

**CONSUMERS OF GENERIC DRUGS SEARCH
FOR COMPENSATION: THE EFFECT
OF *PLIVA V. MENSING* ON THE
CONTE/FOSTER DICHOTOMY**

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INTRODUCTION

In *PLIVA v. Mensing*, the Supreme Court held that federal drug regulation¹ preempts state law claims against manufacturers of generic drugs for failure to adequately warn consumers of potential harms faced by taking those drugs.² Consumers of generic drugs injured by inadequate warnings are now left searching for an alternative means of recovery.³ One potential alternative for these consumers is to bring a claim against the manufacturer of the name-

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1. 21 U.S.C. § 355(j)(2)(A)(v) (2006).

2. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

3. *See id.* at 2592 (Sotomayor, J., dissenting) (“[T]he majority’s pre-emption analysis strips generic-drug consumers of compensation when they are injured by inadequate warnings.”).

brand counterpart of the generic drug that caused their injuries.⁴ Courts will almost certainly see a greater number of these claims by users of generic counterparts as a result of *PLIVA*'s elimination of liability against generic manufacturers.⁵ While this could give name-brand defendants some cause for concern,⁶ courts have until now almost universally rejected the validity of these claims.⁷ *Foster v. American Home Products* was the first and most widely followed case to directly address and reject this type of claim.⁸ The *Foster* approach is not uniformly followed, however, as claims against name-brand manufacturers were allowed in *Conte v. Wyeth*.⁹ Despite the likely increase in claims against brand-name manufacturers brought by consumers of generic drugs as a result of *PLIVA*, reconsideration of *Foster* or widespread adoption of the *Conte* approach is unlikely, and plaintiffs will remain restricted by the barrier *Foster* erected. While *Conte*'s reasoning is only strengthened by *PLIVA*'s holding, judicial change is unlikely because the *Foster* decision is based on a fundamental understanding of products liability law. Understanding the practical ramifications of *PLIVA* in this regard can provide guidance to litigators and motivation for any legislatures that wish to address any existing inequity for consumers of generic drugs.

4. See *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299, 304-05 (Cal. Ct. App. 2008) (upholding claims of fraud, fraud by concealment, and negligent misrepresentation against a name brand manufacturer for injuries suffered by consumer of generic drugs).

5. Some evidence of resurgence is seen in *Gross v. Pfizer, Inc.*, where the plaintiffs petitioned for reconsideration of an adverse summary judgment following *PLIVA*. *Gross v. Pfizer, Inc.*, No. 10-CV-00110-AW, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011).

6. See Michael Healy & Kelly Savage Day, From the Experts: Brave New (Post-Mensing) World, CORPORATE COUNSEL (Aug. 10, 2011), available at http://www.law.com/jsp/cc/PubArticleCC.jsp?id=1202510496208&From_the_Experts_Brave_New_PostMensing_World ("Although *PLIVA* should not be viewed as a harbinger of never-ending, ever-expanding liability for brand-name manufacturers, innovators should expect and prepare for an increase in product liability suits seeking to hold them liable for harm stemming from their generic competitors' products . . .").

7. See, e.g., *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171-72 (4th Cir. 1994); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. Ct. App. 2008). But see *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010); *Conte*, 85 Cal. Rptr. 3d at 305.

8. See *Foster*, 29 F.3d at 171-72. *Foster* has been widely adopted. See *infra* note 27.

9. *Conte*, 85 Cal. Rptr. 3d at 320-21 ("We hold that Wyeth's common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing metoclopramide, whether the prescription is written for and/or filled with Reglan or its generic equivalent.").

This Comment begins by describing two contrasting judicial approaches to the liability of brand-name manufacturers to the consumers of their generic equivalents. The Comment next discusses application of the preemption doctrine in the prescription drug and device context, most recently in *PLIVA v. Mensing*. Finally, this Comment discusses the ramifications of *PLIVA v. Mensing* on the liability of brand-name manufacturers and concludes that courts are unlikely to provide a judicial remedy for consumers of generic prescription drugs alleging a failure to warn.

I. THE *FOSTER/CONTE* DICHOTOMY

When seeking FDA approval, generic drugs piggyback on the more rigorous approval process undergone by their name-brand counterpart. Generic drugs are eligible for an abbreviated FDA approval process if their manufacturers, among other things, precisely copy the warnings of their name-brand equivalent. This piggybacking raises the potential for a claim by consumers of the generic drug against the name-brand manufacturer.¹⁰ Such a claim would be based on the reliance of consumers of generic drugs or their prescribing physicians on representations made by the name-brand manufacturer.¹¹

For this claim to succeed, two propositions must be accepted. First, a claim for intentional or negligent misrepresentation must be separate and distinct from strict products liability claims, since strict products liability claims require that the defendant manufactured the product at issue.¹² Second, name-brand manufacturers must be found to owe a duty of care to consumers of generic drugs.¹³ Such a duty would be based on the foreseeability of a doctor prescribing the generic drug in reliance on representations

10. Generic drug manufacturers are able to file for abbreviated new drug applications under 21 U.S.C. 355(j). This section provides that if a generic manufacturer can show that their proposed product is equivalent to a product whose conditions of use have previously been approved, § 355(j)(2)(A)(i), the strength of the new drug is the same, § 355(j)(2)(A)(iii), their drug is bioequivalent to said approved drug, § 355(j)(2)(A)(iv), and the labeling is the same as the previously approved drug, § 355(j)(2)(A)(j)(v), then approval of the new drug shall be granted or denied within 180 days. § 355(j)(5)(A).

