stating that the presumption against preemption should be applied in federal preemption cases, but held in the opposite:

While the Rehnquist Court has, at times, endorsed just such a “presumption against preemption” in words, it has consistently rejected such an approach in practice. In cases dealing with a wide cross-section of regulatory arenas, the Justices have overwhelmingly sided with those advocating the invalidation of state regulation and against their erstwhile allies, the states. Though the numbers have leveled off a bit in the last few terms, for much of its time together, the Rehnquist Court was finding preemption in over two-thirds of the cases raising the issue. During the 1999 and 2000 terms, the Court did itself one better and found preemption in every single case raising the issue (seven out of seven).99

95 Id.
96 Id.
97 Bratton, supra note 51, at 653.
99 Siegel, supra note 53, at 1166.
As the above passage makes clear, the Rehnquist Court was stating one thing and heading in the opposing direction. Those justices that are usually known for defending states’ rights—Rehnquist, O’Connor, Scalia, Kennedy, and Thomas—were shown to be a formidable bloc upholding preemption on several occasions. Accordingly, although the Rehnquist Court strained to make it appear as though it was taking the same course as its conservative counterpart, the Burger Court, it was really taking the focus away from states’ rights and moving more toward a presumption of preemption.

On the other hand, three of the seven cases that Siegel notes in his pronunciation were expressly preempted. There were, of course, dissents in all three cases holding that the state regulation was not expressly preempted. Resultantly, there was some argument that the Court could still find that the state law was not preempted and could stand alongside the federal regulatory scheme in question. The other four cases, however, used implied preemption and found that federal law trumped. The Rehnquist Court, therefore, was still...

100 Id. at 1167; see also The National Legal Center for the Public Interest, Federal Preemption: The Court Steps Back From States’ Rights, 24 NO. 11 JUD./LEGIS. WATCH REP. 4 (2003) available at http://web.archive.org/web/20050206081857/http://nlcpi.org/books/pdf/JLWR_October03.pdf (showing five cases in the 2002–2003 term in which “switch-hitting” occurred by the Justices who were usually states’ rightists; “[p]erhaps the single most striking trend of the 2002–2003 Term was the spectacle of a Court that had previously been obsessed with the Ninth, Tenth, and Eleventh Amendments suddenly ‘switch-hitting’ on federal preemption issues”).


103 Siegel, supra note 53; see, e.g., Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 343 (2001) (ruling that state law claims that a manufacturer committed fraud on the federal Food and Drug Administration were preempted by federal law); Crosby v. Nat’l Foreign Trade Council, 530 U.S. 363, 366 (2000) (finding federal preemption of a state law barring state entities from buying goods or services from companies doing business with Burma); Geier v. Am. Honda Motor Co., 529 U.S. 861, 881 (2000) (determining that a state law tort action posed an obstacle to the purposes of the Federal Motor Vehicle Safety Act and was therefore preempted); United States v. Locke, 529 U.S. 89 (2000) (finding some state oil spill prevention regulations preempted by the federal Ports and Waterways Safety Act and remanding for a decision on others).
showing a willingness to find preemption in situations where it was not clearly blocked by an express Congressional provision.

3. The Roberts Court

The Roberts Court spanned from 2005 to the present.104 The Roberts Court has taken on numerous preemption cases and has taken a regulatory view (rather than a compensatory view whereby states are providing remedies to citizens rather than simply regulating an area of law) of federal preemption in those cases.105 The Court, however, has used the regulatory paradigm in cases both in which it found preemption and those in which it found that state law was not preempted.106 The Court seems to be taking great leeway with the federal preemption cases and has left federal preemption open for manipulation depending on who can manage a majority.107 It seems, however, as though the more conservative view of old, that would not find preemption (as the Roberts Court held), has switched to the modern view that preemption should be found more often than not.108

The Roberts Court has left itself this additional room because of its characterization of what "regulatory" means in federal preemption cases.109 The Court has held that tort lawsuits are regulatory in nature, and that these lawsuits thus interfere with administrative regulatory regimes.110 Hence, the door has been opened to allow for federal defendants to make a strong case for preemption against state regulatory schemes that lead to private cause of actions. Even in Wyeth, where the outcome was against preemption, the Court found that the tort system was "acting as 'a complementary form of drug regulation' in which '[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." 111


105 Wells, supra note 24, at 794.


107 See Wells, supra note 24, at 794.

108 Id. at 795.

109 Id.

110 Id.

111 Id. at 811–12 (quoting Wyeth, 555 U.S. at 578–79).
The "compensatory paradigm," in contrast, views state tort lawsuits and regulations as methods of controlling conduct through obligating defendants to pay compensation.\textsuperscript{112} This paradigm was used early on by the Roberts Court to uphold state regulation.\textsuperscript{113} The compensatory paradigm is traditionally used where there is no explicit preemption clause in the legislation in question and the breadth of the possible preemption of state law is vast.\textsuperscript{114} This paradigm is used by the Justices who are in the minority of the \textit{PLIVA} opinion\textsuperscript{115} and can lead to the uncertainty that has been shown in the Roberts Courts' decisions. In the compensatory cases "the Court [has] found against preemption because it viewed common law tort verdicts as not having an effect on businesses similar enough to statutes and regulations to amount to conflicting legal mandates."\textsuperscript{116} As stated above, however, the trend in the Court now is the adoption of the regulatory paradigm in both for-preemption and against-preemption cases, leaving even more uncertainty as to what argument will lead to what end.\textsuperscript{117}

\textbf{C. Pre-PLIVA: The Wyeth Decision}

This section will provide a short summary of \textit{Wyeth} and the background of that case. Because \textit{Wyeth} was the precursor to \textit{PLIVA}, it is important to review how the Court was able to split hairs between the brand-name manufacturers involved in \textit{Wyeth} and generic name manufacturers in \textit{PLIVA}. Thus, the latter part of this section connects \textit{Wyeth} to the decision in \textit{PLIVA} and discusses why the Court had different holdings in the two cases.

