St. Mary's Law Journal

Volume 47 | Number 1 Article 6

1-1-2015

Resolving Drug Manufacturer Liability for Generic Drug Warning Label Defects.

Frank Scaglione

COMMENT

RESOLVING DRUG MANUFACTURER LIABILITY FOR GENERIC DRUG WARNING LABEL DEFECTS

FRANK SCAGLIONE*

I. INTRODUCTION

At nearly $1 trillion a year in revenue, the pharmaceutical industry is one of the largest and most cost intensive industries in the world.[1] It is

* The author wishes to express his love and appreciation for his wife, Sarah, and children, Abigail, Jacob, and Jennifer, whose sacrifices made this Comment possible. He would like to thank his parents for their constant support in helping him deal with the rigors of law school and all the editors who made this the best product possible.

1. *See* Lawrence Epperly, *Generic Drug Manufacturers,* HENRY B. TIPPIE SCH. MGMT. 1, 2 (Apr.

characterized by relatively few successful companies, high profit margins for those companies, and very long-term horizons for returns on investment.[2] The pharmaceutical industry, especially in the United States, has been responsible for dramatic improvements in standards of living over the last fifty years.[3] However, due to research and development costs, breakthrough medications may be prohibitively expensive for many Americans.[4] One reason for this is pharmaceuticals, more than any other industry, are necessarily dependent on intense regulation.[5]

The United States Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch–Waxman Act, in an effort to reduce the cost of prescription drugs by encouraging the proliferation of generic drugs.[6] One of the ways the law encourages generic drug proliferation is through the Abbreviated New Drug Application (ANDA) process, which allows generic manufacturers to bypass costly safety and effectiveness studies if they can prove their drug is identical to a previously approved drug.[7] In this regard, the law has been

---

23, 2013), http://tippie.uiowa.edu/henry/reports13/generics.pdf (reporting the global pharmaceutical industry was valued at $956 billion in 2011 with growth rates between 4%–5% in the United States and more than 10% in developing nations).

2. *See* Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVS. DRUG DISCOVERY 959, 959–61 (2009) (finding only 261 out of the 4,300 companies in the pharmaceutical industry have registered at least one new drug since 1950 and only 32 are still in existence today); Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1134 (2011) (detailing industry revenues have increased by 580% since 1990, and the average successful company produces 23% annual returns for shareholders). *But see* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 268–69 (2012) (indicating the effectiveness of pharmaceutical patents, prior to the Hatch–Waxman Act, was minimal because safety and effectiveness studies can consume up to eight years from the start of patent protection).

3. *See* Munos, *supra* note 2, at 959 (noting 1,222 new drugs have been brought to market since 1950).

4. *See* Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFF. 420, 427 (2006) (mentioning the average cost of bringing a new drug to market to be more than $800 million and disclosing a range of about $521 million to $2.12 billion).

5. *See* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1276 (10th Cir. 2013) (acknowledging under amendments to the Federal Food, Drug, and Cosmetic Act, passed in 1962, all drug manufacturers had to prove their products were safe, effective, and their labels were adequate and accurate); Morris, *supra* note 2, at 252 (explaining the FDA places heavier regulations on the pharmaceutical industry than on food, dietary supplements, or cosmetics).

6. Ann K. Wooster, Annotation, *Construction and Application of Hatch-Waxman Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994))*, 180 A.L.R. Fed. 487, 508 (2002); *see also* Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 711 (N.D. Ill. 2014) (emphasizing the 1984 amendments to the Hatch–Waxman Act were an effort to make generic drugs more widely available, safer, and inexpensive).

7. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503,

very successful, illustrated by the fact that approximately 75% of all drugs prescribed today are generic.[8] However, there are serious unintended consequences that are only now being felt.[9]

One of the most daunting unintended consequences is the confusion regarding how to affix liability for warning label defects when a generic drug harms the plaintiff.[10] The majority view is generic drug consumers cannot maintain a claim against brand-name manufacturers for harm caused by its generic equivalent.[11] This view is informed by the doctrines of foreseeability,[12] intent of communication,[13] and public policy.[14]

510–11 (2009) (estimating the average cost of bringing a generic drug to market to be around $2 million compared to $800 million for brand-name drugs); *see also* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169 (4th Cir. 1994) (providing background information on the ANDA process and its benefits to generic manufacturers).