11. See *Conte*, 85 Cal. Rptr. 3d at 304–05.

12. *Foster*, 29 F.3d at 168 (“Maryland law requires a plaintiff seeking to recover for an injury by a product to demonstrate that the defendant manufactured the product at issue.”).

13. See *id.* at 171 (“The *Fosters*’ negligent misrepresentation action against Wyeth also fails because Wyeth is under no duty of care to the *Fosters*.”).

made by the name-brand manufacturer.¹⁴ Both of these propositions were rejected in *Foster v. American Home Products* but accepted in *Conte v. Wyeth*.¹⁵ The following section discusses both cases in detail.

A. *Foster v. American Home Products and Its Progeny*

Foster v. American Home Products held that name-brand manufacturers cannot be liable for injuries caused to consumers of generic drugs by inadequate labeling.¹⁶ In *Foster*, two twins were given promethazine syrup, a generic form of Phenergan, as treatment for colic.¹⁷ After receiving the treatment for several days, one of the twins perished from Sudden Infant Death Syndrome.¹⁸ This death was attributed to the promethazine syrup prescribed by the Fosters' pediatrician,¹⁹ and a suit was brought against the name-brand manufacturer, Wyeth.²⁰ The court rejected this potential liability of name-brand manufacturers. First the court held that, under Maryland law, negligent misrepresentation claims against manufacturers of injury-causing products are subsumed within products liability law.²¹ Because a defendant must have manufactured the product at issue to be liable under a products liability claim, a negligent misrepresentation claim against a name-brand manufacturer is invalid when the consumer has taken only the generic drug.²² Next the court held that name-brand manufacturers owe no duty of care to consumers of generic drugs.²³

14. See *Conte*, 85 Cal. Rptr. 3d at 311–13 (holding that name-brand manufacturers do owe a duty to consumers of generic drugs after finding that “it is eminently imminently foreseeable that a physician might prescribe [a generic equivalent] in reliance on” representations of the name-brand manufacturer); see also *Foster*, 29 F.3d at 171 (“The Fosters contend that a duty exists in this case because it was foreseeable to Wyeth that misrepresentations regarding Phenergan could result in personal injury to users of Phenergan’s generic equivalents.”).

15. Compare *Foster*, 29 F.3d at 171–72, with *Conte*, 85 Cal. Rptr. 3d at 311–13.

16. *Foster*, 29 F.3d at 171–72.

17. *Id.* at 167.

18. *Id.* (“The autopsy report attributed Brandy’s death to Sudden Infant Death Syndrome (‘SIDS’).”).

19. *Id.* (“A pediatrician from the Maryland SIDS Center at the University of Maryland opined that Brandy’s death was caused by the promethazine.”).

20. *Id.*

21. *Id.* at 168.

22. *Foster*, 29 F.3d at 168.

23. *Id.* at 170 (“There is no legal precedent for using a name brand manufacturer’s statements about its own product as a basis for liability for injuries caused by other manufacturers’ products, over whose production the name brand manufacturer had no control.”).

Since the claim in *Foster* was against a name-brand manufacturer, it was unnecessary for the court to evaluate the preemption of claims against generic manufacturers; nevertheless, the *Foster* court denied in dicta the existence of any preemption defense for generic manufacturers.²⁴ In the *Foster* court's opinion, generic manufacturers, as experts, are responsible for the accuracy of their labels, and therefore are subject to the threat of liability.²⁵ The *Foster* court also found no congressional intent to preempt claims against generic manufacturers.²⁶

The *Foster* opinion has been widely adopted and endorsed by other courts taking a strong position against any possibility of holding name-brand manufacturers liable for injuries caused by their generic equivalents.²⁷ A Florida court, for example, stated: "[I]t is axiomatic that every manufacturer is responsible for harm caused by its own products, in and out of the pharmaceutical industry."²⁸ Other courts have rested similar decisions on state legislation that restricts "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the . . . warning, instruction, marketing, packaging, or labeling of any product" to a product liability action requiring that the product at issue be manufactured by the defendant.²⁹

24. *Id.* at 169.

25. *Id.* at 170.

26. *Id.*

27. *See, e.g.*, *Mensing v. Wyeth, Inc.*, Civ. No. 07-3919 (DWF/SRN), 2008 WL 4724286, at *4 (D. Minn. Oct. 30, 2008) ("The Court finds *Foster* persuasive."), *aff'd*, 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom.*, *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011) ("The Court finds *Foster* persuasive."); *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060, at *2 (D. Colo. Oct. 15, 2004) (agreeing with the reasoning in *Foster* for claims of both negligent representation and products liability); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34 (La. Ct. App. 2008) ("As noted in *Foster*, a manufacturer cannot reasonably expect that consumers will rely on the information it provides when actually ingesting another company's drug."); *see also Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 538-39 (E.D. Pa. 2006), *aff'd sub nom. Colacicco ex rel Estate of Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009) ("[W]e hold that a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug . . .").

