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WYETH AND PLIVA: THE LAW OF INADEQUATE DRUG LABELING

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In *Wyeth v. Levine*, decided in 2009, the U.S. Supreme Court held that consumers *could* sue brand-name drug manufacturers under state tort laws for inadequately labeling a drug (where the drug's label did not warn, or warn sufficiently, of side effects that the drug company knew or should have known of).¹ Just two years later, the Supreme Court held in *PLIVA Inc. v. Mensing* that consumers *could not* sue generic drug manufacturers for inadequately labeling a drug.² The result in *PLIVA*, viewed in light of *Wyeth*, seems unfair for two reasons. First, why should a consumer's right to compensation depend on whether he purchased a brand-name or generic drug? Second, and this happened in *PLIVA*, sometimes plaintiffs are prescribed a brand-name drug, but, because of state drug substitution laws, their pharmacists dispense the generic equivalent.³ The result is that state-sanctioned (and in some states even mandated) substitution causes the plaintiffs to lose their compensation.⁴

The Court itself noted that its distinction between lawsuits against brand-name drug manufacturers and lawsuits against generic drug manufacturers from the perspective of the plaintiffs "makes little sense."⁵ Nonetheless, the majority felt compelled to make the distinction because the Food and Drug Administration's ("FDA's") regulations distinguish between brand-name drug companies and generics. Generic drug companies cannot change their labels without prior FDA approval, while brand-name companies may do so unilaterally.⁶ Since federal law forbids generic drug companies from unilaterally changing their labels, allowing state tort suits for inadequate labeling would put generics in an impossible situation: state tort law would

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1. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

2. *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

3. *Id.* at 2581.

4. *Id.* For discussion of these substitution laws, see *infra* Part III.

5. *PLIVA*, 131 S. Ct. at 2581.

6. *Id.* at 2575. The explanation for this distinction is that the FDA does not want generic drug companies to have labels that differ in any substantive way from those of their brand-name equivalents. See *infra* note 160 and accompanying text.

require generics to label their drugs in a manner that federal law forbids.⁷ The Court therefore held that federal law preempted state tort suits against generic drug companies for inadequate labeling.⁸

This Note argues that the Court was right that the distinction between *Wyeth* and *PLIVA* “makes little sense.” A plaintiff’s right to compensation now depends on the vagaries of state drug substitution laws.⁹ Worse yet, as this Note will explain, under *Wyeth* and *PLIVA* only some generics will be preempted from suit. Authorized generics, those produced by the brand-name company, will still be suable. This makes even less sense.

To be fair, the Court is not the only government institution responsible for this state of affairs. The FDA—by permitting brand-name drug companies to unilaterally alter their label,¹⁰ while forbidding generic drug companies from changing their label under identical circumstances¹¹—created the distinction between generic drugs and brand-name drugs. The Courts in *Wyeth* and *PLIVA* merely took this distinction one step further, tying liability to the right to alter labels unilaterally.

There is a danger that the combination of these two decisions, *Wyeth* and *PLIVA*, will create public pressure on states, doctors, and pharmacists to avoid generic drug substitutions. This could result in states weakening or repealing their substitution laws, doctors prescribing brand-name drugs and prohibiting drug substitutions, pharmacists refusing to substitute drugs, or patients insisting on receiving the brand-name drug.

A backlash against generic drug substitution would be harmful. Generic drug substitutions save society billions of dollars a year and patients who are prescribed generic drugs, which are cheaper, are more likely to comply with their drug regimen.¹² Importantly, this backlash would come from the inequivalence of the legal status of brand-name and generic drugs. Which substantive law is to be applied (whether both should or should not be suable) is not the concern of this Note.

There are a number of ways (aside from the Court reversing either *Wyeth* or *PLIVA*) that patients who take generic drugs could have the same legal

7. *Id.* at 2574–75.

8. *Id.* at 2582.

9. *Id.* at 2581.

10. *Wyeth v. Levine*, 555 U.S. 555, 568–71 (2009) (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008); 73 Fed. Reg. 49,604–07 (Aug. 22, 2008)).

11. *PLIVA*, 131 S. Ct. at 2574–75 (citing Brief for the U.S. as Amicus Curiae Supporting Respondents at 16, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 741927 [hereinafter SG Brief]).

12. *See infra* Part III.

rights as those who take brand-name drugs: the FDA, Congress, and states all have means of effecting such a change. The FDA could either permit generic drug companies to change their labels if they learn of new adverse side effects (thus changing the result in *PLIVA*) or it could forbid brand-name drug companies from unilaterally changing the label in similar situations (thus changing the result in *Wyeth*). It is also possible that the FDA, using proper procedures, could create preemption even against brand-name drugs (changing *Wyeth*). Alternatively, Congress could either explicitly preempt suits against brand-name companies (abrogating *Wyeth*) or explicitly permit suits against generic drug companies (abrogating *PLIVA*). Finally, states could allow plaintiffs who are harmed by inadequately labeled generics to sue the brand-name drug that determined the label, or states may require that generic drug companies waive their preemption defense before the state substitutes the generic for a brand-name prescription.

Part I of this Note reviews the facts of *Wyeth* and *PLIVA*. Part II notes that situations like that in *PLIVA*, where adverse side effects are discovered after the generic enters the market are not rare. It also shows that after *Wyeth* and *PLIVA* authorized generics should be treated differently than other generics. Part III argues that the Court's decisions may create a backlash against generic drugs. Finally, Part IV proposes ways that drug companies, the FDA, Congress, and the states could remedy the harmful effects of the Court's distinction between brand-name drugs and generic drugs.

I. THE TWO CASES

A. *WYETH V. LEVINE*: CONSUMERS CAN SUE THE BRAND-NAME MANUFACTURER

In *Wyeth v. Levine*, the Supreme Court held that consumers can sue brand-name drug companies for inadequate drug-labeling, despite the fact that the FDA approved the label of the drug.¹³ The case arose when Levine, who had been treated with Wyeth's drug, sued Wyeth for not adequately labeling the method of delivery of the drug Phenergan.¹⁴ The label did not make clear that Phenergan should be delivered via an IV-drip method (where the drug is mixed with saline solution and dripped through a catheter into the patient's vein) as opposed to an IV-push method (where it is introduced directly into

13. *Wyeth*, 555 U.S. 555.

14. *Id.* at 559–60.

the vein).¹⁵ As a result, a physician's assistant¹⁶ used the IV-push method and Levine developed gangrene, eventually requiring that her arm be amputated.¹⁷ After Levine settled her case against the health center and clinician, she brought a state law tort action in Vermont, alleging that the inadequate labeling caused her injury.¹⁸ Wyeth argued that the FDA's approval of the Phenergan label should preempt the state law cause of action,¹⁹ and supported its argument with the FDA's explicit statement, in the preamble to one of its regulations, that FDA approval preempts state suits.²⁰ The Vermont Supreme Court, however, sided with the plaintiffs.²¹

The Supreme Court, in a majority opinion by Justice Stevens, joined by Justices Kennedy, Souter, Ginsburg, and Breyer, affirmed the Vermont Supreme Court, holding that since Wyeth could have modified its label unilaterally (i.e. without FDA approval) there was no conflict between the FDA's approval of Wyeth's label and Levine's suit against Wyeth.²² The Court bolstered its decision by noting that the Food, Drug, and Cosmetic Act ("FDCA") explicitly stated that it did not preempt state tort suits for actions that did not involve a "direct and positive conflict" with the federal law.²³ Moreover, given that the FDCA preempted state tort law suits for medical devices but made no similar provision for drugs, it seemed reasonable to rule that state tort law should not be preempted.²⁴ Justice Thomas, in concurrence, agreed with the Court that Wyeth should not be immune to a state tort suit.²⁵ However, he thought this was so solely because Wyeth could have changed its label unilaterally.²⁶

15. *Id.* at 560. As a result of the risk of developing gangrene, Phenergan is now delivered via deep intramuscular injection. *Phenergan Injection*, DRUGS.COM, <http://www.drugs.com/pro/phenergan-injection.html> (last revised Feb. 29, 2012).

16. The physician's assistant was also clearly at fault. She "administered a greater dose than the label prescribed, . . . may have inadvertently injected the drug into an artery rather than a vein, and . . . continued to inject the drug after Levine complained of pain." *Wyeth*, 555 U.S. at 564. The dissent argued that on this ground the Court should have found for Wyeth. *Id.* at 605 (Alito, J., dissenting). The majority argued that this issue was no longer on appeal. *Id.* at 564 n.2.

17. *Id.* at 558.

18. *See id.* at 559.

19. *Id.* at 563–64.

20. *Id.* at 575.

21. *Id.* at 563 (citing 183 Vt. 76, 84 (2006), *aff'd*, 555 U.S. 555).

22. *Id.* at 575–77 (disagreeing with the FDA); *id.* at 569–71 (holding Wyeth could unilaterally modify its label); *id.* at 574–75 (reasoning that there was no conflict).

23. *Id.* at 568 (citing 21 U.S.C. §§ 301–399d (2010)).

24. *Id.* at 567.

25. *Id.* at 582–83 (Thomas, J., concurring).

26. *Id.* at 583.

B. *PLIVA v. MENSING*: CONSUMERS CANNOT SUE THE GENERIC MANUFACTURER

PLIVA also involved a suit for inadequate drug labeling, but this time for a generic drug.²⁷ The plaintiffs, Mensing and Demahy, were prescribed Reglan, a brand-name drug, and their pharmacists dispensed metoclopramide, a generic version of the same drug, some of which was produced by PLIVA.²⁸ Additionally, Mensing's pharmacists dispensed a generic drug produced by the brand-name company, Wyeth.²⁹ As a result of taking metoclopramide, the plaintiffs developed tardive dyskinesia,³⁰ a disease characterized by involuntary movements.³¹

The pharmacists who substituted the prescribed brand-name drug for its generic alternative acted pursuant to state law.³² Specifically, in Minnesota, where Mensing received metoclopramide, a pharmacist *must* substitute a brand-name drug with a generic drug unless the patient objects.³³ In Louisiana, where Demahy received metoclopramide, it is unclear whether a pharmacist may or must substitute a generic drug—so long as the patient does not object.³⁴

The plaintiffs sued the generic drug manufacturers of metoclopramide, including PLIVA, for not listing tardive dyskinesia as a potential side effect.³⁵ The cause of action was a state law tort claim for inadequate labeling. The

27. *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

28. *See id.* at 2573.

29. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 n.1 (8th Cir. 2009), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567.

30. *PLIVA*, 131 S. Ct. at 2573.

31. Jeffrey M. Karp et al., *Metoclopramide Treatment of Tardive Dyskinesia*, 246 J. AM. MED. ASS'N 1934, 1934 (1981).

32. *PLIVA*, 131 S. Ct. at 2581.

33. MINN. STAT. § 151.21 (2011).

34. *See* LA. REV. STAT. ANN. § 37:1241 (2007 & Supp. 2012) (“The board may [punish a person who] (17)(a) Has knowingly selected an equivalent drug product if the practitioner or authorized prescriber instructs otherwise by either of the following: (i) On a written prescription drug order, handwriting a mark in a check-off box labeled with ‘Dispense as Written’, or the abbreviation ‘DAW’, or both, and personally handwriting his signature on a printed-single-signature line. . . . (ii) On an oral prescription, verbally indicating that a specific brand-name drug or product is ordered by the practitioner or authorized prescriber or his agent. The pharmacist shall note such information on the file copy of the prescription. (b) The patient shall be informed of, and consent to, the equivalent drug product interchange when the practitioner or authorized prescriber permits the equivalent drug product interchange.”).

35. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010), *rev'd sub nom., PLIVA*, 131 S. Ct. 2567 (stating that Demahy sued the generic drug company, Actavis); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009), *rev'd sub nom., PLIVA*, 131 S. Ct. 2567 (stating that Mensing sued Actavis Elizabeth, Pliva, Teva, Wyeth, and UDL Laboratories).