8. Wesley E. Weeks, Comment, *Picking up the Tab for Your Competitors: Innovator Liability After* PLIVA, Inc. v. Mensing, 19 GEO. MASON L. REV. 1257, 1257 (2012) (citing PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2584 (2011) (Sotomayor, J., dissenting) (tracing the effects of the Hatch-Waxman Amendments on market shares since the use of generic drugs rose from 19% in 1984 to approximately 75% in 2009).

9. *See* Morris, *supra* note 2, at 247 (arguing although the act was very successful in reducing the cost of drugs currently available, it failed in its second objective of preserving brand-name pharmaceuticals' incentive to pioneer new drugs); Weeks, *supra* note 8, at 1259 (advocating brand-name manufacturers should be held liable for generic warning label defects because of their sole ability to change the labels, but recognizing this outcome is not ideal because it will provide negative incentives for pioneer manufacturers to leave the marketplace).

10. *See* Kelso L. Anderson, *Who's to Blame When Generic Drugs Harm Patients?*, 39 LITIG. NEWS, Summer 2014, at 12, 13 ("*Dolin* exemplifies the unsettled tension between product liability and tort actions against brand-name manufacturers for injuries caused by generic versions of their products.").

11. *See* Guarino v. Wyeth, LLC, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."). *But see* Germain v. Teva Pharms., USA, Inc. (*In re* Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.), 756 F.3d 917, 938–39 (6th Cir. 2014) ("A minority of courts have held the opposite, first finding generic consumers' common law claims distinct from product liability claims and then concluding that brand manufacturers owe a duty to avoid causing injury to generic consumers that can give rise to liability.").

12. *See* Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009) (agreeing with the Fourth Circuit to conclude that holding brand-name manufacturers liable would stretch foreseeability too far), *rev'd sub nom.* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

13. *See* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1285 (10th Cir. 2013) (reasoning since brand-name manufacturers do not intend to communicate with the customers of their competition, their warnings and representations do not create a basis for liability to generic drug customers); *Mensing*, 588 F.3d at 613 n.9 (holding a generic drug consumer could not maintain a fraud claim against a brand-name manufacturer because the brand-name manufacturer never intended any communication with the generic consumer).

14. *See Schrock*, 727 F.3d at 1285 (listing the doctrines that form the majority view); *see also* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994) (discussing expenses incurred by brand-name manufacturers when developing pioneer drugs, which are almost completely avoided by

These doctrines are judicially sound, but leave those harmed by generic drugs in a precarious position because generic manufacturers can escape liability as they have no control over the product or the warning label.[15] In response, courts have begun imposing liability on those who do have control over the drugs and warning labels: brand-name manufacturers.[16]

This Comment analyzes the negative effects the emerging minority view will have on innovation and sets forth a common sense and judicially sound solution that balances society's need to keep drug costs low with an individual's right to justice when harmed by generic drugs. This Comment also outlines the background of how this impasse in the law developed, examines the economic and social consequences of the new approach in tort law, and discusses how the problem can be fixed by altering the Hatch–Waxman Act to allow generic manufacturers control over their labeling and creating express federal preemption over state tort laws.

II. BACKGROUND

A. *Hatch–Waxman and Public Policy*

The Hatch–Waxman Act was passed in 1984 as a response to the ever-increasing prices of therapeutic drugs.[17] It had two seemingly disparate objectives: lowering costs by reducing barriers to entry for generic manufacturers and preserving brand-name manufacturers' incentives to

generic manufacturers).