28. *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at *4 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007) (*per curiam*). The *Sharp* court's holding was conditioned on finding "no case law, in or out of Florida, that eliminates a generic manufacturer's legal duty to its customers." *Id.*

29. *See Neal v. Teva Pharms. USA, Inc.*, No. 09-CV-1027, 2010 WL 2640170, at *2 (W.D. Ark. July 1, 2010) (quoting ARK. CODE ANN. § 16-116-102(5) (2011)); *see also, e.g., Morris v. Wyeth, Inc.*, No. 09-0854, 2009 WL 4064103, at *2-5 (W.D. La. Nov. 23, 2009) (finding that Louisiana statute requires that in product liability suit

B. Conte v. Wyeth

Despite the widespread adoption of *Foster*, a California Court of Appeal in *Conte v. Wyeth* took the opposite position and found that the common law duty of care owed by name-brand manufacturers could extend to consumers of generic drugs where reliance is shown.³⁰ In *Conte*, the plaintiff alleged that her serious, irreversible neurologic condition was the result of long-term consumption of a generic prescription drug, metoclopramide.³¹ Conte brought suit against Wyeth, the manufacturer of the name-brand equivalent of metoclopramide,³² despite never having used the name-brand product.³³ The *Conte* court first held that misrepresentation claims were not subsumed under the requirements of products liability law, meaning liability for misrepresentation is not restricted only to the manufacturer of the product at issue;³⁴ therefore, liability could exist against a party that did not manufacture the specific injury-causing product. The court next held that the duty owed by name-brand manufacturers could extend to consumers of generic drugs.³⁵

The appellate court in *Conte* did not discuss the question of preemption of claims against generic manufacturers.³⁶ Although the trial court had found that the claims against the generic manufacturer Purepac Pharmaceutical Company were preempted,³⁷ the Court of Appeals never addressed preemption because it upheld summary judgment in favor of Purepac on other grounds.³⁸ Consequently, it was able to avoid this issue.

The *Conte* decision has attracted a great deal of criticism for failing to characterize misrepresentation claims as subject to the requirements of products liability and for extending the duty of care

defendant must have manufactured the product); *Sloan v. Wyeth*, 2004 Extra Lexis 202, at *3–12 (N.J. Super Ct. Law. Div. Oct. 13, 2004) (citing the New Jersey Products Liability Act, N.J. STAT. ANN. § 2A:58C-1 (1987), as the exclusive remedy available to the plaintiffs).

30. *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299, 320-21 (Cal. Ct. App. 2008).

31. *Id.* at 304.

32. *Id.* at 305.

33. *Id.*

34. *Id.* at 309-11.

35. *Id.* at 311. *Conte* found the extension of duty sensible based on “common sense” and California’s common law. *Id.*

36. *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299, 311 (Cal. Ct. App. 2008)

37. *Conte v. Wyeth, Inc.*, No. CGC-04-437382, 2006 WL 2692469 (Cal. Super. Ct. Sept. 14, 2006), *aff’d on other grounds*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

38. *Conte*, 85 Cal. Rptr. 3d at 319–20 (affirming summary judgment for generic defendants based on plaintiff’s failure to show reliance).

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owed by name-brand manufacturers too far.³⁹ Despite this criticism,⁴⁰ *Conte* has been called “the most careful and sophisticated consideration” of the issue addressed,⁴¹ and a federal district court in Vermont has adopted the *Conte* position.⁴²

39. See, e.g., Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitors Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 684-93 (2010); James M. Beck & Mark Herrmann, *Generic Drug Pioneer Liability*, DRUG & DEVICE L. BLOG (Nov. 7, 2008, 4:10 PM), <http://druganddevicelaw.blogspot.com/2008/11/generic-drug-pioneer-liabilty.html> (predicting the potentially devastating effects of *Conte* given the lack of an “effective limitation on the scope of the [negligent misrepresentation] theory”); James M. Beck & Mark Herrmann, *More Thoughts On Conte v. Wyeth*, DRUG & DEVICE L. (Nov. 13, 2008, 4:52 PM), <http://druganddevicelaw.blogspot.com/2008/11/more-thoughts-on-conte-v-wyeth.html>; Melissa Maleske, *Brand-Name Burdens*, INSIDECOUNSEL (Feb. 1, 2009), <http://www.insidecounsel.com/2009/02/01/brandname-burdens>. Beck and Herrmann criticize *Conte* for two reasons. Beck & Herrmann, *More Thoughts On Conte v. Wyeth*, *supra*. The first is the “Lipstick On A Pig” fallacy, namely that if you put lipstick on a pig, this does not change the pig’s true identity. *Id.* Beck and Herrmann argue that the *Conte* court succumbs to this fallacy when it allows intentional/negligent misrepresentation claims to proceed against a non-manufacturer where a products liability claim would be unable to proceed. *Id.* They argue that this holding goes against the long-standing position of *Greenman v. Yuba Power* that “[t]he purpose of [products] liability is to insure [sic] that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market” *Id.* (quoting *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963)). The second concern of Beck and Herrmann is that *Conte* has expanded foreseeability too far by holding that reliance upon “another manufacturer’s warnings from much longer ago, read anywhere, trumps nonreliance [sic] on the warnings that came with the product that the doctor actually prescribed.” *Id.* They provide a hypothetical supposedly analogous to the facts of *Conte* to demonstrate their perceived absurdity of the *Conte* decision. See *id.* In their hypothetical they argue that following *Conte*’s logic of foreseeability, if a family owns two cars with identical warnings and one vehicle is crashed, the family could sue the manufacturer of the other vehicle for inadequate warnings because it would be foreseeable that the driver of the crashed vehicle relied on the other vehicle’s warnings. *Id.* Beck and Herrmann use the absurdity of this hypothetical to demonstrate their fear of *Conte*’s expansion of foreseeability. *Id.*

40. It should be noted that criticism of *Conte* is also noticeably defendant-sided, as Beck is counsel for Dechert LLP, http://www.dechert.com/james_beck/, and Herrmann was formerly a partner at Jones Day. *Above the Law, Above the Law Launches a New Column for In-House Counsel*, ABOVE THE LAW (Nov. 16, 2010), <http://abovethelaw.com/2010/11/above-the-law-launches-a-new-column-for-in-house-counsel>. Both of these firms are renowned for their defense of businesses in products liability suits. CHAMBERS & PARTNERS, CHAMBERS ASSOCIATE: THE STUDENT’S GUIDE TO LAW FIRMS 122, 194 (Cecilia Soler ed. 2011).