\textbf{1. A General Overview of Wyeth}

\textit{Wyeth}, as it has been alluded to in this Note, also resulted from a failure-to-warn claim that dealt with the labeling requirements of brand-name drugs on the federal and state level.\textsuperscript{118} The plaintiff had been administered an anti-nausea medication, Phenergan, with the IV-push method.\textsuperscript{119} This resulted

\begin{footnotesize}
\begin{enumerate}
\item \footnote{Wells, \textit{supra} note 24, at 794.}
\item \footnote{\textit{Id.} at 804, 812; \textit{see} Exxon Shipping Co. v. Baker, 554 U.S. 471, 474 (2008).}
\item \footnote{\textit{See generally} Exxon Shipping Co., 554 U.S. at 489.}
\item \footnote{PLIVA v. Mensing, 131 S. Ct. 2567, 2592 (2011).}
\item \footnote{Wells, \textit{supra} note 24, at 794–95; \textit{see, e.g.}, Bates v. Dow Agrosciences, L.L.C., 544 U.S. 431 (2005).}
\item \footnote{Wells, \textit{supra} note 24, at 795.}
\item \footnote{Wyeth v. Levine, 555 U.S. 555, 558–61 (2009).}
\item \footnote{The Court noted that:}
\item \footnote{[Phenergan] can be administered \ldots intravenously \ldots through either the "IV-push" method, whereby the drug is injected directly into a patient's vein, or the "IV-drip" method, whereby the drug is introduced into a saline}
\end{enumerate}
\end{footnotesize}
in the onset of gangrene and the amputation of the patient’s arm. Although the states required a stricter standard of labeling than the FDA, the Court upheld the state regulation against the preemption claims. The Court held that the brand-name drug manufacturers could unilaterally change their label to make it stronger and to comply with state law. The Court felt that it was possible for the manufacturers to comply with both federal and state law, resulting in the demise of the impossibility preemption argument raised by the defendant. The Court additionally found that requiring the manufacturer to comply with the stronger state law did not obstruct the purposes and objectives of federal drug labeling regulation because of the FDA’s mixed signals and the statutory language of the Federal Food, Drug, and Cosmetics Act (“FDCA”).

The Court saw the federal labeling standards, and believed the FDA did too, as a “floor upon which [s]tates could build.”

Wyeth followed the regulatory paradigm discussed previously; however, it was only followed because the regulatory aspects of state tort law were non-conflicting (it was not a pure regulatory paradigm case). Wyeth thus is an example of when federal preemption has not been found while using the Roberts Court’s regulatory argument, viewing tort suits as simply a regulatory function of the state. Further, although the FDA had “recently adopted [the] position that state tort suits interfere with its statutory mandate,” the Court afforded it no weight. The Court did, however, find the lack of express preemption and the “long-standing coexistence of state and federal law” under the FDA enough to find that the state regulatory scheme could coexist with that of the federal scheme.

2. Distinguishing Between Wyeth and PLIVA

The Court found in PLIVA that the brand-name versus generic prescription drug distinction made the underlying issue distinguishable from

solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient’s vein. [Phenergan] is corrosive and causes irreversible gangrene if it enters a patient’s artery.

Id. at 559.

Id.

Id. at 558–59, 566–69.

Id. at 573.

Id. at 579–81.

Id. at 574–80.

Id. at 577.

Wells, supra note 24, at 811–12.

Id.

Wyeth, 555 U.S. at 581.

Id.

https://researchrepository.wvu.edu/wvlr/vol115/iss1/17
Because the brand-name drug manufacturers could act unilaterally, they were able to comply with both state and federal law, something the generic drug manufacturer could not do because of its reliance on the brand-name manufacturers under the FDA’s regulations.

The Court focused, as it believed the Wyeth majority had, on the unilateral action a brand-name manufacturer could take under the CBE process. Because the federal statutes and regulations were “meaningfully different” as applied to brand-name manufacturers compared to generic manufacturers, a different finding of preemption was logical. The majority conceded that Congress’s scheme may be “unusual or even bizarre,” but that because of the legislative scheme governing prescription drug manufacturers, the Court would not distort the Supremacy Clause in order to change an outcome that made “little sense” from the plaintiffs’ perspectives. Thus, because of the special regulation for generic drugs under the Hatch-Waxman Amendments, which were meant to expand the generic drug market quickly, a dissimilar preemption outcome was applied to a “dissimilar statutory scheme.”

D. Justice Kennedy’s Missing Concurrence

Justice Kennedy concurs in all but section III part B-2 of the PLIVA decision, which deals with the application of the so-called non obstante provision of the Supremacy Clause. In this section, the Court reasoned that the text of the Supremacy Clause allows for a reading that there is a “non obstante provision in the Supremacy Clause [and it] ... suggests that federal law should be understood to impliedly repeal conflicting state law.” The Court held that because of the provision, it only needed to look at the “ordinary meaning” of federal law, and should not distort federal law to accommodate conflicting state law.