15. *See* Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 580 (6th Cir. 2013) (explaining the doctrine of impossibility prevented failure-to-warn suits from going forward against generic manufacturers because it is impossible for them to comply with state tort duties to adequately warn and simultaneously meet their federal duty of label sameness); *see also* Rostron, *supra* note 2, at 1126 (clarifying how courts have routinely declined to hold brand-name manufacturers liable for injuries caused to generic drug consumers).

16. *See generally* Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014) (holding a duty of care extends to remote and unknown people under Illinois law); Kellogg v. Wyeth, Inc., 762 F. Supp. 2d 694, 705–06 (D. Vt. 2010) (finding a brand-name manufacturer liable for harm caused by its generic counterpart because expert testimony revealed doctors routinely rely on brand-name product information when prescribing generics); Wyeth, Inc. v. Weeks, 159 So. 3d 649, 676 (Ala. 2014) (stating a brand-name manufacturer may be liable for fraud or misrepresentation based on statements related to the manufacture of a brand-name drug when a consumer is injured by the generic version of that drug); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 320–21 (Cal. Ct. App. 2008) (extending the common law duty of care to brand-name manufacturers when consumers are harmed by generic counterparts).

17. *See Dolin*, 62 F. Supp. 3d at 711 ("In 1984, in an effort to make generic versions of name-brand drugs more widely, safely, and inexpensively available, Congress passed the Drug Price Competition and Patent Term Restoration Act, also commonly known as the Hatch-Waxman Act."); *Schrock*, 727 F.3d at 1276 (explaining the intention of the act was to decrease the time it took to get generic drugs to market by eliminating pre-market testing).

pioneer new drugs.[18] The Act did this by creating an expedited approval process, ANDA, for generic manufacturers seeking to enter the market once the brand-name manufacturer's patent expired.[19] The ANDA process can save a generic manufacturer more than eight years and hundreds of millions of dollars in costly safety and effectiveness studies and allow a generic manufacturer to begin marketing its drug the moment the brand-name patent expires.[20]

However, under this process, the generic drug's design and warning label must match that of the brand-name drug exactly.[21] The Supreme Court explained the extent to which a generic drug must be similar to a brand-name drug in *Mutual Pharmaceutical Co. v. Bartlett*.[22] The two drugs must be chemically similar, bio-equivalent, and have the same label.[23] The reflection of the different manufacturers is the only difference allowed on their labels.[24] These labeling and bio-equivalency requirements should not be construed to mean the brand-name drug and its generic counterparts are identical copies of each other. The FDA allows generic manufacturers to use different inactive ingredients in their versions, which can

18. *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 389 (1999) (describing the Hatch–Waxman Act of 1984 as "an unprecedented attempt to achieve two seemingly contradictory objectives"); *see also* Morris, *supra* note 2, at 247 (explaining the Hatch–Waxman Act was intended to balance two separate and opposing tasks: to reduce costs by facilitating increased market entry of cheaper generic substitutes of brand-name drugs, without compromising brand-name manufacturers' incentives to continue developing new drugs).

19. *See Foster*, 29 F.3d at 169 (offering information on the ANDA process and its benefits to generic manufacturers); *Dolin*, 62 F. Supp. 3d at 711 (providing background on the Hatch–Waxman Act).

20. *See* Rostron, *supra* note 2, at 1130 (mentioning the average time from when a brand-name manufacturer initially synthesizes a drug to when it obtains FDA approval is about eight and one-half years); *see also* Adams & Brantner, *supra* note 4, at 427 (finding the range of development costs to be between $521 million and $2.12 billion); Roin, *supra* note 2, at 510–11 (estimating the average cost of bringing a generic drug to market to be around $2 million compared to $800 million for brand-name drugs).

21. *See Dolin*, 62 F. Supp. 3d at 711 (stipulating the design and labels of a generic drug must match its brand-name counterpart exactly). *But see* Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1843 (2013) (noting FDA requirements allow generic manufacturers to use different release mechanisms, binders, and preservatives).

22. Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2471 (2013).