41. Allen Rostron, *Prescription For Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1190 (2011).

42. Kellogg v. Wyeth, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010)

II. PREEMPTION IN THE PRESCRIPTION DRUG AND DEVICE CONTEXT

Foster and *Conte*, although not expressly ruling on the issue, have different perspectives on the preemption of claims against generic manufacturers for inadequate warnings. In 2011, the Supreme Court settled this issue in *PLIVA v. Mensing* by finding these claims preempted by federal law.⁴³ This preemption decision by the Supreme Court may call into question the *Foster/Conte* dichotomy.⁴⁴

A. *Brief Overview of Preemption Doctrine*⁴⁵

Preemption is rooted in the Supremacy Clause of the Constitution, which states that “the Laws of the United States . . . shall be the supreme law of the land.”⁴⁶ Under the Supreme Court’s preemption doctrine, state laws are inapplicable where they are either expressly preempted by federal statute or where preemption is implied because either Congress has intended to occupy an entire field or a given state law “actually conflict[s] with the statute or federal standards.”⁴⁷ Conflict can exist either where compliance with both the state and federal law is “a physical impossibility,” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”⁴⁸

B. *Riegel v. Medtronic and Wyeth v. Levine: First Looks at Preemption in the Prescription Drug/Device Context*

One of the first major Supreme Court cases addressing preemption in the drug/device context was *Riegel v. Medtronic*.⁴⁹ *Riegel* questioned whether “the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars common-

43. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

44. See Rostron, *supra* note 41, at 1135 (“[I]f the Supreme Court should find that federal law preempts claims against generic drug manufacturers, the question of whether brand-name drug makers can be liable to those who took generic drugs will take on greater significance than ever before.”).

45. For a diverse array of scholarly perspectives on preemption, see generally PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM’S CORE QUESTION (William Buzbee ed., 2009).

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

47. *Geier v. Am. Honda Motor Co. Inc.*, 529 U.S. 861, 868 (2000) (citing *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (internal quotation marks omitted)).

48. Caleb Nelson, Preemption, 86 Va. L. Rev. 225, 228 (2000) (citations and internal quotation marks omitted).

49. 552 U.S. 312, 315 (2008).

law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA).⁵⁰ The Court found that common law claims were preempted under the Medical Device Amendments' express preemption clause.⁵¹

In *Riegel*, the plaintiff brought several state law products liability claims against the manufacturer of the balloon catheter that ruptured when used by his physician in an attempt to dilate his artery.⁵² The defense argued that common law claims would create requirements different from and in addition to those that were created by the FDA after the extensive approval process required for Class III medical devices, and therefore the common law claims were preempted.⁵³ The Court adopted the defense's position, citing *Medtronic, Inc. v. Lohr*⁵⁴ for the proposition that common law causes of action for strict liability and negligence do impose requirements.⁵⁵ As requirements, these common law claims were preempted under §360k(a), which forbids any state from adopting requirements different from or in addition to any requirements of federal law applicable to the medical device.⁵⁶

In a second case involving the conflict between a common law suit and FDA approval, *Wyeth v. Levine*, the Supreme Court held that common law claims against prescription drug manufacturers were not preempted.⁵⁷ From a legal standpoint, this case was identical to *Riegel* except that it involved a prescription drug instead of a medical device. However, this difference proved determinative because prescription drug legislation does not contain an express preemption clause, unlike §360k(a) in the medical device context.⁵⁸

50. *Id.*

51. *Id.* at 330 (affirming the Second Circuit's finding of express preemption).

52. *Id.* at 320. The plaintiff brought a wide range of common law claims including strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter. *Id.*

53. Brief for Respondent at 12–13, *Reigel v. Medtronic*, 552 U.S. 312 (2008), (No. 06–179), 2007 WL 3082217.

54. 518 U.S. 470 (1996).

55. *Riegel*, 552 U.S. at 323–24 (citing *Lohr*, 518 U.S. at 512).

56. *Id.* at 330.

57. 555 U.S. 555, 581 (2009) (affirming the Vermont Supreme Court's holding that state law claims were not preempted).

58. *Id.* at 574 (“[D]espite its 1976 enactment of an express preemption provision for medical devices, see § 2, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a) (2006)), Congress has not enacted such a provision for prescription drugs.”). Beyond the relevance of this difference from an express preemption standpoint, the court also took the absence of an express preemption clause into account when considering whether a state law claim would be an obstacle to Congress's purpose

In *Wyeth*, Diana Levine brought suit against Wyeth after she was stricken with gangrene following administration of the drug Phenergan by I-V push.⁵⁹ A Vermont jury had found Wyeth liable for “fail[ing] to provide an adequate warning of that risk and awarded damages to respondent Diana Levine to compensate her for the amputation of her arm.”⁶⁰ Wyeth appealed the jury verdict under the theory that Levine’s claim was preempted because Wyeth could not comply with both state and federal law when designing its warning⁶¹ and, in the alternative, that allowing a state law claim in this instance would be an obstacle to the accomplishment of Congressional objectives.⁶²

The United States Supreme Court rejected both of Wyeth’s preemption arguments and affirmed the holding of the Vermont Supreme Court.⁶³ It first denied Wyeth’s impossibility argument because, under the “changes being effected” or “CBE” regulation,⁶⁴ manufacturers of drugs may update their labels to “add or strengthen a contraindication, warning, precaution, or adverse reaction” or to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product” without waiting for FDA approval.⁶⁵ This regulation allowed Wyeth to change its label without being in violation of federal regulation as long as the change was in light of “newly acquired information.”⁶⁶ The extent of newly acquired information is not limited to new data, but also encompasses “new analyses of previously submitted data.”⁶⁷ Wyeth’s ability to unilaterally change its la-

when discussing implied preemption. *Wyeth*, 555 U.S. at 574 (“If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history.”).