Minnesota Supreme Court (where Mensing sued), in a 1977 case,³⁶ and the Louisiana Supreme Court (where Demahy sued), in a 1994 case,³⁷ held that state law required a manufacturer to warn prospective buyers of potential dangers. Explaining why preemption was inapplicable, the plaintiffs argued that generic drug companies could have legally effectuated a warning to the buyers in one of three ways.³⁸ First, the defendants could have unilaterally changed their label to add warnings about potential side effects.³⁹ Second, the generic drug manufacturers could have unilaterally sent “Dear Doctor” letters warning doctors of the potentially adverse side effects.⁴⁰ Finally, the defendants should have petitioned the FDA to require that both the generic and the brand-name drugs add warnings to their labels.⁴¹

PLIVA argued that the Hatch-Waxman Act, which sets forth general labeling laws, preempted state tort laws.⁴² The Act states that a generic drug application must contain “information to show that the labeling proposed for the new drug is the same as the labeling approved for the [brand-name] drug.”⁴³ PLIVA argued that the Hatch-Waxman Act required the generic label to be identical to the brand-drug label.⁴⁴ FDA regulations also stressed that the generic label had to be “the same as” the brand label.⁴⁵ Thus, PLIVA claimed that it could not both maintain the same label as the brand-name drug—which did not adequately state the risk of developing tardive dyskinesia—while also changing the label to comply with state law.⁴⁶ Similarly, PLIVA argued that “Dear Doctor” letters would constitute

36. *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977) (cited in *PLIVA*, 131 S. Ct. at 2573).

37. *Hines v. Remington Arms Co., Inc.*, 648 So. 2d 331, 337 (La. 1994) (cited in *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 270 (5th Cir. 2002) (applying Louisiana law) (cited in *PLIVA*, 131 S. Ct. at 2573)).

38. Interestingly, the Eighth Circuit suggested that if there were no way for generic drug companies to warn customers of potential dangers then the generic drug companies should have just left the market. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), *rev'd sub nom. PLIVA*, 131 S. Ct. at 2567 (“The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product.”).

39. *PLIVA*, 131 S. Ct. at 2574–55.

40. *Id.* at 2576.

41. Brief for Respondents Gladys Mensing and Julie Demahy at 28–30, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 686400. *See PLIVA*, 131 S. Ct. at 2576–77.

42. Brief for Respondents, *supra* note 41, at 28–30 (citing 21 U.S.C. § 355 (2010)).

43. § 355(j)(2)(A)(v).

44. *PLIVA*, 131 S. Ct. at 2574–76.

45. 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7) (2011); *see PLIVA*, 131 S. Ct. at 2574.

46. *PLIVA*, 131 S. Ct. at 2574–76.

unauthorized labeling and therefore were also prohibited.⁴⁷ Finally, PLIVA argued that they had no duty to petition the FDA for a label change, and, in any event, state tort law should be preempted given the tenuousness of PLIVA's ability to change the label: PLIVA would have to convince the FDA, an independent actor, that a label change was necessary, and then the FDA would need to convince the brand-name manufacturer to change the label before PLIVA could change its own label.⁴⁸

The FDA, through an amicus brief filed by the Solicitor General, agreed with PLIVA that generic drug companies could not change their labels or send "Dear Doctor" letters without FDA approval, but it nevertheless agreed with the plaintiffs that suits against generic drug companies should not be preempted.⁴⁹ It argued that PLIVA was required to petition for broader warnings⁵⁰ and that this requirement made PLIVA liable for plaintiffs' injuries in cases where it did not petition for a label change.⁵¹ Congressman Waxman, an author of the Hatch-Waxman Act, agreed with the plaintiffs that the Hatch-Waxman Act should not be read to preempt state tort suits.⁵²

The Supreme Court, in an opinion by Justice Thomas, ruled in favor of PLIVA. First, the Court granted *Auer*⁵³ deference to the FDA's interpretations that generic drug companies cannot unilaterally change their

47. Brief of Petitioners PLIVA, Inc.; TEVA Pharms. USA Inc.; and UDL Labs, Inc. at 46–47, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 219554; see *PLIVA*, 131 S. Ct. at 2576.

48. Brief of Petitioners, *supra* note 47, at 47–55; see *PLIVA*, 131 S. Ct. at 2577.

49. *PLIVA*, 131 S. Ct. at 2574–76 (citing the SG Brief, *supra* note 11).

50. *Id.*

51. SG Brief, *supra* note 11, at 25–29.

52. Brief of Rep. Henry A. Waxman as Amicus Curiae in Support of Respondents Urging Affirmance, *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794113, at 2.

53. *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (opinion by Scalia, J.) (discussing deference to the interpretation of the Secretary of Labor described in an amicus brief and stating, "[b]ecause the . . . test is a creature of the Secretary's own regulations, his interpretation of it is, under our jurisprudence, controlling unless plainly erroneous or inconsistent with the regulation") (internal citations omitted). Although Justice Scalia signed onto the majority opinion in *PLIVA*, he questioned the validity of *Auer* deference in a decision published two weeks before *PLIVA*. *Talk America, Inc. v. Michigan Bell Telephone Co.*, 131 S. Ct. 2254, 2266 (2011) (Scalia, J., concurring) ("It is comforting to know that I would reach the Court's result even without *Auer*. For while I have in the past uncritically accepted that rule, I have become increasingly doubtful of its validity."). Of course, Justice Scalia was part of the dissent in *Wyeth* that thought that even suits against brand-names drug companies should be preempted. *Wyeth v. Levine*, 555 U.S. 555, 604 (2009) (Alito, J., dissenting). So he did not need to defer to the FDA's interpretations to find preemption.

labels or send “Dear Doctor” letters.⁵⁴ Under *Auer*, since the FDA’s interpretations were reasonable interpretations of its own regulations, the FDA’s position was upheld.⁵⁵

Given that generic drug companies could not unilaterally change their label or send “Dear Doctor” letters, the Court found that the Hatch-Waxman Act preempted suits against generic drug companies. The Court began by noting that since the Act did not discuss preemption, the task of inferring any such preemption fell to the courts.⁵⁶ The Court quickly dismissed the FDA brief as deserving little deference.⁵⁷ It then noted that even had PLIVA requested that the FDA change the label, the FDA would still have discretion whether to change the label.⁵⁸ Moreover, until 2007, when the plaintiffs’ injuries occurred, even if the FDA thought the label should be changed, it would need the brand-name to agree to a label change.⁵⁹ Thus, PLIVA, on its own, could not have changed its label and, therefore, it was impossible for PLIVA, without the assistance of the FDA, to both fulfill its state law and federal law obligations.⁶⁰ Since a label change would require decisions by a third party, the Court found it difficult to believe that Congress in enacting the federal law, which can preempt state law, did not intend to do so.⁶¹

54. *PLIVA*, 131 S. Ct. at 2576.

55. *Id.* at 2575–76

56. *Id.* at 2577 n.5.

57. *Id.* at 2575 n.1. Presumably, the reason the Court did not defer to the FDA’s claim of preemption is that preemption is a question of statutory interpretation (as opposed to the questions of label changes and “Dear Doctor” letters that are questions of the agency interpreting its own regulations) and statutory interpretation questions receive only strong deference (what is commonly known as *Chevron* deference, a reference to *Chevron, U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)) if the agency used extensive procedures. *United States v. Mead Corp.*, 533 U.S. 218, 227, 235–38 (2001). Because the FDA did not promulgate its brief based on extensive procedures, it received only a low level of deference which was ultimately overcome. *See Riegel v. Medtronic*, 555 U.S. 312, 326–27 (2008) (opinion by Scalia, J., for a unanimous Court). However, Scalia’s opinion on this question has not been consistent. *See Christensen v. Harris Cnty.*, 529 U.S. 576, 589 (2000) (Scalia, J., concurring in part and concurring in judgment) (arguing that a Solicitor General’s brief deserved *Chevron* deference).

58. *Id.* at 2578–79.

59. Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, § 355, 121 Stat. 823, 925 (2007); *see also Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (“In 2007, for the first time, [Congress] granted the FDA statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug’s initial approval.”).

60. *PLIVA*, 131 S. Ct. at 2579.

61. U.S. CONST. art. VI, cl. 2.

C. DISTINGUISHING *PLIVA* FROM *WYETH*

The decisions in *Wyeth* and *PLIVA*, allowing state tort suits against brand-name drug companies but not against generics, are in tension because they are founded on opposing assumptions about the role of the FDA. *Wyeth's* foundation is that the FDA cannot, on its own, effectively monitor drug labels, and therefore it allows state tort suits as a private means of enforcement.⁶² By contrast, the result in *PLIVA* implies that the FDA's seal of approval is sufficient assurance of drug safety, and therefore private tort suits would be redundant. Indeed, only Justices Thomas and Kennedy saw the two cases as legally distinguishable.⁶³

Justice Thomas, in keeping with his concurrence in *Wyeth*, distinguished *Wyeth* from *PLIVA* on the grounds that brand-name manufacturers could unilaterally change drug labels, whereas generic drug companies still needed FDA approval before they could change their labels.⁶⁴ Although Justice Kennedy did not join Justice Thomas's concurrence in *Wyeth*, that Kennedy joined both the *Wyeth* and the *PLIVA* majorities indicates that he too thought this distinction was meaningful.⁶⁵

The majority in *PLIVA* recognized that, from a policy perspective, its decision led to a strange, and in some ways unfair, result because the patients lost their right to compensation as a result of state substitution laws.

Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits

62. See *Wyeth*, 555 U.S. at 578–79 (“The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.”).

63. This case is an example of a situation where many justices (seven of nine) thought two cases (*Wyeth* and *PLIVA*) were analogous and should be decided in the same manner, but a minority of justices (Thomas and Kennedy) saw the cases as meaningfully distinguishable. As a result, a new doctrine emerged that distinguished between the two cases in a fashion that most justices thought was irrelevant. A more famous example of this is the combination of affirmative action cases, *Gratz v. Bollinger*, 539 U.S. 244 (2003) (6–3), and *Grutter v. Bollinger*, 539 U.S. 306 (2003) (5–4), where a distinction that only Justices O'Connor and Breyer thought was meaningful carried the day. Other tribunals avoid this problem by joining several questions in a way that judges have to vote on them all together. See, e.g., Case Concerning Oil Platforms (Iran v. U.S.), 2003 I.C.J. 161, 387 (Nov. 6) (separate opinion of Judge *ad hoc* Rigaux) (noting that he voted as he did because two issues were tied in the vote, so he either had to vote for both or neither).

64. *PLIVA*, 131 S. Ct. at 2579.

65. Only Justices Thomas and Kennedy were in the majority in both *Wyeth* and *PLIVA*.

would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.⁶⁶

However, they argued that the absurdity should not be overstated, since it is uncommon for “genuinely new information” to surface about drugs that have been in use for a long time.⁶⁷

In dissent, Justice Sotomayor, joined by Justices Ginsburg, Breyer, and Kagan, disagreed.⁶⁸ They argued that preemption should only apply if PLIVA could show that it could not have obtained a label change.⁶⁹ Here, PLIVA could have requested a label change.⁷⁰ Thus, the burden should have been on PLIVA to show that such a request would have been ineffective.⁷¹ Since PLIVA had not met this burden, the dissent would not have found PLIVA’s state tort liability preempted.⁷²

The dissent argued that the result in *PLIVA* was problematic for several reasons. First, once generic drug manufacturers enter a drug market, the brand-name drug often leaves the market.⁷³ Indeed, approximately a quarter of drugs on the market no longer have brand-name equivalents.⁷⁴ Based on *PLIVA*, no private entity has the incentive to discover new harmful side effects: the brand-name no longer exists on the market and the generic manufacturers are immune from suit.⁷⁵ Second, while the first-order effect of *PLIVA* helps generic drug companies by immunizing them from inadequate labeling suits, the long term effect may be to reduce consumer trust in generics.⁷⁶ This, in turn, may lead states to revoke their drug substitution laws

66. *Id.* at 2581 (internal citations omitted).

67. *Id.* at 2581 n.9.

68. *Id.* at 2582 (Sotomayor, J., dissenting).

69. *Id.*

70. *Id.* at 2587.

71. *Id.* at 2588–89.

72. *Id.* at 2593.

73. *Id.* at 2592–93 (citing sources).