23. *Id.* (defining chemically similar to mean having the same "'active ingredients,' 'route of administration,' 'dosage form,' and 'strength' as its brand-name counterpart" and bioequivalent to mean having "the same 'rate and extent of absorption'" (citation omitted)).

24. 21 U.S.C. § 355(j)(2)(v) (2012); *see also* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1277 (10th Cir. 2013) (asserting a generic manufacturer may lose approval for its drug if its label ceases to be consistent with its brand-name counterpart).

occasionally lead to different patient reactions to the different versions of the drug.[25]

Once a generic drug is approved, the manufacturer may not make any changes to the warning label.[26] This creates very different duties with regard to product liability.[27] A brand-name manufacturer is responsible for the accuracy and adequacy of its label.[28] A generic manufacturer, on the other hand, is only responsible for ensuring its warning label is identical to the brand-name label.[29]

In light of these very different duties, courts have traditionally refused to apply liability to brand-name manufacturers for the defects of a generic version of the brand-name product.[30] The Fourth Circuit articulated the policy reasons behind this jurisprudence in *Foster v. American Home Products Corp.*[31] by stating it would be unfair to allow a generic manufacturer to reap the benefits of copying brand-name drugs and labels in light of all the expenses brand-name manufacturers incurred from developing, studying, and advertising the drugs.[32]

---

25. *See* Schwartz et al., *supra* note 21, at 1843 (explaining the subtle differences in brand-name and generic drugs the FDA permits).

26. *See* 21 C.F.R. § 314.150(b)(10) (2015) (providing the approval for a generic drug may be rescinded if the generic label described in ANDA ceases to be consistent with the reference brand-name drug).

27. *See* Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 711 (N.D. Ill. 2014) (finding generic manufacturers, but not brand-name manufacturers, are prohibited from making unilateral changes to a drug's warning label); *see also* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169 (4th Cir. 1994) (recognizing generic manufacturers can avoid costly safety and effectiveness studies as long as they can prove their product is legally identical to the brand-name reference drug).

28. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2011) (identifying as soon as there is reasonable evidence showing a drug contains a serious hazard, its labeling must be revised to include a warning); Schwartz et al., *supra* note 21, at 1844–45 (indicating brand-name manufacturers must conduct post-market research to verify the safety of its product even after the patent expires and generic manufacturers may rely solely on the brand-name manufacturer's research).

29. *See PLIVA*, 131 S. Ct. at 2574 (comparing the responsibilities of brand-name manufacturers with generic manufacturers under 21 U.S.C. § 355). *But see id.* (Sotomayor, J., dissenting) (arguing even though it was very difficult for generic manufacturers to provide new labeling information, there was a process whereby they could petition the FDA for a label change).

30. *See* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1286 (10th Cir. 2013) (recognizing the application of liability against brand-name manufacturers for harm caused by generic drugs runs counter to dozens of rulings from state and federal courts); Levine v. Wyeth, Inc., 684 F. Supp. 2d 1338, 1344 (M.D. Fla. 2010) (holding *Conte* runs against the overwhelming majority of case law and under Florida law, a court cannot impose liability on brand-name manufacturers).

31. Foster v. Am. Home Prods. Corp., 29 F.3d 165 (4th Cir. 1994) (holding, under Maryland law, a brand-name manufacturer does not owe a duty of care in its representations to users of a generic equivalent of a drug).

32. *See id.* at 170 (explaining how generic manufacturers benefit from the brand-name manufacturer's development, research and advertising by copying its labels).