59. *Id.* at 559.

60. *Id.* at 558.

61. *Id.* at 563. The impossibility claim was an attempt to apply the *Riegel v. Medtronic, Inc.* holding to prescription drugs despite the absence of an express pre-emption clause. See Brief for Petitioner at 31, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249), 2008 U.S. S. Ct. Briefs LEXIS 458, at *49 (“Similar features of FDA’s premarket approval of Class III medical devices recently led this Court to find preemption of state-law tort claims in that analogous context.”) (citing *Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008)).

62. *Wyeth*, 555 U.S. at 563–64.

63. *Id.* at 581.

64. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008).

65. *Wyeth*, 555 U.S. at 568 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A),(C) (2008)) (internal quotation marks omitted).

66. *Id.*

67. *Id.* at 569 (quoting Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603,

bels led the Court to find that it was not impossible for the company to comply with both state and federal law.⁶⁸

The Supreme Court also held that Levine's claim was not preempted as an obstacle to the accomplishment of Congressional purposes.⁶⁹ The Court rejected Wyeth's contention that approval under the Federal Food, Drug, and Cosmetic Act⁷⁰ provides both minimum and maximum standards, so liability under state common law would necessarily upset that carefully struck balance.⁷¹ In addition, the court gave weight to Congress' inclusion of a preemption clause in the medical device context, and the noticeable absence of such a provision for prescription drugs.⁷² Finally, the court rejected Wyeth's contention that the agency must be presumed to have preempted state law because of the careful balancing of the risks and benefits of a specific label.⁷³ The court rejected this argument because of the FDA's traditional view that state law claims were complementary to the FDA's own regime.⁷⁴ Overall, the court was not convinced that state law claims would obstruct the purposes of federal regulation of drugs in this instance, and therefore concluded that Levine's claim was not preempted.⁷⁵

III.

PLIVA V. MENSING: PREEMPTION IN THE GENERIC DRUG CONTEXT

A major question left unanswered by *Wyeth v. Levine* was whether state law claims would similarly be allowed to proceed against generic drug manufacturers. Although similarly subject to the approval of the FDA, generic drugs are subject to different standards⁷⁶ and are required to have the same labeling as the approved

49,604 (Aug. 22, 2008) (to be codified at 21 C.F.R. pt. 314) (internal quotation marks omitted)).

68. *Id.* at 571.

69. *Id.* at 581.

70. 21 U.S.C. §§ 301–399a (2006).

71. *Wyeth*, 555 U.S. at 573–74 (“The most glaring problem with [the floor and ceiling] argument is that all evidence of Congress’ purposes is to the contrary.”).

72. *Id.*

73. *Id.* at 575–77. This argument attempted to analogize FDA drug approval to the DOT’s regulation in *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 864–65 (2000). In *Geier*, the Supreme Court held that a state lawsuit that would require the installation of air bags was preempted by the DOT’s standard that allowed for a choice among various passive restraint devices. *Id.* at 886.

74. *Wyeth*, 555 U.S. at 580–81.

75. *Id.* at 581.

76. *See* 21 U.S.C. § 355(j) (2006).

name-brand drug.⁷⁷ *PLIVA v. Mensing* addressed the issue of preemption for generic drugs by holding that federal drug regulations preempt state-law claims against generic drug manufacturers for failure to adequately warn.⁷⁸ *PLIVA* was thought by some, including Justice Sotomayor in dissent in the case, to effectively rewrite the decision in *Wyeth v. Levine*⁷⁹ and was criticized for leaving an injured consumer's right to relief subject to the happenstance of whether the consumer was prescribed a generic or name-brand drug.⁸⁰

In *PLIVA*, plaintiffs Gladys Mensing and Julie Demahy had been prescribed the name-brand drug Reglan.⁸¹ However, as is common practice,⁸² their prescriptions were filled with Reglan's generic equivalent.⁸³ After taking the drug as prescribed for several years, both women developed tardive dyskinesia, a severe neurological disorder.⁸⁴ The plaintiffs alleged that the risk of tardive dyskine-

77. See 21 U.S.C. § 355(j)(2)(A)(v).

78. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

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

80. *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting); Erwin Chermerinsky, *A Devastating Decision*, TRIAL 55 (Sept. 2011) ("The Court's reasoning is questionable on many levels."); see also Alliance for Justice, *Worst Decision*, #6: *PLIVA v. Mensing*, JUSTICE WATCH (Sept. 23, 2011, 10:05 AM), <http://afjjusticewatch.blogspot.com/2011/09/worst-decisions-6-pliva-v-mensing.html>; Steven Berk, *Clarence Thomas, PLIVA v. Mensing, and the Plight of the Consumer*, THE CORPORATE OBSERVER (June 24, 2011, 3:23 PM), <http://www.thecorporateobserver.com/2011/06/articles/in-the-courts/clarence-thomas-pliva-v-mensing-and-the-plight-of-the-consumer> ("Clarence Thomas, once again jettisoning his longstanding principles to reach an expedient result, broadly interpreted federal preemption to cover a wider swath of claims."); Maxwell S. Kennerly, *The Most Unfair Prescription Drug And Medical Device Opinions Of 2011*, LITIGATION AND TRIAL (Jan. 3, 2012), <http://www.litigationandtrial.com/2012/01/articles/attorney/consumer-protection/the-most-unfair-prescription-drug-and-medical-device-opinions-of-2011> (arguing that *PLIVA v. Mensing* is the most unfair prescription drug decision of 2011).