74. Brief for Marc T. Law et al. as Amici Curiae in Support of Respondents at 18, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794111 (cited in *PLIVA*, 131 S. Ct. at 2584) (stating that 22–32% of drugs are available only as generics). One specific example of this is Phenergan, the drug at issue in *Wyeth*, where the brand-name is no longer available. *Generic Phenergan*, EMEDTV, <http://drugs.emedtv.com/phenergan/generic-phenergan.html> (last updated June 17, 2009).

75. *PLIVA*, 131 S. Ct. at 2592–93. All the generic drug companies have to do is pass along information about reported adverse side effects to the FDA, 21 C.F.R. § 314.80 (2009), but they need not analyze this information themselves.

76. *PLIVA*, 131 S. Ct. at 2593.

(laws that either require or permit pharmacists to replace prescriptions for brand drugs with generic drugs),⁷⁷ which would severely harm generic drug companies and more broadly deter consumer use of generic drugs.

II. THE SEVERITY OF THE PROBLEM

This Part details the severity of the problem created by the combination of *Wyeth* and *PLIVA* on two dimensions. First, it notes that it not rare to discover new side effects for generic drugs. Additionally, applying the holdings of *Wyeth* and *PLIVA* to cases of authorized generics, where brand-name companies produce generics of their own drug, leads to truly bizarre results.

A. *PLIVA* IS NOT UNCOMMON

The *PLIVA* majority reasoned that situations where newly discovered adverse side effects emerge after generics have entered the market are “rare.”⁷⁸ The Court’s rationale was that “patent protections ordinarily prevent generic drugs from arriving on the market for a number of years after the brand-name drug appears.”⁷⁹

The Court’s assertion that generics should not enter the market for a number of years is logically appealing. While generic drug companies often challenge the patents of brand-name drugs, they challenge first-generation patents (patents on the compound itself) less frequently,⁸⁰ so the brand-name drug presumably has some years of exclusivity. Moreover, even independent of patents, a company that successfully brings to market a drug that has not been previously approved by the FDA gets five years of exclusivity.⁸¹ Drugs

77. *E.g.*, MINN. STAT. § 151.21(3) (2011) (“When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting ‘dispense as written’ . . . and there is available in the pharmacist’s stock a less expensive generically equivalent drug that, in the pharmacist’s professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist *shall*, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects.”) (emphasis added). Indeed, “all States have some form of generic substitution law [and] [s]ome States require generic substitution in certain circumstances.” *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., concurring) (citations omitted). Presumably in part due to the mandatory substitution laws, “[n]inety percent of drugs for which a generic version is available are now filled with generics.” *PLIVA*, 131 S. Ct. at 2584 (Sotomayor, J., concurring) (citing DEPT. OF HEALTH AND HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 3–4 (2010)).

78. *PLIVA*, 131 S. Ct. at 2582 n.9.

79. *Id.*

80. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL & LEGAL STUD. 613, 621 (2011).

81. 21 U.S.C. § 355(c)(3)(E) (2010).

are thus likely to have been on the market for some time before generics begin producing them, and therefore the label at the end of that period, when the generics can step in, should be fairly accurate and stable.

However, the Court understated the relevance of *PLIVA*. A 2002 study published in the Journal of the American Medical Association showed that of drugs approved for sale between 1975 and 1999, 10.2% acquired a new black box warning (the most serious warning the FDA can require) or were withdrawn from the market after entering the market.⁸² Of those, only half were documented within the first seven years after drug approval.⁸³ As noted by the amicus brief of Public Citizen in *PLIVA*, there are more recent examples of new adverse effects being discovered for old drugs.⁸⁴ For instance, in 2010, the FDA removed propoxyphene from the market because of cardiac risks after it had been on the market for fifty-three years.⁸⁵ In 2008, the FDA added a black-box warning to fluoroquinone antibiotics after they had been on the market for twenty-six years.⁸⁶ The frequent appearance of major label changes more than seven years after drug approval must be considered in light of the fact that the average drug patent is valid for only nine years following FDA approval of the drug, and that average time of validity has been dropping.⁸⁷ In other words, it is increasingly likely that new and severe adverse side effects will be discovered on generic drugs.

82. Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawal for Prescription Medications*, 287 J. AM. MED. ASS'N. 2215, 2216 (2002).

83. *Id.* at 2218.

84. Brief of Public Citizen and AARP as Amici Curiae in Support of Respondents at 11–12, *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 741928.

85. FDA, *Propoxyphene-Containing Products*, FDA, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm233800.htm> (last updated Dec. 6, 2010).

86. FDA, *Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs*, FDA (July 8, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126085.htm>. Other examples abound. *See* Brief of the Am. Med. Ass'n et al. as Amici Curiae in Support of Respondents at 12–17, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 794118. Terbutaline sulfate received a black-box label in 2011. FDA, *FDA Warns Against Certain Uses of Asthma Drug Terbutaline for Preterm Labor: Certain Uses Could Lead to Maternal Heart Problems and Death*, FDA (Feb. 17, 2011), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm243840.htm>. Non-steroidal, anti-inflammatory drugs, like ibuprofen and naproxen, have been on the market since the 1970s. They received black-box warnings in 2005. FDA, *COX-2 Selective (Includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*, FDA (Apr. 7, 2005), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103420.htm>.

87. Kate S. Gaudry, *Evergreening: A Common Practice To Protect New Drugs*, 29 NATURE BIOTECHNOLOGY 876, 876 (2011).

Other evidence for the frequency of the *PLIVA* situation is the attention the case received. In the first four months since *PLIVA* was decided, courts cited *PLIVA* twenty-three times.⁸⁸ Of those, fifteen were cases that similarly involved claims that generic drug companies had provided inadequate labeling.⁸⁹ If *PLIVA* were a rare situation, then it should not be relevant to so many cases. Even if, from this point forward, cases rarely cite *PLIVA*, it will likely be because the only cases that need to cite *PLIVA* are cases where the plaintiff claimed that the generic drug was inadequately labeled. After *PLIVA*, educated plaintiffs' lawyers will not make this claim anymore. A final indication of the importance of *PLIVA* is that twenty-one amicus briefs were filed in the case.⁹⁰ This is more than the average 14.7 amicus briefs the Supreme Court received for decisions published within a week of *PLIVA*.⁹¹

88. Purcell v. Bank of America, 659 F.3d 622, 624 (7th Cir. 2011); Smith v. Wyeth, Inc., 657 F.3d 420, 423 (6th Cir. 2011); Tarrant Reg'l Water Dist. v. Herrmann, 656 F.3d 1222, 1242 (10th Cir. 2011); Metz v. Wyeth, LLC, No. 8:10-CV-2658-T-27AEP, 2011 WL 5024448, *1 (M.D. Fla. Oct. 20, 2011); Morris v. Wyeth, Inc., No. 3:09-CV-854, 2011 WL 4975317, *1 (W.D. La. Oct. 19, 2011); Morris v. Wyeth, Inc., No. 3:09-CV-854, 2011 WL 4973839, at *1 (W.D. La. Oct. 19, 2011); Guilbeau v. Wyeth Inc., No. 09-1652, 2011 WL 4948996, at *1 (W.D. La. Oct. 14, 2011); Cline v. Bank of Am., N.A., No. 2:10-1295, 2011 WL 4857934, at *4 (S.D. W. Va. Oct. 13, 2011); Fisher v. Pelstring, 817 F. Supp. 2d 791, 791 (D.S.C. Sept. 30, 2011); Schork v. Baxter Healthcare Corp., No. 4:10-cv-00005-RLY-WGH, 2011 WL 4402602, at *3 (S.D. Ind. Sept. 22, 2011); Beck v. Teva Pharm. Indus., No. 10-1901, 2011 WL 4062219, at *1 (E.D. La. Sept. 13, 2011); Brasley-Thrash v. Teva Pharm. USA, Inc., No. 10-00031-KD-N, 2011 WL 4025734, at *1 (S.D. Ala. Sept. 12, 2011); Scott v. Baxter Healthcare Corp., No. 10-0186-CG-N, 2011 WL 4007675, at *1 (S.D. Ala. Sept. 09, 2011); Gross v. Pfizer, Inc., No. 10-CV-00110-AW, 2011 WL 4005266, at *1 (D. Md. Sept. 07, 2011); Paisley v. Darwin, No. CV-10-1253-PHX-DGC, 2011 WL 3875992, at *4 (D. Ariz. Sept. 02, 2011); Henderson v. Sun Pharm. Indus., 809 F. Supp. 2d 1373, 1373 (N.D. Ga. 2011); Schedin v. Ortho-McNeil-Janssen Pharm., Inc., 808 F. Supp. 2d 1125, 1125 (D. Minn. 2011); Keck v. Endoscopy Ctr. of S. Nev., LLC, (Nos. A575837, A579660, A5824922011), 2011 WL 3921690, at *1 (Trial Order) (D. Nev. Aug. 19, 2011); Sacks v. Endoscopy Ctr. of S. Nev., LLC, (Nos. 08A572315 (LEAD), 08A576071, 09A583058), 2011 WL 4915174, *1 (Trial Order) (D. Nev. July 28, 2011); Suarez v. Castrillo, No. 11-cv-01762-MSK, 2011 WL 2729074, at *1 (D. Colo. July 13, 2011); Produce Alliance v. Let-Us Produce, No. 2:10cv198, 2011 WL 2634238, *5 (E.D. Va. July 01, 2011); Tohono O'odham Nation v. City of Glendale, No. CV-11-279-PHX-DGC, 2011 WL 2650205, *4 (D. Ariz. June 30, 2011); *In re Dunlap*, 458 B.R. 301, 327 (Bankr. E.D. Va. 2011).

89. *Smith*, 657 F.3d at 423; *Metz*, 2011 WL 5024448; *Morris*, 2011 WL 4973839; *Morris*, 2011 WL 4975317; *Guilbeau*, 2011 WL 4948996; *Fisher*, 817 F. Supp. 2d 791; *Schork*, 2011 WL 4402602; *Beck*, 2011 WL 4062219; *Brasley-Thrash* 2011 WL 4025734; *Scott*, 2011 WL 4007675; *Gross*, 2011 WL 4005266; *Henderson*, 809 F. Supp. 2d 1373; *Schedin*, 808 F. Supp. 2d 1125; *Keck*, 2011 WL 3921690; *Sacks*, 2011 WL 4915174.

90. See Helen W. Nies, *Dissents at the Federal Circuit and Supreme Court Review*, 45 AM. U. L. REV. 1519, 1524 (1996) ("The importance of a case is often gauged by the number of amicus briefs filed.").

91. *PLIVA* was decided on June 23, 2011. Of the eighteen cases decided within a week of *PLIVA*, five had more amici and thirteen had fewer. Goodyear Dunlop Tires Operations,

B. THE EFFECT OF *WYETH* AND *PLIVA* ON AUTHORIZED GENERICS IS TRULY BIZARRE

Wyeth and *PLIVA* together mean that the law explicitly distinguishes, for the purposes of preemption, between brand-name drugs and generic drugs. If the Court's argument is taken to its logical conclusion, then the Court should distinguish further between brands of generics: generics produced by the brand-name manufacturer should be liable for suit, while other generics should be preempted. To understand this, a brief explanation of drug approval is necessary.