Justice Kennedy, who concurred in the rest of the majority opinion, opted out of concurring with this section, but did not write an opinion to give

130 Wyeth. Because the brand-name drug manufacturers could act unilaterally, they were able to comply with both state and federal law, something the generic drug manufacturer could not do because of its reliance on the brand-name manufacturers under the FDA’s regulations.

131 Id. at 2574–75.

132 Id. at 2581–82.

133 Id.

134 Id.

135 Id. at 2582 (noting that “[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire”).

136 Id. at 2571, 2579–81.

137 Id. at 2580.

138 Id. (quoting Wyeth v. Levine, 555 U.S. 555, 588 (2009) (Thomas, J., concurring in judgment)).
his reasoning. Justice Kennedy is known for his concurring opinions because of his place as the “swing vote,” not only on the Roberts Court, but historically on the Rehnquist Court. It is clear, however, that Justice Kennedy sits as the “pivot” on the Roberts Court. Because he is usually the split in the five to four decisions, such as PLIVA, his concurrence would likely help the case editor to understand the reasoning for his vote in this case. Under the circumstances, it is interesting that in such a close case, on a paramount issue, he opted out of writing a concurrence on one section that only takes up about a page and a half of the decision. Further, it is even more perplexing that there is not a single comment from Kennedy when Thomas himself, the majority penman, opted out of writing this section.

Although Kennedy seems to be devoted to states’ rights, “[he] has been quite willing to find federal preemption when it serves deregulation purposes.” Ergo, it would seem that he would agree with the majority on the non obstante provision reasoning because it gives more power to uphold a federal preemption finding and allow state deregulation. Kennedy, however, refuses to concur and offers no reasoning to the editor. It is, consequently, unclear why Kennedy did not iterate why he did not join a small part of the majority opinion, especially one that may continue to be used hereafter. It is, however, a particularly important piece of the case to take note of for practicing attorneys who may come up against a federal preemption question. Arguing against, or not arguing, the non obstante provision contention may, consequently, win favor with the swing justice.

139 Id. at 2571, 2579–81.
142 In the Supreme Court’s 2006 term, Justice Kennedy was the deciding vote in all twenty-four of the Court’s five-member majority decisions. Jason Harrow, Justice Kennedy’s Remarkable OTO6, SCOTUSBLOG, (June 28, 2007, 5:20 PM), http://www.scotusblog.com/2007/06/justice-kennedys-remarkable-oto6.
143 PLIVA, 131 S. Ct. at 2571.
144 Id. at 2579–81.
145 Id. at 2571.
146 Blumm & Bosse, supra note 141.
147 The Author refers to “state deregulation” as when the Court finds that a state’s tort laws and regulations are preempted by a federal law or regulation.
148 PLIVA, 131 S. Ct. at 2579–81.
The lack of concurrence is important because Kennedy has the power to swing a five to four vote in a split case.149 Because of the current composition of the Court, it is worthwhile to know what Justice Kennedy believes because of the weight of his vote.150 Additionally, the back and forth decisions of the Court on the federal preemption issue may be affected by how Justice Kennedy feels about the case. Because PLIVA was a five to four decision, a similar case may be accepted by the Court and afford a chance for a clearer response from Justice Kennedy, and possibly a change in the holding.151

E. Justice Sotomayor’s Dissent

Justice Sotomayor challenges the majority’s findings, and specifically its test for impossibility preemption, in her dissent.152 Further, she finds that the split from Wyeth is incorrect,153 especially because generic drugs make up almost 75% of the prescription drug market because of the Hatch-Waxman Amendments, which implemented separate regulatory standards for generic drug manufacturers in order to allow them to make the drugs more cheaply.154

1. Treating Generic Drugs Differently?

Justice Sotomayor agrees with the majority that generic manufacturers also bear responsibility under federal law “for monitoring the adequacy of their warnings.”155 She further agrees that generic drug manufacturers cannot act unilaterally through the processes that the Plaintiffs had suggested, the CBE

149 Harrow, supra note 142.

150 Id.

151 A case that is currently pending, given an extension for a response petition until October 31, 2012, will provide such an opportunity for Justice Kennedy. The case that is being appealed from the First Circuit involves a woman who was given a generic drug, not by her own choosing, but by the pharmacy’s choosing. The court noted that “[the plaintiff] having lost her warning claim by mere chance of her drug store’s selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief.” Bartlett v. Mut. Pharm. Co., Inc., 678 F.3d 30, 38 (1st Cir. 2012), petition for cert filed, ___ U.S.L.W. ___ (U.S. July 31, 2012) (No. ____), available at http://www.hpm.com/pdf/blog/SULINDAC%20%20Bartlett%20Sup%20Cert%20Pet.pdf. Further, there was a federal preemption case heard in June 2012, however, it dealt with field preemption and did not deal with FDA regulations. It is important, though, because Justice Kennedy again did not take the opportunity to express his views on the non obstante provision. Kurns v. R.R. Friction Prod. Corp., 132 S. Ct. 1261 (2012).