81. *PLIVA*, 131 S. Ct. at 2573. Reglan is the name-brand version of the drug Metoclopramide. "Metoclopramide injection is used to relieve symptoms caused by slow stomach emptying in people who have diabetes. These symptoms include nausea, vomiting, heartburn, loss of appetite, and feeling of fullness that lasts long after meals." Metoclopramide Injection, PUBMED HEALTH (Jan 1, 2010), <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000132/>.

82. Jesse C. Vivian, *Generic-Substitution Laws*, U.S. PHARMACIST, Table 2 (June 19, 2008), <http://www.uspharmacist.com/content/s/44/c/9787> (citing eleven states and Puerto Rico with mandatory generic substitution laws and thirty-eight states as well as Guam and D.C. with permissive substitution). Only Oklahoma prohibits substitution without the authority of the purchaser or prescriber. Vivian, *supra*. Thirty-eight states, Puerto Rico, and D.C. require notification or consent for substitution. *Id.* at Table 2.

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

84. *Id.*

sia was greater than indicated on the label and therefore the generic manufacturers had failed to adequately warn of this danger.⁸⁵

The manufacturer raised a preemption defense, arguing that it could not comply with both federal regulations and any alleged state tort-law duty.⁸⁶ Its argument relied on 21 U.S.C. § 355(j)(2)(A)(v), which states that a generic manufacturer must have labeling that is the same as that of the name-brand drug.⁸⁷ It therefore argued that the generic manufacturer's exclusive responsibility is "ensuring that its warning label is the same as the brand-name's."⁸⁸

The dispute in *PLIVA* was whether and to what extent generic manufacturers may change their labels after initial approval.⁸⁹ The FDA's view was that manufacturers of generic drugs have an ongoing duty to ensure that their labeling is identical to their name-brand counterpart's.⁹⁰ As a result, the FDA denied the generic manufacturer's ability to unilaterally change its labels with the CBE process that was available to Wyeth in *Wyeth v. Levine*.⁹¹ The FDA nonetheless argued that claims against generic drug manufacturers should not be preempted. The Supreme Court deferred to the FDA's interpretation of the availability to *PLIVA* of the CBE,⁹² citing *Auer* deference.⁹³

Despite deferring to the FDA's interpretation of the CBE regulation, the Supreme Court did not adopt the FDA's position on pre-

85. *Id.*

86. *Id.*

87. *Id.* at 2574 (citing 21 U.S.C. § 355(j)(2)(A)(v) (2006)).

88. *PLIVA*, 131 S. Ct. at 2574.

89. *Id.*

90. *Id.* at 2574–75 (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950,17,961 (April 28, 1992) (to be codified at 21 C.F.R. pt. 314) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval.")).

91. *PLIVA*, 131 S. Ct. at 2575 ("The FDA argues that CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's.").

92. *Id.* The FDA and the court similarly foreclosed the availability of "dear doctor" letters to generic manufacturers, which were another way that generic manufacturers could have potentially updated their warnings. *Id.* at 2576.

93. *Id.* (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)). *Auer* deference is a strong form of deference that requires the court to follow an agency's interpretations of its own regulations unless the interpretation is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461 (internal quotations omitted).

emption.⁹⁴ The court instead found that claims against manufacturers of generic drugs were preempted because it was impossible for the manufacturer to comply with both federal regulation requiring sameness and state law requiring a label change.⁹⁵ The court found that if the manufacturers had changed their labels to comply with state law, they would have been in violation of federal law, and therefore state law must yield.⁹⁶

IV. THE RAMIFICATIONS OF *PLIVA V. MENSING*

Although *PLIVA* may encourage plaintiffs to argue that the reasoning in *Foster* should be reexamined and courts should adopt the *Conte* position, any change in the pervasive law is unlikely. Change is unlikely because *PLIVA* only affects the duties of generic manufacturers and has left the bounds and requirements of state products liability law unchanged.⁹⁷ The few courts addressing any potential change in brand-name liability following *PLIVA* have affirmed their reasons for standing by *Foster*.

A. *PLIVA Leaves the Underlying Justifications of Foster and Its Progeny Intact*

Although the presumption of the *Foster* decision that claims against generic manufacturers were available has now been rejected by the Supreme Court in *PLIVA*,⁹⁸ the decision in *Foster* would not have been different if the court had foreclosed liability to generic drug manufacturers. The discussion of generic liability was not of any significant importance to *Foster's* final holding; generic liability was discussed only after the court laid out its rejection of brand name liability. And the *Foster* court only addressed the issue of generic liability as a rebuttal to the plaintiffs' plea that they would be unable to recover if claims were disallowed against name-brand manufacturers.⁹⁹ The *Foster* court was concerned that, given the significant advantages already provided to generic drug manufacturers, the further advantage provided by allowing recovery from brand-name manufacturers by consumers of generic drugs was not

94. *PLIVA*, 131 S. Ct. at 2577–78.