While multibillion-dollar drug corporations may not be the most sympathetic defendants, they do undertake the vast majority of expenses in developing pioneer drugs.[33] They perform the studies necessary to obtain FDA approval and formulate labeling information.[34] Generic manufacturers avoid nearly all of these expenses by duplicating pioneer drugs and their labels.[35] Brand-name advertising also benefits generic competitors because generics are usually sold as substitutes for brand-name drugs, so the more a brand-name drug is prescribed, the more likely sales will increase for generic equivalents.[36]

The Fourth Circuit pointed out: "There is no legal precedent for using a name brand manufacturer's statements [or omissions] about its own product as a basis for liability for injuries caused by . . . [generic] manufacturers' products, over whose production the name brand manufacturer had no control."[37] The Fourth Circuit went on to explain this disparity in expenses "would be especially unfair when . . . 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."[38]

B. *Case Law—A Catch-22*

The prohibition on generic manufacturers altering their warning labels created tension between federal regulations and state tort laws.[39] Two

33. *See* Adams & Brantner, *supra* note 4, at 427 (determining the average cost of bringing a new drug to market).

34. *See* Schwartz et al., *supra* note 21, at 1844–45 (acknowledging the FDA requires brand-name manufacturers to conduct significant post-market analysis of reports and scientific literature to verify the safety of its product even after the patent expires, whereas generic manufacturers are not held to similarly rigorous standards).

35. *See Foster*, 29 F.3d at 169 (discussing the ANDA process allows generic manufacturers to bypass safety and effectiveness studies if they can show their drug and warning label are identical to the brand-name counterpart). *But see* Schwartz et al., *supra* note 21, at 1843 (claiming FDA requirements allow generic manufacturers to use different release mechanisms, binders, and preservatives).

36. *See* Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 316–17 (2000) (indicating all states have replaced anti-substitution laws with laws authorizing pharmacists to substitute generic equivalents unless the physician explicitly required the prescription to be dispensed as written, and managed care plans, such as Medicaid, encourage generic substitution for off-patent drugs).

37. *Foster*, 29 F.3d at 170; *accord* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1285 (10th Cir. 2013) (quoting *Foster* extensively and explaining there is no legal precedent for holding any manufacturer liable for the products of another manufacturer); Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009) (agreeing with *Foster*).

38. *Foster*, 29 F.3d at 170.

39. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011) (finding it impossible to reconcile

seminal U.S. Supreme Court cases on the issue, *Wyeth v. Levine*[40] and *PLIVA, Inc. v. Mensing*,[41] are at the heart of the confusion.[42]

In *Levine*, the Court held a brand-name manufacturer was liable for the amputation of the forearm of a woman who was administered Phenergan.[43] She developed gangrene after the medicine was administered through an "IV-push method" instead of the safer, more common intravenous method.[44] Justice Stevens delivered the opinion of the Court, which held Wyeth, a brand-name manufacturer of Phenergan, liable for failing to change the product's warning label despite having knowledge of the potential for gangrene.[45] The Court held Wyeth could not rely on the defense of federal preemption against Levine's state tort claim because it was not impossible for Wyeth to comply simultaneously with both its state duty to inform and federal labeling requirements.[46]

The tension in case law boiled over two years later in *PLIVA*, when the Court held the Supremacy Clause of the Constitution prevented the plaintiffs from suing generic manufacturers for warning label defects

---

federal regulations and state product liability claims); Anderson, *supra* note 10, at 12 (describing *Dolin* as exemplifying the tensions between product liability law and tort law when brand-name manufacturers are sued for injuries caused by generic copycats).

40. Wyeth v. Levine, 555 U.S. 555 (2009).

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

42. *See id.* at 2581 (acknowledging from the consumer's point of view it makes little sense that federal preemption applies in cases against generic manufacturers and does not apply in cases against brand-name manufacturers).

43. *See Levine*, 555 U.S. at 563–64 (rejecting the defendant's two arguments that it was first, impossible to simultaneously comply with state duties to warn and federal labeling requirements, and second, holding manufacturers liable under both state and federal laws violated the purpose and objective of the applicable federal legislation).