153 Id. at 2588–90.

154 Id. at 2583–84.

155 Id. at 2585.
process and the "Dear Doctor" letters. Justice Sotomayor disagrees with the PLIVA majority, however, and argues that generic drug manufacturers cannot simply continue blindly distributing a generic drug when they find an issue with its labeling:

FDA regulations require that labeling "be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." The FDA construes this regulation to oblige generic manufacturers "to seek to revise their labeling and provide FDA with supporting information about risks" when they believe that additional warnings are necessary.

She finds that the generic drug manufacturers have two duties: they must, under federal law, monitor their products' safety, and approach the FDA to propose a label change when an issue arises that they believe requires a change.

2. The Preemption Defense

Justice Sotomayor relies heavily on Wyeth's language, which the Court had used just two years before PLIVA, in her argument against the majority's finding of preemption, emphasizing that States traditionally regulate health and safety matters and that Congress had not expressly preempted this area (but was in fact silent). She moves on to discuss the impossibility preemption defense that the majority found to be proven. Justice Sotomayor is taken aback by the fact that a mere possibility of impossibility would be enough, and finds that because the Manufacturers had an available mechanism for changing

156 Id.
157 Id. (citing 21 C.F.R. § 201.80(e) (2010)).
158 Id. at 2586.
159 Id. at 2586–87.
160 The impossibility defense is an affirmative defense; a defendant must "demonstrate that 'compliance with both federal and state [law] is a physical impossibility.'" PLIVA, 131 S. Ct. at 2587 (quoting Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–143 (1963)). "The existence of a hypothetical or potential conflict is insufficient to warrant pre-emption of state law." Id. (citing Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)).
161 Id. at 2578–79.
the label (by asking the FDA to change it), it was not impossible to fulfill the requirements of both state and federal law.162 She concludes that the scenario in PLIVA is not that different from the scenario in Wyeth.163 She finds that brand-name manufacturers must still have approval from the FDA to change their labels; accordingly, she believes the argument that the capability of unilateral action is needed in order for non-preemption cannot stand.164

She concludes by finding three problems with the majority’s preemption analysis.165 First, the new impossibility preemption test has no basis in the Court’s precedents, especially not in Wyeth.166 Second, the majority could have found that conflict preemption was not present without rendering it “illusory” because it can be found without impossibility; rather it can be found “where state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”167 Third, the majority should not have adopted the non obstante provision approach because the Court has historically directed that “congressional action does not supersede ‘the historic police powers of the States . . . unless that was the clear and manifest purpose of Congress.’”168 She reiterates this point again with language from Wyeth:

When federal law provides actors with a mechanism for attempting to comply with their state-law duties, “respect for the States as ‘independent sovereigns in our federal system’” should require those actors to attempt to comply with state law before being heard to complain that compliance with both laws was impossible.”169

Justice Sotomayor found that a divergent scheme of liability law has emerged because (1) the majority incorrectly applied the doctrine of impossibility and in fact “invents” its own doctrine just for this case;170 (2) the majority incorrectly allows the silence of Congress to outweigh the states’ traditional role in health and safety issues;171 (3) the majority incorrectly believes that this follows the purpose of the Hatch-Waxman Amendments when, in reality, it will likely make states cut back on the allowance afforded

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162 Id. at 2582, 2587–88.
163 Id. at 2588.
164 Id. at 2588–89.
165 Id. at 2590.
166 Id. at 2589–90.
167 Id. at 2590 (quoting Crosby v. Nat’l Foreign Trade Council, 530 U.S. 363, 373 (2000)).
168 Id. at 2590–92 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).
169 Id. at 2592 (quoting Wyeth v. Levine, 555 U.S. 555, 565–66 n.3 (2009)).
170 Id. at 2582–83.
171 Id. at 2586–87.
generic drug manufacturers;\textsuperscript{172} (4) the majority incorrectly found that there were no unilateral actions that generic drug manufacturers could take;\textsuperscript{173} and (5) the majority incorrectly found that a person should have recourse when prescribed a brand-name drug, but not a generic drug.\textsuperscript{174} Thus, Justice Sotomayor, and her dissenting counterparts,\textsuperscript{175} would find that persons injured by inadequate labeling of a generic drug have the same actionable rights as those who are prescribed a brand-name drug.\textsuperscript{176}

This dissent is important, therefore, because it leaves an avenue for plaintiffs who may be able to find a loophole in the PLIVA holding. Because of the Court's swing vote atmosphere at the moment, a change in facts or circumstances may make the Court more amenable to change. Although at this time it is unlikely to change unless a new scheme is adopted, as discussed in the next section of this Note, the arguments made by the dissent will be helpful to practitioners in framing their future arguments if there is a change in the makeup of the Court or a change in federal preemption regime.

\textbf{IV. FEDERAL PREEMPTION AFTER PLIVA}

Because the Court held that Wyeth, which held that brand-name drug manufacturers were held to state law regulations,\textsuperscript{177} did not extend to generic drug manufacturers,\textsuperscript{178} two questions remain: (1) why generic drug manufacturers are more protected than their brand-name drug manufacturer counterparts and (2) where the federal preemption line should be drawn. Subsequently, Part IV.A discusses the protection now afforded to generic drug manufacturers versus their brand-name counterparts. Finally, Part IV.B reviews two federal district court cases that were decided after PLIVA. These two cases differ substantially from each other and show how PLIVA can be easily followed or how loopholes in the case may be exploited, further emphasizing the need for more clarity in the preemption arena.