95. *Id.*

96. *Id.* at 2578.

97. *See supra* Part III.

98. *See supra* Part III.

99. *Foster v. Am. Home Products Corp.*, 29 F.3d 165, 169 (4th Cir. 1994).

warranted¹⁰⁰ and was potentially inequitable.¹⁰¹ *PLIVA*'s denial of liability for a generic manufacturer's failure to warn exacerbates this market advantage; courts considering *Foster* would be unlikely to extend liability to name-brand manufacturers and worsen their market position.

Courts adopting *Foster* have held that products liability law subsumes misrepresentation claims against manufacturers of injury-causing products;¹⁰² because products liability law requires that the defendant manufactured the product at issue,¹⁰³ misrepresentation claims against brand-name manufacturers by consumers of generic prescription drugs cannot succeed. Courts have also been hesitant to expand their products liability law because of their belief that the resolution of such an issue is the responsibility of the legislature.¹⁰⁴

100. *Id.* at 170 ("There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising.")

101. *Id.* ("[Finding preemption] would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising.")

102. *See, e.g., Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008) ("I am not prepared to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims. In my view, misrepresentation claims against a manufacturer properly collapse into the failure to warn claims."); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 539 (E.D. Pa. 2006), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008), *vacated on other grounds*, 129 S. Ct. 1578 (2009) ("[U]nder Pennsylvania law, the most essential characteristic of any product liability action . . . is that the defendant manufactured or sold the product in question.") (internal quotation marks omitted).

103. *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R, 2008 WL 2677049, at *1 (W.D. Ky. June 30, 2008) ("Whatever products liability theory a plaintiff pursues, there are certain requirements that are found in all products liability cases. One such requirement is a defendant's product must have caused Plaintiff's injury to be liable under Kentucky products liability law.")

104. *Mensing v. Wyeth, Inc.*, Civil No. 07-3919 (DWF/SRN), 2008 WL 4724286, at *5 (D. Minn. Oct. 27, 2008) ("The Court is sympathetic to the fact that Plaintiff may lack a legal remedy due to the fact that she did not ingest name-brand Reglan and that her claims against the generic manufacturers are preempted by federal law. However, such sympathy does not warrant a departure from clear Minnesota law. That Plaintiff is left without a remedy is an issue for the legislature, not this Court."), *aff'd*, 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom.*, *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011); *see also Metz v. Wyeth*, No. 8:10-CV-2658-T-27AEP, 2011 WL 5826005, at *2 (M.D. Fla. Nov. 18, 2011) ("Even assuming, without deciding, that sound policy reasons exist for broadening the scope of brand name pharmaceutical manufacturers' liability in light of *Mensing*, that is a matter best addressed by the Florida Legislature or the Supreme Court of Florida.")

PLIVA leaves state products liability doctrine unaltered, so therefore *PLIVA* has not created a reason to remove misrepresentation claims from the purview and requirements of this law.

B. *PLIVA's Strengthening of Conte's Reasoning*

The best argument for a change in the legal landscape is that the holding of *PLIVA* has strengthened *Conte's* reasoning. Although the *Conte* court did not address the issue of preemption of claims against generic manufacturers, the court would have likely sided with the *PLIVA* majority. To this extent, it has been argued that the potential preemption of claims against generic drug manufacturers influenced the court's decision, since: "Judges, being human beings, don't like putting large numbers of plaintiffs entirely out of court."¹⁰⁵ By preempting claims, *PLIVA* has now expressly left consumers of generic drugs without a judicial remedy for their injuries. This suggests that although the *Conte* court did not expressly adopt the position taken in *PLIVA*, *PLIVA's* holding may in fact reinforce the position.

C. *Recent Decisions After PLIVA*

Despite *PLIVA's* reinforcement of *Conte's* logic, recent decisions have shown no change of heart and have stood with *Foster* in denying claims against name-brand manufacturers.¹⁰⁶ In *Gross v. Pfizer, Inc.*, the plaintiffs requested reconsideration of the District Court of Maryland's grant of summary judgment in favor of a name-brand manufacturer in light of the Supreme Court's decision in *PLIVA*. The district court refused the plaintiffs' request, and held that the Supreme Court's decision in *PLIVA* gave the court no rea-

105. Beck & Herrmann, *Generic Drug-Pioneer Liability*, *supra* note 39 (arguing that *Conte's* true reason for allowing claims against Wyeth was based on pressure put on the product identification requirement by preemption of claims against manufacturer's of generic drugs); *see also* Bridget M. Ahmann & Jennifer Y. Dukart, *Could Preemption Rulings for Generic Manufacturers Be Bitter Pill for Name-Brand Manufacturers?*, FAEGRE, BAKER AND DANIELS, UPDATES & EVENTS (Nov. 13, 2008), <http://www.faegrebd.com/8662> ("An aversion to the lack of remedy facing plaintiffs may explain the California Court of Appeal's decision in *Conte v. Wyeth*.").