When a brand-name company seeks FDA approval of a new drug, it files a New Drug Application ("NDA") with the FDA.⁹² The NDA must show, among other things, that the drug is safe, effective, and appropriately labeled.⁹³ Once an NDA has been granted, other companies can file an Abbreviated New Drug Application ("ANDA") for the right to produce a generic version of the brand-name drug. The ANDA does not need to reprove that the drug is safe.⁹⁴ It only needs to only show that the drug is bioequivalent to an existing drug that the FDA has already approved.⁹⁵ Sometimes, once generics have already entered the market, the brand-name company produces a generic version of its own drug—which are known as authorized generics.⁹⁶ The authorized generic does not require the filing of an

S.A. v. Brown, 131 S. Ct. 2846 (2011) (6 amici); Arizona Free Enter. Club's Freedom Club PAC v. Bennett, 131 S. Ct. 2806 (2011) (28 amici); J. McIntyre Mach., Ltd. v. Nicastro, 131 S. Ct. 2780 (2011) (9 amici); Brown v. Entm't Merch. Ass'n, 131 S. Ct. 2729 (2011) (34 amici); Bullcoming v. New Mexico, 131 S. Ct. 2705 (2011) (8 amici); Freeman v. United States, 131 S. Ct. 2685 (2011) (0 amici); Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011) (27 amici); CSX Transp., Inc. v. McBride, 131 S. Ct. 2630 (2011) (7 amici); Stern v. Marshall, 131 S. Ct. 2594 (2011) (7 amici); *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567, 2567 (21 amici); Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541 (2011) (39 amici); Am. Elec. Power Co. v. Connecticut, 131 S. Ct. 2527 (2011) (48 amici); Turner v. Rogers, 131 S. Ct. 2507 (2011) (13 amici); Borough of Duryea, Pa. v. Guarnieri, 131 S. Ct. 2488 (2011) (8 amici); Davis v. United States, 131 S. Ct. 2419 (2011) (4 amici); J.D.B. v. North Carolina, 131 S. Ct. 2394 (2011) (10 amici); Tapia v. United States, 131 S. Ct. 2382 (2011) (1 amicus); Smith v. Bayer Corp., 131 S. Ct. 2368 (2011) (4 amici); Bond v. United States, 131 S. Ct. 2355 (2011) (5 amici). The average number of amici for those cases is 14.7.

92. 21 U.S.C. § 355(b) (2010).

93. *Id.*

94. § 355(j).

95. *Id.*

96. See, e.g., FTC, *FTC Report Examines How Authorized Generics Affect the Pharmaceutical Market, Propoxyphene-Containing Products*, FDA, (Aug. 31, 2011) <http://www.ftc.gov/opa/2011/08/genericdrugs.shtm>.

ANDA; instead the brand-name company produces it under the original NDA.⁹⁷

The FDA regulations cited in *Wyeth*, distinguish between the NDA holder, who can unilaterally change the label, and the ANDA holders, who cannot.⁹⁸ Since the authorized generic is produced under the NDA (not an ANDA) it should have the right to change its label unilaterally. This makes sense since ultimately it is the brand-name company that dictates how and when the authorized generic is produced and it is the brand-name company producing the authorized generic. If so, authorized generics would not be preempted from suits.⁹⁹

But allowing inadequate drug-labeling suits against authorized generics but not other generics creates a far stranger result than does the direct application of *Wyeth* and *PLIVA*. Even once generics enter a market for a drug, the brand-name can sell for a higher price than do the generics¹⁰⁰—perhaps because people believe that the brand-name has better quality control or because the brand is just more familiar to them.¹⁰¹ Thus, brand-name drug makers are not in exactly the same market as generics. On the other hand, authorized generics and regular generics are selling the same product. If authorized generics are not preempted from state tort suits, but regular generics are, then it will be difficult for authorized generics to remain competitive once generics enter the market (since authorized generics will be subject to suit while their direct competitors will not).

97. 42 C.F.R. § 447.506(a) (2010).

98. 57 Fed. Reg. 17,950, 17,961 (1992) (cited in *PLIVA v. Mensing*, 131 S. Ct. 2567, 2575 (2011)); SG Brief, *supra* note 11, at 16–17).

99. Although the amicus brief for forty-two states assumes (without any argument) that authorized generics would be treated like all other generics, the brief's assumption seems incorrect given the way the Court framed its opinion in *PLIVA*. See Brief of Amici Curiae States of Minnesota, Louisiana, Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Massachusetts, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming, and The District of Columbia in Support of Respondents at 24, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 805229.

100. *Brand-Name vs. Generic Drug Costs*, BLUE CROSS BLUE SHIELD MICH. (Feb. 2011), http://www.bcbsm.com/pdf/ps_generic.pdf; *Generic Drugs: The Same Medicine for Less Money*, CONSUMER REP., <http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/GenericDrugs-FINAL.pdf> (last visited Feb. 19, 2012).

101. *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 787 (7th Cir. 1999).

Indeed, in *PLIVA*, Mensing received generic metoclopramide from, amongst others, the brand-name producer of the drug, Wyeth.¹⁰² By the time the case reached the Supreme Court, Mensing settled with Wyeth,¹⁰³ and therefore she left Wyeth off the list of defendants at the Supreme Court level,¹⁰⁴ even though she listed them in her district court complaint and Eighth Circuit appeal.¹⁰⁵ In the future, however, plaintiffs similarly situated will likely sue manufacturers of authorized generics, arguing that the logic of *PLIVA* does not preempt suits against authorized generics.

III. POTENTIAL SECONDARY EFFECTS OF *WYETH* AND *PLIVA*

Particularly troubling in *PLIVA* is the fact that the doctor prescribed Reglan, the brand-name drug, but because of state substitution laws the pharmacist dispensed the generic.¹⁰⁶ It was this substitution that caused the plaintiffs to lose their right to sue. As the dissent in *PLIVA* notes, it is possible that the case's holding will cause patients to push back on generic drug substitutions for prescriptions for brand-name drugs.¹⁰⁷ To understand this possibility, one must first look at the form of drug substitution laws.

A. DRUG SUBSTITUTION LAWS

With the rising cost of healthcare, states have implemented policies to substitute prescriptions for more expensive brand-name drugs with cheaper generic equivalents.¹⁰⁸ When a medical practitioner prescribes a brand-name drug, and she might do so for any number of reasons,¹⁰⁹ she can put on the

102. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 n.1 (8th Cir. 2009), *rev'd sub nom.*, *PLIVA* 131 S. Ct. at 2567.

103. E-mail from Louis M. Bograd, Counsel for Mensing, to author (Mar. 19, 2012) (on file with author).

104. *Mensing and Demahy Brief*, *supra* note 41.

105. Complaint for Damages Demand for Jury Trial ¶ 53, *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056 (D. Minn. 2008), 2007 WL 4675340; Appellant Gladys Mensing's Opening Brief at 18, *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009) (No. 08-3850), 2008 WL 5707474.

106. *PLIVA*, 131 S. Ct. at 2581; *id.* at 2592 (Sotomayor, J., dissenting).

107. *Id.* at 2592–93 (Sotomayor, J., dissenting).

108. William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFFAIRS 1383, 1383 (2010).

109. Practitioners may require that the brand-name drug be prescribed for a number of reasons, some legitimate and others less so. For instance, practitioners might require that the brand-name drug be dispensed because the patient has had an adverse reaction to the generic or the generic is ineffective. *See, e.g.*, TENN. CODE ANN. § 53-10-204(a) (2008 & Supp. 2011). On the other hand, they sometimes do so because of financial incentives offered by the brand-name drug company. *See* Ben Hirschler, *AstraZeneca Pulls Plug on Free*

prescription “brand medically necessary” or another equivalent term indicating that the brand-name drug, and not a generic, should be dispensed. If the prescriber does so—and this occurs in an estimated 2.7% of prescriptions¹¹⁰—all states (with the possible exception of Oklahoma¹¹¹) agree that pharmacists must dispense the brand-name drug and cannot substitute a generic version.¹¹²

Trips for Doctors, REUTERS, May 27, 2011, available at <http://www.reuters.com/article/2011/05/27/astrazeneca-junkets-idUSLDE74P1YI20110527>. It is also possible that practitioners do so out of habit, since the brand-name drug came to the market first. See Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J.L. & ECON. 299, 305 (1988).

110. See, *infra*, note 137 and accompanying text.

111. See OKLA. STAT. tit. 59, § 353.13(D) (2010 & Supp. 2011) (“No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted therefor, without authority of the prescriber or purchaser, any like drug, medicine, chemical or pharmaceutical preparation.”). The statute seems to imply that the purchaser’s authority alone, even without the prescriber’s approval, permits a pharmacist to substitute a generic drug.

112. ALA. CODE § 34-23-8 (LexisNexis 2010); ALASKA STAT. § 08.80.295(a) (2010); ARIZ. REV. STAT. ANN. § 32-1963.01(D) (2008); ARK. CODE ANN. § 17-92-503(b)(1) (2010); CAL. BUS. & PROF. CODE §§ 4052.5(b), 4073(b) (West 2011 & Supp. 2012); COLO. REV. STAT. § 12-22-124(1) (2011); CONN. GEN. STAT. § 20-619(b) (2008); DEL. CODE ANN. tit. 24, § 2549(a) (2011); FLA. STAT. § 465.025(2) (2007); GA. CODE ANN. § 26-4-81(g) (2003 & Supp. 2011); HAW. REV. STAT. ANN. § 328-92(b) (LexisNexis 2008); RULES OF THE IDAHO BOARD OF PHARMACY § 180(01) (2011), <http://adminrules.idaho.gov/rules/current/27/0101.pdf>; 225 ILL. COMP. STAT. ANN. 85/25 (West 2005 & Supp. 2011); IND. CODE ANN. § 16-42-22-8(a)(1) (West 2007); IOWA CODE § 155A.32(2)(a) (2005 & Supp. 2011); KAN. STAT. ANN. § 65-1637(a)(1) (2002 & Supp. 2009); KY. REV. STAT. ANN. § 217.822(1) (LexisNexis 2007 & Supp. 2010); LA. REV. STAT. ANN. § 37:1241(A)(17)(a) (2007 & Supp. 2012); ME. REV. STAT. tit. 32, § 13781 (1999 & Supp. 2011); MD. CODE ANN. HEALTH-GEN. § 15-118(a)(1) (West 2009 & Supp. 2011); MASS. GEN. LAWS. ch. 112, § 12D (2003 & Supp. 2012); MICH. COMP. LAWS § 333.17755(3) (2008 & Supp. 2011); MINN. STAT. § 151.21(2) (2011); MISS. CODE ANN. § 73-21-117(2)(b) (2008 & Supp. 2011); MO. REV. STAT. § 338.056(2)(1) (2001 & Supp. 2011); MONT. CODE ANN. § 37-7-505(2) (2011); NEB. REV. STAT. § 71-5403(1)(a) (2009); NEV. REV. STAT. § 639.2583(5) (2004 & Supp. 2007); N.H. REV. STAT. ANN. § 146-B:2(I) (LexisNexis 2005 & Supp. 2010); N.J. STAT. ANN. § 24:6E-7 (West 1997 & Supp. 2011); N.M. STAT. ANN. § 26-3-3(C) (2004); N.Y. EDUC. LAW § 6816-a(1)(a) (McKinney 2010 & Supp. 2011); N.C. GEN. STAT. § 90-85.28(b) (2011); N.D. CENT. CODE § 19-02.1-14.1(3) (2009 & Supp. 2011); OHIO REV. CODE ANN. § 4729.38(A)(1) (LexisNexis 2003 & Supp. 2011); OR. REV. STAT. § 689.515(3) (2011); 35 PA. STAT. ANN. § 960.3(a) (West 2003 & Supp. 2011); R.I. GEN. LAWS § 5-19.1-19 (2009 & Supp. 2011); S.C. CODE ANN. § 39-24-40 (1983 & Supp. 2010); S.D. CODIFIED LAWS § 36-11-46.2 (2004 & Supp. 2011); TENN. CODE ANN. § 53-10-204(b) (2008 & Supp. 2011); TEX. OCC. CODE ANN. § 562.008(a) (West 2003 & Supp. 2009); UTAH CODE ANN. § 58-17b-605(5) (West 2007 & Supp. 2011); VT. STAT. ANN. tit. 18, § 4605(a) (2002 & Supp. 2011); VA. CODE ANN. § 54.1-3408.03(A) (2009 & Supp. 2011); WASH. REV. CODE ANN. § 69.41.120 (West 2007 & Supp. 2012); W. VA. CODE ANN. § 30-5-12b(b) (LexisNexis 2007

However, in the absence of a prescriber's explicit order forbidding substitution, state laws vary in regards to when and how substitution of generic drugs is permitted. Eleven states require the prescriber to expressly permit substitution, although they do so in three different ways: Oklahoma forbids generic drug substitution "without authority of the prescriber";¹¹³ seven states require all prescription pads to have one line that says substitution is permissible and one that says substitution is forbidden and by signing on one of the two lines the prescriber either permits or forbids substitutions;¹¹⁴ and finally, Maine, New York, and Pennsylvania require that all prescription forms say that substitution is permitted, so the doctor has to override the boilerplate language to prevent substitution.¹¹⁵ The remaining thirty-nine states permit substitution unless the prescriber expressly forbids it.¹¹⁶

& Supp. 2011); WIS. STAT. ANN. § 450.13(2) (West 1998 & Supp. 2010); WYO. STAT. ANN. § 33-24-148(b) (2011); accord D.C. CODE § 48-803.03(2) (2001 & Supp. 2011); 5 GUAM CODE ANN. § 5271(b) (2011); P.R. LAWS ANN. tit. 20, § 410b(b)(1) (2009); V.I. CODE ANN. tit. 19, § 753(c) (1995 & Supp. 2011); see *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting) ("[A]ll States 'allow the physician to specify that the brand name must be prescribed, although with different levels of effort from the physician.'").