\textit{A. The Unbalanced Outcome: Why Generic Drugs Are Afforded More Protection}

Justice Sotomayor points out in her dissent that the only difference between generic drugs and brand-name drugs is the name and the percentage of

\textsuperscript{172} \textit{Id.} at 2593.
\textsuperscript{173} \textit{Id.} at 2588–89.
\textsuperscript{174} \textit{Id.} at 2592.
\textsuperscript{175} Justice Ginsburg, Justice Breyer, and Justice Kagan all joined in Justice Sotomayor's dissent. \textit{Id.} at 2582.
\textsuperscript{176} \textit{Id.} at 2593.
\textsuperscript{177} Wyeth v. Levine, 555 U.S. 555 (2009).
\textsuperscript{178} \textit{See PLIVA}, 131 S. Ct. at 2581 (Sotomayor, J., dissenting).
sales that each make. It is even more alarming that the majority opinion points out that if the plaintiffs had been given the brand-name drug, instead of the generic drug, they would have a claim. The Hatch-Waxman Amendments, meant to help consumers, are now hurting them by preempting state tort law claims for persons whose prescriptions are filled with the generic form of the drug. This is an outcome which would not have occurred but for the Supreme Court’s recent preemption decisions.

This section of this Note provides a survey of three different preemption arguments for and against the imbalance between brand-name manufacturers and generic drug manufacturers. The first argument is against the imbalance, which focuses primarily on the lack of FDA oversight that leads to the contention that generic drug manufacturers should be held liable to tort suits. The second argument is a middle ground argument which would hold generic drug manufacturers for primary liability and the brand-name manufacturers for secondary liability. The last argument is similar to the majority’s argument in PLIVA and would find that generic drug manufacturers should be held to separate requirements when confronted with state tort liability.

1. Issues with FDA Oversight

An issue that has been prevalent for some time is the lack of oversight that the FDA has wielded as of late. Government studies and surveys of FDA scientists have shown that the FDA has some real concerns when dealing with the oversight of drug manufacturers. These studies have found that the FDA is “currently unable to protect the public from unsafe drugs and devices

179 Id. at 2582–84 (stating that generic drugs make up seventy-five percent of the market).
180 The Court stated:

Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be preempted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law preempts these lawsuits.... We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.

Id. at 2581–82.
182 PLIVA, 131 S. Ct. at 2583.
183 Id. at 2593.
185 Id.
adequately"\textsuperscript{186} and that "[a]ll most seventy percent [of FDA scientists] did not believe the FDA had sufficient resources to effectively perform its mission of protecting public health and helping the public get the accurate, science-based information needed to use medicines and foods to improve its health . . . ."\textsuperscript{187}

Because of the obstacles that the FDA has faced and currently faces, it seems as though the public is at a serious disadvantage when needing compensation for injuries that have occurred because of a generic drug issue. Further evidence has shown that it is common for drugs to be approved by the FDA without extensive studies of their safety and that "82 of the 174 products approved between January 1995 and June 2007 in the United States and/or the European Union . . . were subject to subsequent safety-related regulatory actions."\textsuperscript{188} These problems seem to stem from several shortcomings of the FDA: little post approval oversight, systemic lack of post approval studies, inability to stay astride with adverse event reports, and unknown safety issues prior to FDA approval.\textsuperscript{189} As a result, the FDA has created a situation where consumers are at a higher risk of injury with a lower chance of receiving compensation in the event of an injury, both consequences that the average consumer likely does not take into account when the local pharmacist fills his prescription with the generic form of the prescribed medication.

On the other hand, the argument can be made that the FDA is balancing the desire to release drugs quickly so that diseases can be cured earlier and the desire to protect consumers from unwanted side effects of improperly tested prescription drugs that require longer and additional studies. The author of this Note would argue, however, that because the brand-name drug must undergo these longer studies, this cannot be a strong desire of the FDA. If it truly wanted to decrease the time between the creation of a drug and the time the drug is placed on the market, the FDA would decrease the requirements for brand-name drug manufacturers also.\textsuperscript{190} Additionally, if the average consumer was aware up-front of the lack of extensive studies and the serious side effects of the prescription being taken (as in the case of the PL\textsc{I}VA plaintiffs), then there would likely be a reduced call by the consumer to have a new drug immediately placed on the market.

The current state of the FDA's regulatory process shows that the current liability scheme may not work and will leave injured consumers

\textsuperscript{186} \textit{Id.} at 1284.

\textsuperscript{187} \textit{Id.} at 1285 (citation omitted).

\textsuperscript{188} \textit{Id.} at 1287. The author also notes that "[t]hree years after approval, fourteen percent were the subject of a regulatory action; by ten years after approval, twenty-nine percent were the subject of a regulatory action." \textit{Id.} (citing Catherine D. DeAngelis & Phil B. Fontanaosa, \textit{Prescription Drugs, Product Liability, and Preemption of Tort Litigation}, 300 JAMA 1939 (2008)).

\textsuperscript{189} \textit{Id.} at 1287–1289.