44. The IV-push method involves injecting medication directly into the vein of the patient. *Id.* at 559–60. In contrast, the more common IV-drip method involves slowly dissolving the medication into a saline solution that is delivered into the patient's vein through a catheter. *Id.* Phenergan is highly corrosive to arteries and will cause irreversible gangrene upon contact. *Id.* The IV-push method is considered extremely dangerous for administering Phenergan because it increases the chances the drug will come into contact with the arterial walls through a process known as perivascular extravasation, where the drug seeps out of the vein into the surrounding tissue. *Id.*

45. Phenergan's label actually did contain a warning against administering the drug intravenously, but was found by the jury to be insufficient because it did not contain a warning against the IV-push method specifically. *Id.* at 561–63. Additionally, the record indicated that at least twenty similar amputations occurred since the 1960's. *Id.*

46. *See id.* at 568–69 ("Wyeth could have revised Phenergan's label even in accordance with the amended regulation."). Wyeth's preemption argument was premised on seventeen years of correspondence with the FDA, whereby it proposed changes to its warning label but was told by the FDA, in 1996, to retain the current verbiage that did not include information about the dangers associated with the IV-push method. *Id.* at 562. However, the trial judge instructed the jury, without objection, that they may consider that drug manufacturers are able to change their warning labels without FDA approval. *Id.* at 561–62.

because a generic manufacturer can comply only with its duties under state law by violating federal law.[47] In doing this, the Court upended the judgments of the Fifth and Eighth Circuits when it combined and reversed two cases that rejected the federal preemption argument advanced by drug manufacturers.[48]

In *PLIVA*, the FDA filed an amicus brief arguing if a generic manufacturer made changes unilaterally to strengthen its warning label, it "would violate the statutes and regulations requiring [its] label to match its brand-name counterpart's."[49] The Court recognized the law could be interpreted to allow generic manufacturers the freedom to strengthen their labels, but the FDA's interpretation must control because it was not "plainly erroneous or inconsistent with the regulations."[50] The Court acknowledged its decision essentially left consumers harmed by generic drugs without legal remedies and placed the onus on Congress to straighten out the conundrum created by Hatch–Waxman.[51]

State courts responded to the new judgment-proof position of generic manufacturers by finding vicarious liability for brand-name manufacturers.[52] California courts pioneered this approach[53] and initially

47. *See PLIVA*, 131 S. Ct. at 2581 (acknowledging it is unfortunate federal drug regulations left plaintiffs' and others similarly situated without legal recourse for their injuries); *see also* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344, 347–48 (2001) (holding federal drug and medical device laws preempted a state tort law claim based on a failure to properly communicate with the FDA).

48. *See PLIVA*, 131 S. Ct. at 2574–75 (upholding federal laws requiring generic manufacturers to maintain identical labels with brand-name manufacturers, thus preempting state tort claims); *see also* Demahy v. Actavis, Inc., 593 F.3d 428, 449 (5th Cir. 2010) (rejecting preemption because it would leave a generic drug consumer without legal recourse), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567; Mensing v. Wyeth, Inc., 588 F.3d 603, 614 (8th Cir. 2009) (reversing judgment in favor of generic manufacturers), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567.

49. *PLIVA*, 131 S. Ct. at 2575 (citation omitted).

50. *See id.* (quoting Auer v. Robbins, 519 U.S. 452, 461 (1997)).

51. *See PLIVA*, 131 S. Ct. at 2581–82 ("We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated. But 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" (quoting Cuomo v. Clearing House Ass'n., 557 U.S. 519, 556 (2009) (Thomas, J., concurring in part and dissenting in part))).

52. *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 320–21 (Cal. Ct. App. 2008) (extending the common law duty of a brand-name manufacturer "to use due care in formulating its product warnings . . . to patients whose doctors foreseeably rely on its product information when prescribing" a generic equivalent); *see also* Wyeth, Inc. v. Weeks, 159 So. 3d 649, 677 (Ala. 2014) ("[I]t is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce . . . when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer.").