113. OKLA. STAT. tit. 59, § 353.13(D) (2010 & Supp. 2011).

114. ALA. CODE § 34-23-8(4); DEL. CODE ANN. tit. 24, § 2549(a)(1), (c); IND. CODE ANN. §§ 16-42-22-6, 16-42-22-8(a)(1); MO. REV. STAT. § 338.056; S.C. CODE ANN. § 39-24-40(b); UTAH CODE ANN. § 58-17b-605(1); WASH. REV. CODE ANN. § 69.41.120; accord V.I. CODE ANN. tit. 19, § 753(a).

115. ME. REV. STAT. tit. 32, § 13781 (requiring all Maine prescription forms to contain this text: "Any drug which is the generic and therapeutic equivalent of the drug specified above in this prescription must be dispensed, provided that no check mark () has been handwritten in the box in the lower right-hand corner"); N.Y. EDUC. LAW § 6810 ("Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: 'THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW.'"); 35 PA. STAT. ANN. § 960.3(a) (requiring prescription forms to contain the following language: "In order for a brand name product to be dispensed, the prescriber must handwrite 'brand necessary' or 'brand medically necessary' in the space below.").

116. ALASKA STAT. § 08.80.295(a); ARIZ. REV. STAT. ANN. § 32-1963.01(A); ARK. CODE ANN. § 17-92-503(b); CAL. BUS. & PROF. CODE § 4052.5(b); COLO. REV. STAT. § 12-22-124; CONN. GEN. STAT. § 20-619(b); FLA. STAT. § 465.025(2); GA. CODE ANN. § 26-4-81; HAW. REV. STAT. ANN. § 328-92; RULES OF THE IDAHO BOARD OF PHARMACY § 180(01); 225 ILL. COMP. STAT. ANN. 85/25; IOWA CODE § 155A.32(1); KAN. STAT. ANN. § 65-1637(a); KY. REV. STAT. ANN. § 217.822; LA. REV. STAT. ANN. § 37:1241(17); MD. CODE ANN. HEALTH-GEN. § 15-118(a)(1); MASS. GEN. LAWS. ch. 112, § 12D; MICH. COMP. LAWS § 333.17755(3)(a); MINN. STAT. § 151.21(3); MISS. CODE ANN. § 73-21-117(1); MONT. CODE ANN. § 37-7-505; NEB. REV. STAT. § 71-5403; NEV. REV. STAT. § 639.2583(3); N.H. REV. STAT. ANN. § 146-B:2; N.J. STAT. ANN. § 24:6E-7; N.M. STAT. ANN. § 26-3-3; N.C. GEN. STAT. § 90-85.28; N.D. CENT. CODE § 19-02.1-14.1(3); OHIO REV. CODE ANN. § 4729.38(A); OR. REV. STAT. § 689.515; R.I. GEN. LAWS § 5-19.1-19; S.D. CODIFIED LAWS

Additionally, states differ about whether, if substitution is permitted, pharmacists are obligated to substitute a generic drug or are merely permitted to do so.¹¹⁷ Fifteen states require pharmacists to dispense a generic drug if they are allowed to,¹¹⁸ while thirty-two states merely permit them to do so.¹¹⁹ The laws of Idaho,¹²⁰ Louisiana,¹²¹ and Oklahoma¹²² are unclear on this point.

§ 36-11-46.1; TENN. CODE ANN. § 53-10-204; TEX. OCC. CODE ANN. § 562.008(a); VT. STAT. ANN. tit. 18, § 4605; VA. CODE ANN. § 54.1-3408.03(A); W. VA. CODE ANN. § 30-5-12b(b); WIS. STAT. ANN. § 450.13(2); WYO. STAT. ANN. § 33-24-148(b); *accord* D.C. CODE § 48-803.03; 5 GUAM CODE ANN. § 5271(b) (at least if the drug is being partially paid for by public funds); P.R. LAWS ANN. tit. 20, § 410b(b)(1).

117. Christensen et al., *Drug Product Selection: Legal Issues*, 41 J. AM. PHARM. ASS'N 868, 870 (2001) (cited in *PLIVA v. Mensing*, 131 S. Ct. 2567, 2583 (2011)) tabulates the distinctions between the states on this ground. Since some of their data is not accurate (at least not anymore), I redo this data. The states that Christensen et al. have incorrectly represented are: Hawaii (actually mandates substitution); Maine (actually mandates substitution); Maryland (actually mandates substitution); Mississippi (actually permits substitution); Tennessee (actually mandates substitution); Vermont (actually mandates substitution); Washington (actually permits substitution). *See infra* notes 118, 119.

118. FLA. STAT. § 465.025(2); HAW. REV. STAT. ANN. § 328-92(a); KY. REV. STAT. ANN. § 217.822(1); ME. REV. STAT. tit. 32, § 13781(1); MD. CODE ANN. HEALTH-GEN. § 15-118(a)(1); MASS. GEN. LAWS. ch. 112, § 12D; MINN. STAT. § 151.21(3) (though the Statute requires that the generic drug be “in the pharmacist’s professional judgment . . . safely interchangeable with the prescribed drug”); NEV. REV. STAT. § 639.2583(1); N.J. STAT. ANN. § 24:6E-7; N.Y. EDUC. LAW § 6816-a(1); 35 PA. STAT. ANN. § 960.3(a); R.I. GEN. LAWS § 5-19.1-19; TENN. CODE ANN. § 53-10-205(a); VT. STAT. ANN. tit. 18, § 4605(a); W. VA. CODE ANN. § 30-5-12b(b); *accord*, P.R. LAWS ANN. tit. 20, § 410b(b)(1); V.I. CODE ANN. tit. 19, § 753(c).

119. ALA. CODE § 34-23-8(1); ALASKA STAT. § 08.80.295(a); ARIZ. REV. STAT. ANN. § 32-1963.01(D); ARK. CODE ANN. § 17-92-503(b)(1); CAL. BUS. & PROF. CODE §§ 4052.5(a), 4073(a); COLO. REV. STAT. § 12-22-124(1); CONN. GEN. STAT. § 20-619(b); DEL. CODE ANN. tit. 24, § 2549(a); GA. CODE ANN. § 26-4-81(a); ILL. COMP. STAT. ANN. 85/25; IND. CODE ANN. § 16-42-22-8(a)(1) (though the statute is not entirely clear); IOWA CODE § 155A.32(1) (though if the drug is being even partially paid for by public funds, substitution is mandatory); KAN. STAT. ANN. § 65-1637(a); MICH. COMP. LAWS § 333.17755(1) (though if the purchaser requests the generic drug the pharmacist must substitute); MISS. CODE ANN. § 73-21-117(1); MO. REV. STAT. § 338.056(1); MONT. CODE ANN. § 37-7-505(1); NEB. REV. STAT. § 71-5403(1)(a); N.H. REV. STAT. ANN. § 146-B:2(I); N.M. STAT. ANN. § 26-3-3(A); N.C. GEN. STAT. § 90-85.28(a); N.D. CENT. CODE § 19-02.1-14.1(3); OHIO REV. CODE ANN. § 4729.38(A); OR. REV. STAT. § 689.515(5); S.C. CODE ANN. § 39-24-40(b) (though the statute is not entirely clear); S.D. CODIFIED LAWS § 36-11-46.1; TEX. OCC. CODE ANN. § 562.008(b); UTAH CODE ANN. § 58-17b-605(5); VA. CODE ANN. § 54.1-3408.03(A); WASH. REV. CODE ANN. § 69.41.120; WIS. STAT. ANN. § 450.13(2) (though the statute is not entirely clear); WYO. STAT. ANN. § 33-24-148(b); *accord*, D.C. CODE § 48-803.02(a); 5 GUAM CODE ANN. § 5271(d).

120. *See* RULES OF THE IDAHO BOARD OF PHARMACY § 180(01) (2011), <http://adminrules.idaho.gov/rules/current/27/0101.pdf>.

121. *See* LA. REV. STAT. ANN. § 37:1241(A)(17) (2007 & Supp. 2012).

122. *See* OKLA. STAT. tit. 59, § 353.13(D) (2010 & Supp. 2011).

States also diverge on what say a patient has in the substitution process. Ten states do not require a pharmacist to inform the patient before substituting a generic drug.¹²³ In Arizona, if a third party (generally an insurance company) reimburses the drug then the pharmacist does not have to inform the patient; if not, she does.¹²⁴ In Iowa and Ohio, if the drug is being reimbursed by public funds then the pharmacist does not have to inform the patient; if not, she does.¹²⁵ Five states require the pharmacist to inform the patient of the substitution, but do not say the patient has the right to refuse the substitution.¹²⁶ Maine, Tennessee, and Vermont say the pharmacist must inform the patient who can then refuse the substitution, but if he refuses, then he must pay the additional cost out-of-pocket.¹²⁷ Finally, twenty-seven states allow the purchaser to refuse a substitution and the laws do not say that the purchaser must pay the extra-cost out-of-pocket.¹²⁸

123. ALA. CODE § 34-23-8(4); ILL. COMP. STAT. ANN. 85/25; KAN. STAT. ANN. § 65-1637; MD. CODE ANN. HEALTH-GEN. § 15-118(a); MASS. GEN. LAWS. ch. 112, § 12D; MICH. COMP. LAWS § 333.17755; N.M. STAT. ANN. § 26-3-3; N.Y. EDUC. LAW § 6816-a; N.C. GEN. STAT. § 90-85.28; WYO. STAT. ANN. § 33-24-148; *accord* 5 GUAM CODE ANN. § 5271 (at least if the drug is being partially paid for by public funds).

124. ARIZ. REV. STAT. ANN. § 32-1963.01(B).

125. IOWA CODE § 155A.32(2)(b) (2005 & Supp. 2011); OHIO REV. CODE ANN. § 4729.38 (LexisNexis 2003 & Supp. 2011).

126. CAL. BUS. & PROF. CODE §§ 4052.5(e), 4073(e) (West 2011 & Supp. 2012); COLO. REV. STAT. § 12-22-124(3) (2011); DEL. CODE ANN. tit. 24, § 2549(a)(2) (2011); IND. CODE ANN. § 16-42-22-8(a)(2) (West 2007); VA. CODE ANN. § 54.1-3408.03 (2009 & Supp. 2011).

127. ME. REV. STAT. tit. 32, § 13781 (1999 & Supp. 2011); TENN. CODE ANN. § 53-10-205(d) (2008 & Supp. 2011); VT. STAT. ANN. tit. 18, § 4605 (2002 & Supp. 2011).