\textsuperscript{190} See supra Part III.A.
without recourse. If state tort law continues to be federally preempted for generic drug manufacturers, then Congress or the FDA itself should take steps to ensure that more stringent precautions are taken by the FDA (which may be the only protection that consumers of generic drugs now have). Otherwise, the argument must stay that generic drug manufacturers will not be held liable for the wrongs that they impose, while brand-name manufacturers will be held liable. A generic drug, not properly regulated by the FDA at the outset, will reach a consumer who, if injured, will not have a compensation option. The Court found in Wyeth that state tort suits do perform essential functions that the FDA cannot: they "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," and "[t]hey also serve a distinct compensatory function that may motivate injured persons to come forward with information." The Court has, therefore, found that state tort suits do have their place in filling the gap where the FDA cannot, and it can be argued that the same should be applied to generic drug manufacturers.

2. Make Brand-Name Drug Manufacturers Liable for Generic Drug Issues

This section discusses two federal preemption arguments that would hold brand-name drug manufacturers liable for issues with generic drugs. Part a discusses a case from the California Court of Appeals which held a brand-name drug manufacturer liable, but not its generic drug counterpart, although the generic drug manufacturer was technically the tortious wrongdoer in the case. Part b reviews an argument which would hold both manufacturers liable, based on a dichotic damages scheme that would have the generic drug manufacturer primarily liable and the brand-name manufacturer secondarily liable.

a. The Conte Case

In Conte v. Wyeth, a California Court of Appeals found that a brand-name drug manufacturer may be held liable in some instances for tortious conduct of a generic drug manufacturer that caused a plaintiff's injuries. The court did not hold the generic drug manufacturer liable because it did not supply the information that the physician used in prescribing the drug.

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191 PLIVA, 131 S. Ct. at 2581–82.
192 Id.
193 Id.
195 PLIVA, 131 S. Ct. at 2581–82.
197 Id. at 307–318.
only one case that found this way, however, and a subsequent federal court
decision criticized the decision for being in contrast to every other decision that
a court has handed down on the issue. 198

This argument would contend that a brand-name drug manufacturer,
who was the first to disseminate information about the drug and thus what
physician’s relied upon when prescribing a “like” generic form of the drug,
should be liable where a generic drug manufacturer cannot be found liable. 199
Because this argument seems to stretch the possibilities of this area of law, and
because only one court has advocated it in the face of severe criticism, this
argument seems fairly unlikely to ever have a strong hold in the federal
preemption jurisprudence.200

This argument is not strong, especially considering the state of the law
at present. It would be a complete turnaround from where the Supreme Court
has settled in PLIVA. Further, it does seem to place the “unfairness” quotient
that is applied to consumers under PLIVA squarely on brand-name drug
manufacturers. This would be a hard policy to uphold because the generic drug
manufacturer would still be free to injure consumers prescribed the generic
form without any repercussions directly against the generic drug manufacturer.

b. Holding Both Brand-Name and Generic Manufacturers
Liable

Another argument heralded by constitutional scholar and professor of
law Allen Rostron is that, where appropriate, a plaintiff could assert a claim
against both the brand-name and generic drug manufacturers.201 He contends
that in the scenario where a consumer takes the generic form of a drug which
caused injuries but the brand-name manufacturer also was negligent in
designing the product or failing to give adequate warnings, the generic
manufacturer should “bear primary liability for the plaintiff’s injuries, with the
brand-name manufacturer having only secondary liability in the event that the
generic drug maker has gone out of business or is otherwise unable to pay the
damages.”202 Under those circumstances, both manufacturers would be liable
for their significant roles in the injury.

*10 (D. Nev. Mar. 20, 2009). The Eighth and Fourth Circuits have also held that brand-name
manufacturers cannot be held liable for generic drug manufacturers’ harm. Mensing v. Wyeth,
Inc., 588 F.3d 603, 613 (8th Cir. 2009); Foster v. Am. Home Prods. Corp., 29 F.3d 165, 171 (4th
Cir. 1994).
199 Conte, 85 Cal. Rptr. 3d at 304–05
200 Foster, 29 F.3d at 165; Mensing, 588 F.3d at 603.
201 Allen Rostron, Prescription for Fairness: A New Approach to Tort Liability of Brand-
Name and Generic Drug Manufacturers, 60 DUKE L.J. 1123, 1128 (2011).
202 Id. at 1128–29.
Rostron’s proposal, however, was given before the *PLIVA* decision was handed down. It may be a good foundational framework, however, if the issue is revisited and the Court needs a way to ignore its precedent in *PLIVA* and go in a new direction. This burden-sharing scenario seems to strike a balance that mirrors that which the FDA has put through with the FDCA and the Hatch-Waxman Amendments, whereby the generic drug manufacturers are less liable than their brand-name counterparts but still have some avenues for remedying issues that arise. Thus, if there is a change in tide in the federal preemption framework, which has been seen over the changing majority/minority platforms, this may be a comfortable position for those “sitting on the fence.”

Rostron’s proposal does seem to be a strong argument that would comfortably fit with a five to four Supreme Court majority. The problem, however, is that it does directly place liability on the generic drug manufacturer in a private action. This concept is hard to square with the current federal preemption doctrine. Another alternative may need to be a stepping point between the current holding in *PLIVA* and this argument, reducing the whiplash of a dramatic shift in Supreme Court precedent. As far as policy is concerned, however, this seems to be a strong argument because it holds all tortious parties responsible while allowing for the current state of federal regulation to have some impact on the separation of liability.