53. *See Conte*, 85 Cal. Rptr. 3d at 320–21 (holding Wyeth could be liable under a theory of negligent misrepresentation for harm caused from the use of the generic drug).

faced severe criticism.[54] A popular response was to emphasize how many other courts previously rejected the California approach for common sense policy reasons.[55]

However, the California trend is catching on, with some praise from the academic community.[56] Unfortunately, advocates of holding brand-name manufacturers liable for generic warning label defects mischaracterize the rationale of the majority rule as an argument in equity rather than in law.[57] For example, one article describes courts' use of the majority rule as "based more on a perception that innovator liability is unfair or wrong than on a judgment of the legal merits of its underlying rationale," and innovator liability as "simply an application of straightforward negligence doctrine in a particularized context."[58] This simply is not true in jurisdictions that adhere to the majority rule.[59] Jurisdictions that follow the majority rule often reject the idea of holding brand-name manufacturers liable for generic defects specifically because their laws prevent inferring a duty of care without some direct relationship.[60]

54. *See* Meade v. Parsley, No. 2:09-cv-00388, 2009 WL 3806716, at *3 (S.D. W. Va. Nov. 13, 2009) (finding *Conte*'s negligent misrepresentation theory unavailable in West Virginia despite identical facts); *see also* Burke v. Wyeth, Inc., No. G-09-82, 2009 WL 3698480, at *3 (S.D. Tex. Oct. 29, 2009) (characterizing *Conte* as an anomaly and declining to follow it because doing so would violate the application of foreseeability); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1267 (W.D. Okla. 2009) (arguing to follow *Conte*'s reasoning "would 'extend the concept of duty beyond reason and good sense' as a matter of public policy" (quoting Rose v. Sapulpa Rural Water Co., 631 P.2d 752, 757 (Okla. 1981))).

55. *See Burke*, 2009 WL 3698480, at *2–3 (listing fifteen previous decisions that rejected placing liability on brand-name manufacturers); *Schrock*, 601 F. Supp. 2d at 1267 (noting twenty-four other courts rejected *Conte*'s reasoning).

56. *See* Rostron, *supra* note 2, at 1127 (describing *Conte* as the first case where a court got warning label liability right, despite its initial criticism); Weeks, *supra* note 8, at 1291 (advocating that, though not ideal, holding brand-name manufacturers liable for generic warning label defects is the fairest course of action).

57. *See* Weeks, *supra* note 8, at 1273 (arguing the emphasis placed on fairness between brand-name and generic manufacturers distracts courts from ruling in accordance with traditional negligence standards).

58. *Id.*

59. In fact, it is the emerging minority view that is at odds with the law in most states. *See Schrock*, 727 F.3d at 1285 (articulating the first of three rationales used by majority jurisdictions is that traditional common law negligence principles permit manufacturers to be held liable only for products they create); *see also Meade*, 2009 WL 3806716, at *3 (stating West Virginia's product liability law follows *Foster*, meaning a plaintiff is only permitted recovery when the plaintiff proves the drug was flawed when it left the manufacturer and proximately caused the injury); Huck v. Wyeth, Inc., 850 N.W.2d 353, 356 (Iowa 2014) (declining to overrule the long standing products liability law that prevents brand-name manufacturers from being held liable for injuries caused by their generic competitors).

60. *See* Guarino v. Wyeth, LLC, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus . . . is that a brand-name manufacturers cannot be liable for injuries caused by the

Moreover, the article belies the fact that innovator liability under the minority rule is truly the creature of equity when, in response to the notion that innovator liability is unfair because brand-name manufacturers lose business, rather than profit from generic competition, it rhetorically asks: "But why should profit matter?"[61] Profits matter because public policy encourages innovation, and without profits, innovation does not exist.[62]