128. ALASKA STAT. § 08.80.295(a) (2010); ARK. CODE ANN. § 17-92-503(b)(3) (2010); CONN. GEN. STAT. § 20-619(b) (2008); FLA. STAT. § 465.025(2)-(3) (2007); GA. CODE ANN. § 26-4-81(f) (2003 & Supp. 2011); HAW. REV. STAT. ANN. § 328-92(a) (LexisNexis 2008); RULES OF THE IDAHO BOARD OF PHARMACY § 180(01) (2011), <http://adminrules.idaho.gov/rules/current/27/0101.pdf>; KY. REV. STAT. ANN. § 217.822 (LexisNexis 2007 & Supp. 2010); LA. REV. STAT. ANN. § 37:1241(A)(17)(b) (2007 & Supp. 2012); MINN. STAT. § 151.21(3) (2011); MISS. CODE ANN. § 73-21-117(3) (2008 & Supp. 2011); MO. REV. STAT. § 338.056 (2001 & Supp. 2011); MONT. CODE ANN. § 37-7-505 (2011); NEB. REV. STAT. § 71-5403(1)(b) (2009); NEV. REV. STAT. § 639.2583(3)(b) (2004 & Supp. 2007) (forbidding substitution, however, if the government is paying the difference. This suggests that if the payer is a third party other than the government, then the patient can refuse the substitution and the insurance would have to foot the difference); N.H. REV. STAT. ANN. § 146-B:2(I) (LexisNexis 2005 & Supp. 2010); N.J. STAT. ANN. § 24:6E-7 (West 1997 & Supp. 2011); N.D. CENT. CODE § 19-02.1-14.1(3) (2009 & Supp. 2011); OKLA. STAT. tit. 59, § 353.13(D) (2010 & Supp. 2011); OR. REV. STAT. § 689.515(4) (2011); 35 PA. STAT. ANN. § 960.3(b) (West 2003 & Supp. 2011); R.I. GEN. LAWS § 5-19.1-19 (2009 & Supp. 2011); S.C. CODE ANN. § 39-24-40(e) (1983 & Supp. 2010); S.D. CODIFIED LAWS § 36-11-46.3 (2004 & Supp. 2011); TEX. OCC. CODE ANN. § 562.009(a) (West 2003 & Supp. 2009); UTAH CODE ANN. § 58-17b-605(1)(b) (West 2007 & Supp. 2011); WASH. REV. CODE ANN. § 69.41.130 (West 2007 & Supp. 2012); W. VA. CODE ANN. § 30-5-12b(n) (LexisNexis 2007 & Supp. 2011);

B. ADVANTAGES OF DRUG SUBSTITUTION LAWS

In a study of 5.6 million prescriptions, Shrank et al. showed two reasons why drug substitution is generally good for healthcare.¹²⁹ First, drug substitution lowers the cost of healthcare for society generally whether it is public insurance, private insurance, or the patients themselves who are paying for the drugs. In their sample, patients and their insurance plans paid, respectively, an average of \$17.90 and \$26.67 for generic drugs, but an average of \$44.50 and \$135.26 for brand-name drugs where a generic existed.¹³⁰ The FDA's data indicates a similar price reduction. The price for generic drugs is, on average, 15% of the price of the brand-name drug before generic entry.¹³¹ Shrank et al. estimate that if substitution occurred in all feasible situations, "patient charges could be reduced by as much as \$1.2 billion annually and health system costs could be reduced by as much as \$7.7 billion."¹³²

Additionally, when generic drugs are not substituted, patients are less likely to comply with their drug regimen. When substitution is forbidden, the chance that patients will not purchase a drug at all increase by 42% and the chances that a patient will not refill a prescription increase by 61% as compared with prescriptions where substitution is permitted.¹³³ Presumably this is due to the fact that generic drugs are cheaper. In short, generic substitution for brand-name drugs is extremely efficient and important for society as a whole.¹³⁴

C. PLIVA MAY RESULT IN A DECREASE IN DRUG SUBSTITUTION

Ironically, while the generic drug company won the preemption battle in *PLIVA*, it is possible that generics' preemption from suit will lead to a

WIS. STAT. ANN. § 450.13(1) (West 1998 & Supp. 2010); *accord*, D.C. CODE § 48-803.03(1) (2001 & Supp. 2011); P.R. LAWS ANN. tit. 20, § 410b(b)(1) (2009); V.I. CODE ANN. tit. 19, § 753(c) (1995 & Supp. 2011).

129. William H. Shrank et al., *The Consequences of Requesting "Dispense as Written,"* 124 AM. J. MED. 309 (2011).

130. *Id.* at 311.

131. FDA, *Facts and Myths About Generic Drugs*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/cm167991.htm> (last updated Oct. 13, 2009).

132. Shrank et al., *supra* note 129, at 314.

133. *Id.* at 313.

134. It is true, however, that those who believe that medical patent terms are too short would likely consider any way to extend the effective life of a patent, including limiting generic drug substitutions, to be a boon to society. See Richard A. Epstein, *Branded Versus Generic Competition? A Kind Word for the Branded Drugs*, 3 HASTINGS SCI. & TECH. L.J. 459, 470 (2011).

backlash against generic drug companies that will decrease the number of generic substitutions for brand-name prescriptions. This could happen on a local level because doctors might stop permitting drug substitutions, pharmacists might stop dispensing generic substitutes, and patients may start requesting the brand-name drug. This could also happen on a broader level if states changed their drug substitution laws to prevent or limit situations where generic drugs are substituted.

1. *Doctors, Pharmacists, or Patients May Prevent Substitutions*

Fear of what happened in *PLIVA* may cause doctors, pharmacists, and patients to avoid generic drug substitutions altogether. This is a particularly potent concern in the case of doctors, since their discretion to prevent generic substitutions is virtually unchecked.¹³⁵ Thus, if doctors fear that patients will not be compensated for harms arising from newly-discovered side effects, then, as the dissent in *PLIVA* notes, doctors might start prohibiting substitutions more frequently.¹³⁶ A recent study by Shrank et al., conducted before the Court's decision in *PLIVA*, showed that of 5.6 million prescriptions, 2.7% had a prescriber's order preventing substitution.¹³⁷ This percentage will likely rise if doctors feel that patients may be harmed by taking generic drugs.

Doctors' motivation for preventing substitutions could be altruistic. By requiring pharmacies to dispense the brand-name drug, the doctor ensures that if it later turns out that the drug was inadequately labeled the consumer can be compensated. Weighing against this, however, is the fact that brand-name drugs cost more than their generic equivalents, though insurance often absorbs some portion of the cost of patient prescriptions.¹³⁸

However, self-interest may also lead doctors to prevent substitutions. Injured patients can sue multiple sources for their injury. For example, in *Wyeth*, Levine sued both Wyeth, for inadequate labeling, and the physician's assistant who dispensed Phenergan, for doing so negligently.¹³⁹ However, once plaintiffs have been made whole by suing the drug company, they can no longer sue the doctor for the same injury; if they receive only partial or no

135. Only Tennessee expressly limits the situations where doctors can declare that a brand-name drug is medically necessary, TENN. CODE ANN. § 53-10-204(a)(1) (2008 & Supp. 2011), and even Tennessee has a broad exception for "clinically based prescriber determined need[s]." § 53-10-204(a)(1)(C).

136. *PLIVA v. Mengin*, 131 S. Ct. 2567, 2593 (2011) (Sotomayor, J., dissenting).

137. Shrank et al., *supra* note 129, at 311.

138. See Elizabeth Mendes, *More Americans Uninsured in 2011*, GALLUP WELLBEING (Jan. 24, 2012), <http://www.gallup.com/poll/152162/Americans-Uninsured-2011.aspx>.

139. *Wyeth v. Levine*, 555 U.S. 555, 559 (2009).

compensation from the drug company then they can sue the doctor for only some of the damage.¹⁴⁰ Thus, forcing patients to take brand-name drugs may help doctors avoid, or at least reduce, medical malpractice claims.

Like doctors, pharmacists, in states where they have discretion (and that is most states),¹⁴¹ may dispense brand-name drugs to leave open the possibility of suit for patients who may be hurt by inadequate labeling. Pharmacists may also dispense brand-name drugs so that, in case of later suit, the plaintiff might seek recovery from the brand-name drug company to shoulder some or all of the liability.¹⁴² Individual pharmacists, or entire pharmacies more broadly, may implement such a policy.

Finally, patients may prevent substitution of generic drugs. As noted above, in most states a patient may prevent a drug substitution, perhaps without having to pay for the difference in price between the brand-name and the generic drug.¹⁴³ Even before *PLIVA*, Shrank et al. showed that 2.0% of patients requested that their prescriptions be filled with the brand-name drug.¹⁴⁴ With the Court's decision, patients have one more reason to try and prevent a drug substitution since receiving the brand-name drug maintains their ability to sue.

2. States May Change Their Substitution Laws

Among states that have changed their drug substitution laws within the last ten years, the trend has been nearly uniform towards promoting drug substitution.¹⁴⁵ However, the same pressures that may lead doctors,

140. *See, e.g.*, *Monroe v. Standard Oil Co.*, 452 U.S. 549, 562 & n.13 (1981) (assuming that double compensation should not be granted).

141. *See supra* notes 118, 119 and accompanying text.

142. As they do sometimes. *See, e.g.*, *Griffith v. Blatt*, 51 P.3d 1256 (Or. 2002).

143. *See supra* notes 123–128.

144. Shrank et al., *supra* note 129, at 311.

145. *Compare* ARIZ. REV. STAT. ANN. § 32-1963.01(D) (2001); 225 ILL. COMP. STAT. ANN. 85/25 (West 2001); KAN. STAT. ANN. § 65-1637(a)(1) (State 2001); ME. REV. STAT. tit. 32, § 13781 (2001); MD. CODE ANN. HEALTH-GEN. § 15-118(a)(1) (West 2001); MASS. GEN. LAWS ANN. ch. 112, § 12D (2001); N.J. STAT. ANN. § 24:6E-7 (West 2001); N.C. GEN. STAT. ANN. § 90-85.28(b) (West 2001); TENN. CODE ANN. § 53-10-204 (West 2001) *with* the modern versions of the statutes. Virginia actually changed its statutes in two ways: on the one hand, the earlier version of the statute required the doctor to explicitly permit substitution by signing under a line that says substitution is permitted, whereas the modern version assumes substitution is permissible unless the doctor explicitly forbids it. *Compare* VA. CODE ANN. § 54.1-3408.03(A) (2001) *with* the modern version of the statute. On the other hand, in 2001, when that condition was met, substitution was mandatory, whereas now substitution is in the discretion of the pharmacist. *Compare* VA. CODE ANN. § 54.1-3408.03(A) (2001) *with* the modern version of the statute. Only Wisconsin made substitution uniformly less likely. *See* WIS. STAT. ANN. § 450.13(2) (West 2001), *amended by* WIS. STAT. ANN. § 450.13(2) (Supp. 2011) (requiring substitution where it is permitted).

pharmacists, and patients to attempt to avoid substitutions may also lead states in the future to choose not to strengthen, and perhaps even weaken, their substitution laws. Indeed, Maine (but so far, only Maine) already limits substitution of generic drugs to drugs manufactured by companies “doing business in the United States that [are] subject to suit and the service of legal process in the United States.”¹⁴⁶ Thus, Maine already considers the generic’s potential to be sued a prerequisite for substitutions.

As a result of *PLIVA*, other states may change their laws to make drug substitution more difficult. For instance, as noted above, states vary as to the ability they give a patient to choose or prevent drug substitutions.¹⁴⁷ Ten states do not even require the patient to be informed of the substitution.¹⁴⁸ After *PLIVA*, these states might consider it unfair to force patients to take the generic version of the drug and thereby lose their right to compensation. Shrank et al. have shown that requiring patient consent strongly correlates with a decrease in the frequency of drug substitutions made.¹⁴⁹ Specifically, in a study of prescriptions for the brand-name drug Zocor and its generic equivalent simvastatin, the results of the study showed that requiring patient consent prior to substitution led to an approximately 25% decrease in generic drug substitution.¹⁵⁰ This disproportionately affected less-educated patients, since they were the most likely to disfavor generic drugs.¹⁵¹

Similarly, states may require prescription pads to explicitly state whether a doctor is permitting generic drug substitution—instead of permitting substitution by default. It stands to reason that some doctors who now simply fill a prescription without thinking about substitution (thus defaulting to substitution in many states), might instead prohibit substitution if they were explicitly required to consider the question.¹⁵² Finally, states may require pharmacists to inform patients that if they take the generic drug the patient will not be able to sue the manufacturer for compensation in case of harm.