3. Generic Drug Manufacturers Should Be Treated Differently

This section of the Note reviews two scenarios that, if implemented, would treat generic drug manufacturers differently than brand-name manufacturers. Part a discusses the “attorney general” argument, which would allow a state’s attorney general to bring suit in place of a private citizen. Part b delves into the “completely block” liability argument, which would block all private suits against generic drug manufactures, such as the one in *PLIVA*.

a. Attorney General Scenario

Another scheme that has been proposed by Jason Miller in his student Note is to allow state attorneys general to bring suits on behalf of consumers, but to block private actions. This scheme, he argues, could be implemented

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203 The *PLIVA* decision was delivered in June of 2011, while Rostron’s article was published in February of 2011. *PLIVA* v. Mensing, 131 S. Ct. 2567 (2011); Rostron, *supra* note 201, at 1123; see Table of Contents, 60 DUKE L.J. i (2011).

204 Rostron, *supra* note 201, at 1128.

either generally, for all prescription drugs, or for generic drugs specifically. Then, the FDA’s focus on allowing generic drugs more leeway in order to produce a more low-cost system of production would still be feasible, but there would also be a form of protection for consumers. The problem, however, is that Congress would need to act before a state could adopt an alternative like the state attorney general model if it was to be applied to generic drug manufacturers.

This shortcoming may lead to the argument’s demise. It could, however, prove to be a good tactic for a state that wishes to still have some control over its state tort liability structure and allow more protection of its own citizens. Hence, if states want to try a semi-legitimate loophole to the problem, but still keep generic drug manufacturers more protected and satisfy the FDA, this may be the way out. Because of PLIVA’s holding that states cannot implement regulation that would allow private actions against generic drug manufacturers, the attorney general model will allow states to give some sort of action for harmed persons in their jurisdiction.

This argument will likely require a large amount of movement at the grass roots level, but is currently the best argument for a way out of applying the PLIVA holding. States will likely be more open to the suggestion because it will allow them to have more control; additionally, state legislators will likely have an easy pitch to constituents who are prescribed generic drug a majority of the time. Further, the argument takes into account that generic drug manufacturers are treated differently under current federal regulation, but still allows a remedy against tortious injuries.

b. Completely Block Liability Scenario

This scenario mirrors that of the majority opinion in PLIVA, arguing that there is no private action remedy for those injured by a generic drug manufacturer whose labels are inadequately labeled. Because of the FDA regulations, the argument can be made that it is impossible for a generic manufacturer to comply with federal law while complying with more strict labeling regulations of the states. In a predictive student Note, Hannah Murray foresaw that the Court would find that because of the FDA’s long-asserted perspective that “generic manufacturers may not modify their drug warning labels” and because the FDA had opposed generic modifications of the

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206 Id. at 571.
207 Id. at 585.
208 PLIVA, 131 S. Ct. at 2568.
209 Id. at 2577–78.
brand-name drug, state tort law claims were completely preempted against
generic drug manufacturers.211

This contention follows suit behind that of the PLIVA majority and
would clearly find that generic drug manufacturers, because of the special
statutory scheme afforded them under federal law, are not liable to private
actions in state tort lawsuits. Because state tort claims are completely blocked
for generic drug manufacturers under this argument, it parallels the holding of
PLIVA that plaintiffs do not have a cognizable failure-to-warn claim against
generic drug manufacturers for insufficient labeling.212

B. Application in the Lower Courts

The previously discussed alternatives are especially important when
one surveys the cases rising through the federal system. Federal courts, now
attempting to apply PLIVA, are churning out prime examples of the confusion
created in preemption law. More poignantly, two Federal District Court cases
show signs of what is occurring and will likely continue to occur in the lower
federal courts. The first, Schedin v. Ortho-McNeil-Janssen Pharm. Inc.,213
involved a suit against a brand-name manufacturer for failing to warn about
certain risks, notably tendon rupture which occurred in the plaintiff's cases,
when a patient would take the drug Levaquin.214 The second, Brasley-Thrash v.
Teva,215 involved a plaintiff who initiated a failure-to-warn claim against a
generic drug manufacturer who administered the same drug as in PLIVA—
 Reglan—but in generic form. The plaintiff in Brasley-Thrash also developed
tardive dyskinesia.216

1. Application to Brand-Name Manufacturers

The Minnesota District Court found in Schedin that the brand-name
drug manufacturer defendant could not use PLIVA in order to avoid a state
failure-to-warn claim.217 The defendant argued that it should be given a new
trial because a jury verdict against it was against the clear weight of evidence
and because PLIVA should control in its case.218 The Court found first that the

211 Murray, supra note 210, at 270–77.
212 PLIVA, 131 S. Ct. at 2581; Murray, supra note 210, at 274.
214 Id. at 908.
2011).
216 See Schedin, 776 F. Supp. 2d at 915–16.
217 Id. at 908–09.
preemption analysis of *Wyeth*, not *PLIVA*, was controlling because the
defendant was a brand-name drug manufacturer, despite the defendant’s claims
that *PLIVA* should still be applied.\textsuperscript{219} The Court further found that the
defendant had not met its requirement to show “clear evidence” that the FDA
would not have approved a label change had the defendant asked for one.\textsuperscript{220}
The defendant had submitted to the Court citizens’ petitions from the FDA that
stated that it did not believe that a label change was required.\textsuperscript{221} The Court
found that because the petitions were written in 2005, 2006, and 2007, a time at
which the FDA had the authority to require a label change, and it was not in
response to the defendant or a manufacturer asking for a label change, it did not
meet *Wyeth* or *PLIVA*’s requirements for demonstrating impossibility
preemption.\textsuperscript{222} The defendant, thus, was held to a heightened duty under both
*Wyeth* and *PLIVA* because it was a brand-name manufacturer.\textsuperscript{223}