106. *See, e.g., In re Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 3984871, at *2 (E.D. Ky. 2012); *Baymiller v. Ranbaxy Pharm., Inc.*, No. 3:11-CV-858-RCJ-VPC, 2012 WL 3929768, at *9 (D. Nev. 2012); *Phares v. Actavis-Elizabeth LLC*, No. CIV. B:11-63, 2012 WL 3779227, at *10 (S.D. Tex. 2012); *Metz*, 2011 WL 5826005, at *2-3; *Morris v. Wyeth, Inc.*, Civil Action No. 3:09-CV-854, 2011 WL 4975317, at *2 (W.D. La. Oct. 19, 2011); *Gross v. Pfizer, Inc.*, No. 10-CV-00110-AW, 2011 WL 4005266, at *2 (D. Md. 2011).

son to rethink its initial grant of summary judgment in favor of a name-brand manufacturer.¹⁰⁷ *Gross* denied that *PLIVA* had any effect on the duties of name-brand manufacturers.¹⁰⁸

Similarly, in *Metz v. Wyeth*, the District Court of Minnesota rejected the plaintiff's contention that *PLIVA* overturned *Foster's* holding.¹⁰⁹ *Metz* held that *Foster's* primary justification was "based on. . . the general rule that one manufacturer cannot be held liable on a negligent misrepresentation theory for injuries caused by another manufacturer."¹¹⁰ The court did not find any conclusions in *Foster* that had been rejected by *PLIVA*.¹¹¹

Gross and *Metz* provide the best evidence of how courts will likely address brand-name liability following *PLIVA*. Before *PLIVA*, courts following *Foster* had shown hostility towards expanding the duties of name-brand manufacturers.¹¹² Although *Foster* was decided in part based on assumptions expressly rejected by *PLIVA*,¹¹³ *Foster* was driven by an understanding of the duties of name-brand manufacturers and the definitions and requirements of products liability claims.¹¹⁴ These are the aspects of *Foster* that have been so heavily adopted and relied upon by other courts.¹¹⁵ *Gross* and *Metz*

107. *Gross v. Pfizer, Inc.*, 10-CV-00110-A W, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011) (denying plaintiff's motion for reconsideration).

108. *Id.* ("The Supreme Court's holding in [*PLIVA v.*] *Mensing* neither created nor abrogated any duty under Maryland law with regard to brand-name manufacturers . . .").

109. *Metz*, 2011 WL 5826005, at *2 ("The thrust of Plaintiffs' argument is that the Fourth Circuit's holding in the seminal case of *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir.1994), was based on the proposition (discussed in dicta) that consumers could recover from generic manufacturers for misrepresentations relating to their products. *Id.* at 170. While it is true that this proposition was rejected by the Supreme Court in *Mensing*, this proposition was by no means central to the ultimate holding in *Foster*.").

110. *Metz*, 2011 WL 5826005, at *2.

111. *Id.*

112. *See, e.g.*, *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1348 (S.D. Ala. 2010) ("The fact that federal law allowed generic manufacturers to streamline the approval process by relying on the initial warning labels provided by Wyeth and/or Schwarz, does not create a duty between Wyeth/Schwarz and a generic consumer."); *Craig v. Pfizer, Inc.*, No. 3:10-00227, 2010 WL 2649545, at *3 (W.D. La. May 26, 2010), *adopted by*, 2010 WL 2649544 (W.D. La. June 29, 2010) ("Louisiana state cases and cases interpreting Louisiana law clearly indicate that a brand name manufacturer of a drug does not owe a duty to a consumer of the generic formulation of the drug.").

113. *See supra* Part II.A.

114. *See supra* Part II.A.

115. *See, e.g.*, *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716, at *3 (S.D. W.Va. Nov. 13, 2009) (applying *Foster's* conclusions about Maryland's products liability law to analogous laws in West Virginia); *Burke v. Wyeth, Inc.*, No. G-

affirm the continued relevance of these aspects of *Foster* and will prove influential for other courts.

D. Sources of Solutions

Since courts are unlikely to independently create a remedy, changes in the law must now come from other sources if consumers of generic drugs are going to receive compensation for the harms they suffer. State legislatures could change the law and allow claims by generic consumers to be brought against name-brand manufacturers by expressly expanding the duties of name-brand manufacturers to cover consumers of generic drugs. One complication, however, is that a state-created cause of action could be preempted by federal law. Change could also come at the federal level. Federal compensation funds could be established for injured consumers of generic drugs, similar to what has been done in the vaccine context.¹¹⁶ Any attempt at reform will need to resolve the conflict between the desire to keep the price of generics low and the desire to compensate victims. Striking that balance is a decision that the courts will leave to the legislatures.¹¹⁷

CONCLUSION

A doctrinal change following *PLIVA* is unlikely because at the heart of the holding in *Foster* is a broad conception of the bounds of products liability law and a denial of a name-brand manufacturer's duty to consumers of generic drugs. Although *PLIVA* has made it more difficult for consumers of generic drugs to recover if injured due to inadequate warnings, its holding did nothing to change the bounds of products liability or expand the duties of name-brand

09-82, 2009 WL 3698480, at *3 (S.D. Tex. Oct. 29, 2009) (adopting the view of *Foster* that imposing a duty upon name-brand manufacturers is to stretch foreseeability too far).

116. For discussion of an example of a compensation fund, see discussion of the vaccine compensation system in *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073–74 (2011). See also National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 300aa-34 (2006).

117. *Mensing v. Wyeth, Inc.*, Civ. No. 07-3919 (DWF/SRN), 2008 WL 4724286, at *5 (D. Minn. Oct. 30, 2008) (“The Court is sympathetic to the fact that Plaintiff may lack a legal remedy due to the fact that she did not ingest name-brand Reglan and that her claims against the generic manufacturers are preempted by federal law. However, such sympathy does not warrant a departure from clear Minnesota law. That Plaintiff is left without a remedy is an issue for the legislature, not this Court.”), *aff'd*, 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom.*, *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011).

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manufacturers. Therefore, the basic and essential understandings relied upon by the *Foster* court have been left unchanged and will continue to be relied upon in future decisions.