To summarize, states have laws that permit the substitution of a generic drug for a brand-name drug. These substitutions are important, both financially and as a matter of patient compliance with drug regimens. But *PLIVA* and *Wyeth* in combination may decrease the use of substitution over

146. ME. REV. STAT. tit. 32, § 13781 (1999 & Supp. 2011).

147. See *supra* notes 123–128 and accompanying text.

148. See *supra* note 123.

149. Shrank et al., *supra* note 108.

150. *Id.*

151. *Id.*

152. See *Mosley v. Wyeth*, 719 F. Supp. 2d 1340, 1347 n.6 (2010) (arguing that generic drug substitution “is less likely to occur . . . in Alabama” where explicit doctor’s permission is required).

the long run. This combination of the two cases, therefore, is harmful to society. The next Part examines several institution that can make patients taking brand-name drugs and patients taking generics be treated equivalently.

IV. FIXING THE PROBLEMS CREATED BY THE COURT

Any of several different actors could independently harmonize the treatment of patients harmed by brand-name and generic drugs. First, the Court could reverse or limit either *Wyeth* or *PLIVA*. Though it is unlikely that the Court would do so *sua sponte*, a change by the FDA may cause the Court to reconsider its decisions, since a fundamental ingredient in the Court's decisions in *PLIVA* (and maybe *Wyeth* as well) was the FDA's own regulations and interpretations.

Additionally, generic drug companies could themselves waive their preemption defense, or states could force generic drug companies to do so. States could also permit plaintiffs, even those harmed by *generic* drugs, to sue the brand-name company. Finally, Congress could step in and statutorily overrule either of the two decisions.

A. JUDICIAL REVERSAL OR LIMITATION OF THE DECISIONS

It is always possible that the Court might reverse or limit the holdings in *PLIVA* or in *Wyeth*. The majority in *PLIVA* makes a cryptic comment that, perhaps, is meant to imply that for injuries sustained after 2007, the result in *PLIVA* may be different. The Court says “[a]ll relevant events in these cases predate the Food and Drug Administration Amendments Act of 2007. We therefore refer exclusively to the pre-2007 statutes and regulations and express no view on the impact of the 2007 Act.”¹⁵³

What the Court means by that comment is unclear, but several possibilities emerge. One possibility is that the Court believes that the 2007 amendment's grant to the FDA of the power to require post-market studies¹⁵⁴ would affect the decision in *PLIVA*. The rationale is this: if generic drug companies are required to conduct post-market studies, then the FDA can trust that those companies will have sufficient information about potential side effects so that the FDA should allow them to amend their

153. *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567, 2574 n.1 (2011) (internal citations omitted).

154. FDAAA, Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 923 (2007) (amending 21 U.S.C. § 355(o)(3) (2010)) (“[T]he Secretary may . . . require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug . . .”). See generally *id.* at 923–26 (laying out the FDA's new powers to require post-market studies).

labels first and ask the FDA later (just as brand-name drugs can). If that is so, then the generic drug manufacturers are not in an impossible situation where the FDA forbids label changes but state tort law requires it. Therefore, state tort law would not be preempted.

Another possibility is that the Court is referring to the Act's granting the FDA the ability to mandate a label change.¹⁵⁵ Before 2007, the FDA could only suggest to a brand-name drug company that they should change their label, but the manufacturer could refuse to change the label (although the FDA could then withdraw approval of the drug).¹⁵⁶ The plaintiff's claim against *PLIVA* was particularly attenuated because it was brought under the pre-2007 Act. *PLIVA* would have had to convince the FDA that a label change was warranted and the FDA would have had to convince the brand to change the label.¹⁵⁷ The 2007 amendments erode this difficulty, since the FDA would not need to convince the brand-name company. Thus, one could argue, that for injuries that occur post-2007, suits against generic drug companies would not be preempted, even under *PLIVA*. However, the Court's focus on *PLIVA*'s ability to "independently" change its label¹⁵⁸ makes it unlikely that its preemption reasoning depended on the FDA's inability to mandate a label change, given that either way the generics could not "independently" effect a label change.

B. NEW FDA REGULATIONS

The most likely candidate to change the result created by *PLIVA* is the FDA. The reason the Court distinguished between generic drug companies and brand-name companies was because the FDA did the same.¹⁵⁹ The FDA argued that it forbade generics from unilaterally updating their label because it wanted brand-name and generic drugs to be equivalent.

[T]he fundamental premise of the [generic drug approval process is] that a generic drug can be relied upon as a therapeutic equivalent of its [brand-name equivalent]. Accordingly, FDA places a very high priority on assuring consistency in labeling, so as to minimize any cause for confusion among health care professionals and

155. *Id.* § 901(a), 121 Stat. at 924 (amending 21 U.S.C. § 355(o)(4)).

156. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009).

157. *See PLIVA*, 131 S. Ct. at 2578 (describing the chain of events as a game of "Mouse Trap").

158. *PLIVA*, 131 S. Ct. at 2579 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it.").

159. *PLIVA*, 131 S. Ct. at 2575–79.

consumers as well as to preclude a basis for lack of confidence in the equivalency of generic versus brand name products.¹⁶⁰

Importantly, the FDA believed that even with its regulations, the plaintiffs' suit against the generic drug companies in *PLIVA* should prevail. Finding preemption would "deprive injured parties of a long available form of compensation and . . . do so in . . . an inconsistent manner."¹⁶¹ The Court disagreed. The FDA is therefore on the horns of dilemma. It must either allow generic drugs unilaterally to update their labels—thus potentially causing consumers to believe there is a difference between brand-name and generic drugs—or must allow state tort suits against brand-name but not generic drugs—with the same effect.

However, even without the result in *PLIVA*, the advantages of allowing generic drug companies to add extra warnings unilaterally when they discover that there are potential new side effects itself outweighs the benefit of insuring identical labeling between generics and brand-name companies.¹⁶² After all, if the FDA agrees with the proposed change, then the brand-name company will also have to change its label, and if the FDA does not agree, then the generic drug company will revert to the brand-name label. Moreover, it is already possible that brand-name drugs and their generic drug equivalents will have differing labels. If a brand-name company discovers new adverse side effects it must change its label to reflect these new adverse side effects even before the FDA reviews the label change.¹⁶³ It will take the generics time to change their label, and, during this period of time, the brand-name and generic labels will differ. Given the bizarre result in *PLIVA*, the argument that generics should be allowed to unilaterally change their labels is all the more compelling.¹⁶⁴

It thus seems likely that the FDA will change its position and allow generics to change their labels in light of newly discovered adverse side effects.¹⁶⁵ That the FDA can change its regulations, and therefore the result

160. SG Brief, *supra* note 11, at 4.

161. *Id.* at 26–27.

162. *But see* *PLIVA et al. Brief, supra* note 47, at 37–38 (arguing that while brand-name companies should be required to revise their labels when they learn of new side effects, generics should not, since brand-name companies have access to more information).

163. *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009).

164. *See* Brian Wolfman & Dena Feldman, *PLIVA v. Mensing and Its Implications*, BNA INSIGHTS: HEALTH LAW RESOURCE CENTER, http://healthlawrc.bna.com/hlrc/4203/split_display.adp?fedfid=22851209&vname=hllifenotallissues&split=0 (last visited Feb. 21, 2012).

165. *See* Petition from Sidney M. Wolfe et al. to Food and Drug Admin., Dep't of Health and Human Servs. 1, 6 (Aug. 29, 2011), *available at* <http://www.citizen.org/documents/Citizen-Petition-8-26.pdf> (requesting that the FDA change its regulations to

in *PLIVA*, is clear. The Court itself admits, “[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire.”¹⁶⁶

However, administrative law may throw a hurdle in the way of the FDA. Though the FDA’s interpretation (in its brief) of its regulations—prohibiting generic drug companies from unilaterally altering their labels—was an interpretive rule and therefore did not require notice-and-comment,¹⁶⁷ according to the D.C., Third, Fifth, and Sixth Circuits (and perhaps the Second Circuit as well)¹⁶⁸ the FDA would have to use notice-and-comment to alter its interpretation; the First and Ninth Circuits disagree.¹⁶⁹ Nonetheless, the FDA could clearly change its regulations (at least through notice-and-comment) to explicitly permit generic drug companies to unilaterally change their labels.

Finally, it is possible that the FDA could change the result in *Wyeth*. In *Wyeth* the Court did not defer to the FDA’s assertion that federal law should preempt state tort suits for several reasons. First, the Court noted that the FDA did not use notice-and-comment.¹⁷⁰ Second, the FDA’s position that state tort suits should be preempted was “at odds with what evidence we have of Congress’s purposes,” and third, the FDA’s position “reverse[d] the

allow generic drug companies to unilaterally alter their label in the case of newly-discovered adverse side effects, in part to avoid the result in *PLIVA*).

166. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

167. *See Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995). Notice-and-comment is where an agency notifies the public of a proposed interpretation and requests public comment. *See* 5 U.S.C. § 553 (2011).

168. *See Visiting Nurse Ass’n of Brooklyn v. Thompson*, 378 F. Supp. 2d 75, 90 (E.D.N.Y. 2004) (“The Second Circuit . . . has hinted on at least one occasion that it would . . . requir[e] administrative agencies to employ notice and comment in altering established interpretations of applicable regulations.”).

169. *See generally* *United States v. Magnesium Corp. of Am.*, 616 F.3d 1129, 1139 (10th Cir. 2010) (“[T]he issue whether an agency may alter its interpretation of its own regulation without notice and comment is the subject of a circuit split, with the Third, Fifth, and Sixth Circuits apparently adopting the D.C. Circuit’s view [that it cannot] and the First and Ninth Circuits seemingly taking the contrary position.”). These courts are talking about cases where the agency interpretation is set out in a regulation, not in a brief. However, at least the stated logic of the Sixth Circuit would apply equally well to opinions stated in briefs. *See Dismas Charities, Inc. v. U.S. Dept. of Justice*, 401 F.3d 666, 682 (6th Cir. 2005) (“It is true that once an agency gives a regulation an interpretation, notice and comment will often be required before the interpretation of that regulation can be changed. This is because once an agency has promulgated its own regulation, a change in the interpretation of that regulation is likely to reflect the agency’s reassessment of wise policy rather than a reassessment of what the agency itself originally meant. The determination of wise policy—unlike legal interpretation—is the kind of determination for which notice and comment procedures are particularly appropriate.”) (internal citations omitted).

170. *Wyeth v. Levine*, 555 U.S. 555, 577 (2009).

FDA's own longstanding position without providing a reasoned explanation."¹⁷¹ The first and third of the Court's criticisms are within the FDA's power to fix: the FDA could use notice-and-comment to promulgate a decision to preempt all state tort suits, even against brand-name companies, and it could explain in detail why it thinks this is necessary. The FDA cannot, however, legally do anything about the Court's understanding of Congress's purposes. It is therefore possible, though not certain, that the FDA could convince the Court to overrule *Wyeth* by using proper procedures to promulgate its understanding. However, it is possible that even if before *Wyeth* it was ambiguous whether the FDCA intended to preempt lawsuits against brand-name drug manufacturers, the very fact that the Supreme Court ruled on the issue makes the statute legally unambiguous.¹⁷²

C. MANUFACTURER WAIVER OF THE PREEMPTION DEFENSE

If the number of generic drug substitutions were to decrease as a result of the Court's decision in *PLIVA*, generic drug companies—the very companies that argued for federal preemption from suit in *PLIVA*¹⁷³—might find it worthwhile as a business matter to waive their preemption defense. That generic drug companies can waive their defense at trial is clear. With exceptions not relevant here, preemption is a waivable affirmative defense.¹⁷⁴

However, generic drug companies attempting to waive their *PLIVA* rights face a collective action problem. Generic drug companies are, on the whole, indistinguishable; consumers normally identify the generic drug based on the generic's chemical name, which is identical for all generic equivalents

171. *Id.*

172. An agency can interpret an ambiguous statute even after a Court of appeals has interpreted the statute differently. *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967 (2005). Whether this also applies to Supreme Court decisions is debated. *Compare id.* at 1003 (Stevens, J., concurring) (“a decision by this Court that would presumably remove any pre-existing ambiguity [in an ambiguous statute]”) with *Hernandez-Carrera v. Carlson*, 547 F.3d 1237, 1247 (10th Cir. 2008) (disagreeing).