This case shows a path that the lower courts will likely follow when
dealing with brand-name prescription drug manufacturers. Because both *Wyeth*
and *PLIVA* emphasize the higher standard applied to brand-name
manufacturers, most lower courts, it can be surmised, will follow in the same
footsteps as the Minnesota District Court. It must be remembered, however,
that defendants will always have novel defenses and that this case only shows
one of them. Although it did not work in this case, this defense or some other
may work in the future. Additionally, it is yet to be seen what will count as
“clear evidence” that the FDA would not approve a change in a label.
Depending on whether the threshold is set higher or lower by the lower federal
courts, the Supreme Court may once again have to review part of its test in this
area once the first hurdle of preemption is cleared.

2. Application to Generic Drug Manufacturers

The Alabama District Court seemed to address the *PLIVA* holding by
allowing loopholes for the plaintiffs in *Brasley-Thrash*.\textsuperscript{224} In *Brasley-Thrash*, the Court issued an order allowing the plaintiff to amend her complaint after
the *PLIVA* holding was announced during the course of the litigation.\textsuperscript{225} The
order was simply one to allow the plaintiff to amend her complaint once the

\textsuperscript{219} Id. at 909–10.
\textsuperscript{220} Id. at 910–11.
\textsuperscript{221} Id. at 912.
\textsuperscript{222} Id.
\textsuperscript{223} Id.
12, 2011).
\textsuperscript{225} Id. at *1.
PLIVA holding was announced. The defendant argued simply that because the plaintiff's claim was preempted by the PLIVA holding, the plaintiff's effort would be useless. The Court, however, found that it could distinguish the plaintiff's claim from that in PLIVA. It found that the plaintiff was merely asserting that the defendant should have sent "Dear Doctor" letters about the approved warning label (reiterating the warnings on the approved label), not that it should have sent letters that did not coordinate with the FDA approved warning label.

This order is important to note because it seems as though this may be the way that some lower federal courts will handle the PLIVA holding. The lower courts may claim to follow PLIVA but ultimately give way for plaintiffs that they feel have a claim, despite their being given the generic form of a drug at the pharmacy window. If other courts follow suit, it may soon turn out that another case will be ripe for the Supreme Court's taking in order to tie up loose ends that they may not have seen in PLIVA.

V. CONCLUSION

The policy that has been set forth in PLIVA, that only certain drug consumers are protected, should not be one that the Court upholds. The lack of alternatives other than private action, because of the FDA's current failure to fully regulate drug manufacturing and drug labeling, makes it clear that there is a need for some sort of repercussion against generic drug manufacturers who otherwise have minimal responsibility at this point. If a similar case is heard, the Supreme Court should seriously consider the message it has sent that there is no remedy for a consumer who is injured by a truly guilty party. The alternatives provided in this Note are points that the Court may consider; however, there are pros and cons to each one. The easiest alternative may be the attorney general argument, which leaves the states with the power to protect consumers if a serious threat is raised by a generic drug manufacturer by allowing the attorney general to bring a suit against the manufacturer. The argument will also allow the Supreme Court to save face by treating the generic drug manufacturers, still protected from a direct private action, differently than brand-name drug manufacturers.

PLIVA is an important turning point in the Roberts Court's preemption jurisprudence. Because the Court had previously left itself leeway because of the regulatory framework it preferred to use, it seems that it has now drawn a line that may help in forecasting the Court's future decisions. The stronger definition of what makes "impossibility," how far the presumption against

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226 Id. at *1–2.
227 Id. at *2.
228 Id. at *3.
229 Id. at *2–3.
preemption can reach, and the stronger federal sway of the non obstante provision that the Court found in the Supremacy Clause, show that the Court may now be leaning toward a presumption for preemption. The way to reach a higher point of clarity in the realm of federal preemption that the Court has chosen—allowing state tort claims of rightful plaintiffs to go unheard based solely on whether they were prescribed a generic prescription drug or a brand-name prescription drug—does not seem to sit well with the dissent in PLIVA or with overall good conscience. Because a change in majority justices can easily occur with the current composition of the Court, it may be questioned how concrete the Court’s precedent actually is.

Further, it remains unseen what the lower federal courts may do with the PLIVA versus Wyeth paradigm. There seems to be some loopholes that may already be coming undone in the lower courts, and the Supreme Court may find itself facing another federal preemption case involving a generic drug manufacturer, or both a generic drug manufacturer and brand-name manufacturer. The many elements at play—for instance, the states themselves that may grapple for more power to protect their own citizens—leave the question still unanswered as to how this area of federal preemption will play out in the future.

Although the Court was trying to find a settling point for federal preemption law, it has opened doors that will likely need closing in the future. The policy behind the dissent’s argument in PLIVA makes the most sense; an unknowing consumer should be protected no matter what type of manufacturer made the drug. The Court has left loopholes that are already being exploited and which may be further exploited not only by the judiciary, but by concerned state legislatures who want to provide avenues for injured citizens (i.e. through the attorney general scenario). As a consequence, the Court will have to deal with this issue again, even though it appears that is exactly what it was trying to avoid.

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