173. Reply Brief of Petitioners Actavis and Actavis Elizabeth, *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 1059615, at *3; Reply Brief of Petitioners *PLIVA*; Teva Pharm. USA; and UDL Labs at 4, *PLIVA*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 1059616; Brief of Apotex, Inc. as Amicus Curiae in Support of Petitioners at 14, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 288894; Brief of the Generic Pharm. Ass'n as Amicus Curiae in Support of Petitioners at 19, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 343069; Brief for Morton Grove Pharm., Inc. and Impax Lab., Inc. as Amici Curiae in Support of Petitioners at 13, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 343070.

174. *See Int'l Longshoremens Ass'n, AFL-CIO v. Davis*, 476 U.S. 380 (1986). The only type of preemption that is not waivable is preemption that removes subject matter jurisdiction. *Id.* at 385.

of a single drug.¹⁷⁵ As a result, generics do not advertise their products because any advertisements they invest in will benefit all generics that have the same chemical name.¹⁷⁶ This same problem exists if legislative limits on drug substitution laws cause a generic drug manufacturer, or even all generic drug manufacturers, to recognize that *PLIVA* harms their interest. If a generic drug company permits consumers to sue, this permission will either be diluted by all the other drug companies that do not waive their federal preemption defense or all the other companies will get to free-ride on consumers' positive association from the first company's waiver (even if the other companies themselves refuse to waive liability). It may therefore prove difficult for generic drug companies to avoid the result in *PLIVA*, even if, in the long run, the result is harmful to their interests.

D. STATE ACTION

Since the decision in *PLIVA* rests on federal preemption, and thus on the Supremacy Clause,¹⁷⁷ states cannot statutorily overrule *PLIVA* directly. They do, however, have a number of potential options.

1. Required Waiver

One model for improvement is Maine's drug substitution statute. Maine limits substitution of generic drugs to companies "doing business in the United States that [are] subject to suit and the service of legal process in the United States."¹⁷⁸ Other states could extend Maine's approach and limit drug substitution to generic drugs provided by manufacturers that have waived their preemption defense.¹⁷⁹ The state would create a list of generic drug companies that have waived their preemption defense, allowing substitutions of their drugs only. Thus, generic companies would face a Hobson's choice: they could refuse to waive their tort liability, in which case they would not be substituted for brand-name prescriptions—and therefore they would be sold far less frequently¹⁸⁰—or they could waive their preemption defense. If the state required waiver is legally enforceable, such a scheme could effectively overrule *PLIVA*.

175. RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 153 (2006); Adam R. Young, *Generic Pharmaceutical Regulation in the United States with Comparison to Europe: Innovation and Competition*, 8 WASH. U. GLOBAL STUD. L. REV. 165, 178 (2009).

176. EPSTEIN, *supra* note 175, at 153; Young, *supra* note 175, at 178 (2009).

177. U.S. CONST. art VI, cl. 2.

178. ME. REV. STAT. tit. 32, § 13781 (1999 & Supp. 2011).

179. Which can be waived. *See supra* Section IV.C.

180. *See* Karolina Anderson et al., *Impact of a Generic Substitution Reform on Patients' and Society's Expenditure for Pharmaceuticals*, 81 HEALTH POL'Y 376 (2007).

What is unclear, though, is whether a contractual waiver of a preemption defense is judicially enforceable.¹⁸¹ The First Circuit has held that a preemption defense may not be contractually waived if it “do[es] violence to the public policy underlying the legislative enactment.”¹⁸² Whether a state mandated waiver of liability does violence to the public policy expressed in *PLIVA* is closely related to a second question.

It is possible that federal law may preempt a state’s demand for a waiver of liability. Most justices consider any state law that is “an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”¹⁸³ preempted by federal law (obstacle preemption). If, as the majority in *PLIVA* holds, allowing state tort suits for inadequate labeling conflicts with the requirements of the Hatch-Waxman Act, then state laws effectively forcing generic manufacturers to waive their right to such a defense likely would be invalidated under obstacle preemption.

What makes this more confusing is that Justice Thomas does not accept obstacle preemption since he believes that attempting to intuit Congress’s goals is too speculative.¹⁸⁴ Since *PLIVA* was a 5–4 decision, with Justice Thomas in the majority, this might be crucial. Whether a state requirement for waiver was constitutional would therefore depend on whether at least one of the dissenting justices in *PLIVA* would follow *stare decisis*, upholding the result in *PLIVA* from which they dissented, in which case the generics would be preempted and the waiver of liability would be impermissible since all the justices except for Justice Thomas accept obstacle preemption.¹⁸⁵ If the four liberal justices continue resisting preemption for generic drug manufacturers, Justice Thomas would likely join them—agreeing only in result, since he would uphold the waiver of liability—thereby creating a plurality upholding liability against generic drug manufacturers. Perhaps the First Circuit’s “violence to the public policy” test is similar to the obstacle

181. *See* *Tompkins v. United Healthcare of New Eng.*, 203 F.3d 90, 97 (1st Cir. 2000) (“Although in some circumstances contractual waiver of statutory rights is permissible, we find no case holding that parties may contractually waive the right to assert ERISA preemption. Our decision in *Wolf v. Reliance Standard Life Ins. Co.*, 71 F.3d 444, 449 (1st Cir.1995), relied upon by the Tompkinses, merely holds that ERISA preemption, as an affirmative defense rather than as an element of the court’s jurisdiction, is waived if not timely raised. But *Wolf*, which addresses only procedural waiver, offers no support for the Tompkinses’ contractual waiver argument.”) (internal citations omitted).

182. *Id.* (citing sources).

183. *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 373 (2000).

184. *Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1142 (2011) (Thomas, J., concurring); *Haywood v. Drown*, 129 S. Ct. 2108, 2133 (2009) (Thomas, J., dissenting); *Wyeth v. Levine*, 555 U.S. 555, 604 (2009) (Thomas, J., concurring).

185. *See supra* note 184.

preemption test and Justice Thomas would likewise reject is as being too speculative. In that case, depending on the liberal justices' application of *stare decisis*, such a waiver might garner a majority.

2. *Allow Suits Against Brand-Name Drug Companies*

A different potential solution is to grant patients harmed by generic drugs the right to sue the brand-name drug company that makes the equivalent brand-name drug. The logic is simple. Had the brand-name changed its label, the FDA would have considered whether to update the labeling requirements on the drug.¹⁸⁶ If the FDA had updated the label then the generic label would have had to follow suit¹⁸⁷ and therefore the generic label would have been more accurate. Though a couple of courts have accepted this argument and held that brand-name drug companies can be liable for harm from the generic equivalents of a drug,¹⁸⁸ those decisions are the exception.¹⁸⁹ Courts, as a matter of state tort law, almost uniformly require that a plaintiff be injured by ingesting the defendant's drug.¹⁹⁰

Importantly, a number of the courts that ruled in favor of the brand-name manufacturers reasoned that consumers should just sue the generic drug company.¹⁹¹ However, given that *PLIVA* forecloses this option, perhaps state courts or legislatures will permit suits against brand-name drug companies for harm from their generic equivalents.¹⁹² One caveat is that in cases where the brand-name drug company has left the market, it seems very unfair to force the brand-name drug to continue monitoring the safety of the drug or else be liable for suits for inadequate labeling of a drug they no longer produce.¹⁹³

186. *See Wyeth*, 555 U.S. at 571.

187. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2576–77 (2011).

188. *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 109–11 (2008); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010).

189. *See* Kenneth Sills, *Liability of Name Brand Drug Manufacturer for Injury or Death Resulting from Use of Prescription Drug's Generic Equivalent*, 56 A.L.R. 6th 161 (2010).

190. *Id.* (collecting cases).

191. *E.g.*, *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994); *Bartlett v. Mutual Pharm. Co.*, 659 F. Supp. 2d 279, 308–09 n.40 (D.N.H. 2009); *Schrock v. Wyeth*, 601 F. Supp. 2d 1262, 1267 (W.D. Okla. 2009); *Fields v. Wyeth*, 613 F. Supp. 2d 1056, 1061 (W.D. Ark. 2009); *Swicegood v. PLIVA*, 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008).

192. *Cf.* Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Manufacturers*, 60 DUKE L.J. 1123, 1177–78 (2011) (arguing for brand-name manufacturer liability in light of the possibility that the then pending *PLIVA* decision would turn out as it did).

193. *See* Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 691–92 (2010) (questioning whether courts

E. CONGRESSIONAL ACTION

A final possibility is that Congress could explicitly make uniform the preemption laws for generic and brand-name drugs: either both are preempted or both are not.¹⁹⁴ After all, both *Wyeth*¹⁹⁵ and *PLIVA*¹⁹⁶ imply that, had Congress been explicit about wanting or not wanting preemption, then the Court would have acquiesced to that decision. The Supreme Court, in other cases, makes this point explicitly.¹⁹⁷ Additionally, like the FDA, Congress could permit generic drug companies to unilaterally change drug labels upon learning of new adverse side effects and this would effectively reverse *PLIVA*, or it could forbid brand-name drug companies from unilaterally changing their labels, thus reversing the result in *Wyeth*.¹⁹⁸ Obviously getting specific Congressional action is never a simple task, but given the importance of the drug industry, it might be possible.¹⁹⁹

V. CONCLUSION

There is significant tension between the Court's 2009 decision in *Wyeth v. Levine* and its 2011 decision in *PLIVA v. Mensing*. The result of the combination of the two cases is that brand-name drug companies can be sued for inadequate labeling, whereas generic drug companies cannot.²⁰⁰ In

that permit plaintiffs harmed by generic drugs to sue the brand-name drug would extend this to cases where the brand-name drug has left the market).

194. Nothing in the Health Care and Education Reconciliation Act of 2010 touches on these questions. See Pub. L. No. 111-152, 124 Stat. 1029 (2010).

195. 555 U.S. at 574–75.

196. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2577 n.5, 2579 (2011).

197. *E.g.*, *Cipollone v. Liggett Grp. Inc.*, 505 U.S. 504, 516 (1992) (“Accordingly, the purpose of Congress is the ultimate touchstone of pre-emption analysis.”) (internal citations and alterations removed); see also Katie Stewart, *Should Congress Seek To Alter the Preemption Schism Established by Wyeth v. Levine and PLIVA v. Mensing*, 1 FDLPS FOOD & DRUG POLY FORUM, Oct. 26, 2011, at 5–6 (arguing that Congress should always say whether they intend for state law to be preempted, but especially in the context of food and drug law). The argument that Congress should generally specify whether a federal law preempts state law is debatable. In many instances, *a priori* it may be difficult to determine how state and federal law will interact. Thus, it may be better to let a court determine *ex post* whether preemption applies.

198. See Stewart, *supra* note 197, at 6–7.

199. As this Note was going to press, the *New York Times* reported that Congressman Waxman “was exploring ways to address [*PLIVA*], either through legislation or a rule change.” Katie Thomas, *Generic Drug Proving Resistant to Damage Suits*, N.Y. TIMES, Mar. 12, 2012, at A1.

200. Lest one worry that the Court was advantaging generic drug manufacturers against brand-name manufacturers, on the same day *PLIVA* was decided the Court also decided *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), ruling in favor of brand-name drug companies that states cannot prohibit doctors from releasing pharmacy records that detail

the case of authorized generics, it may be that one generic can be sued while the rest cannot. The potentially unfortunate result could be a decrease in the number of generic drugs dispensed. This is harmful both because it wastes resources and because patients who have to take brand-name drugs are less likely to comply with their drug regimen.²⁰¹

While it is unlikely that the Court will reverse either of its decisions without prompting, the FDA might change its regulations, and this would in turn change the law. Additionally, it is possible that Congress might get involved and abrogate either *Wyeth* or *PLIVA*. Finally, while states cannot abrogate *PLIVA*, since it is based on the Constitutional Supremacy Clause, they can allow patients harmed by generic drugs to sue brand-name drug companies. This is not as unfair as it may seem, since the brand-name company is the company that set the label in the first place. States may also be able to force generic drug companies to waive their preemption defense before the generic is substituted. Hopefully, the numerous potential fixes mean that the broader benefits of generic drug substitution will not be harmed.

the prescribing practices of individual doctors. *See id.* at 2670 (explaining why such a law harms the brand-name manufacturer's interests). So, on the whole, it breaks even.

201. *See supra* Section III.B.