Most recently, the Seventh Circuit weighed in on the debate by denying mandamus after the U.S. District Court for the Northern District of Illinois held the estate of a man, who ultimately committed suicide after taking a generic drug, could sue the brand-name manufacturer based on the latter's duty of care to the plaintiff.[63] The district court's holding was based partly on the Supreme Court's decision in *Levine* that federal preemption could not protect brand-name manufacturers.[64] In *Levine*, the Court refused to extend to brand-name manufacturers the federal preemption protections over state tort claims enjoyed by generic manufacturers through the Hatch–Waxman Act because Congress never expressly authorized preemption.[65] The Northern District of Illinois in *Dolin v. SmithKline Beecham Corp.*[66] combined the Supreme Court's refusal

ingestion of [its generic counterpart]."); Bell v. Pfizer, Inc., 716 F.3d 1087, 1093 (8th Cir. 2013) (interpreting Arkansas law to state a defendant manufacturer cannot be held liable unless the plaintiff actually used the product it produces); Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 183 (5th Cir. 2012) (per curiam) (explaining under Louisiana law, the plaintiffs' claims failed because they did not consume the product produced by the defendant).

61. *See* Weeks, *supra* note 8, at 1288 (opining the ultimate question of fairness should be irrelevant to the determination of a manufacturer's liability).

62. *See* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994) (listing the expenses in development, research, and promotion undertaken by brand-name manufacturers as public policy reasons to not hold them liable); Morris, *supra* note 2, at 247 (indicating the Hatch–Waxman Act was intended to increase the market entry of generic substitutes of brand-name drugs while also incentivizing brand-name manufacturers to continue developing new drugs); *see also* Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 306 (2008) (illustrating when demand is highly elastic, producers may simply forego innovation if they are not "able to pass enough of the extra cost to consumers").

63. *See In re* GlaxoSmithKline, LLC, 557 F. App'x 578, 579 (7th Cir. 2014) (denying GlaxoSmithKline's writ of mandamus because the district court had not "abuse[d] its power by taking one view, rather than another, of a debatable legal issue"); Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014) (holding it was foreseeable SmithKline's design and label could harm a consumer through a generic counterpart and therefore owes a duty of care to generic consumers).

64. *See* Wyeth v. Levine, 555 U.S. 555, 581 (2009) (finding preemption protections under Hatch–Waxman do not extend to brand-name manufacturers because Congress has repeatedly chosen not to expressly preempt state law for brand-name manufacturers).

65. *See id.* ("Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight.").

66. Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705 (N.D. Ill. 2014).

to allow federal preemption for brand-name manufacturers with the assumption that under Illinois' drug substitution laws, GlaxoSmithKline would have intended all consumers, even generic drug consumers, to believe the specific chemical at issue was safe to create the latest incarnation of this minority view.[67]

However, despite recent developments in state courts and the Northern District of Illinois' holding in *Dolin*, most jurisdictions continue to maintain the majority rule.[68] Eleven federal courts have criticized *Conte v. Wyeth*.[69] Additionally, the Sixth Circuit conducted an *Erie*[70] analysis of twenty-two states and determined under the laws of every state examined, courts would reject the emerging minority rule.[71] Currently, six federal

67. *Id.* at 719 (holding GlaxoSmithKline's interest in the general public's acceptance of paroxetine as a safe chemical was sufficient to overcome the argument that it did not intend to communicate with consumers of generic substitutes).

68. *See* Germain v. Teva Pharms., USA, Inc. (*In re* Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.), 756 F.3d 917, 939 (6th Cir. 2014) (concluding under Kentucky and Tennessee laws, generic drug consumers could not maintain an action against brand-name manufacturers).

69. Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 304–05 (Cal. Ct. App. 2008) (holding "the common law duty [of] care owed by a name-brand prescription drug manufacturer when providing product warnings extends . . . to those [patients] whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug"). However, many courts have disagreed with *Conte*. *See Germain*, 756 F.3d at 939 (finding every federal court of appeals to address the issue has refused to apply liability to brand-name manufacturers); Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011) (explicitly rejecting *Conte*); Buch v. Xanodyne Pharm., Inc. (*In re* Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.), No. 2: 11-324-DCR, 2013 WL 663575, at *30 (E.D. Ky. Feb. 22, 2013) (noting *Conte* as a departure from accepted case law); Baymiller v. Ranbaxy Pharms., Inc., 894 F. Supp. 2d 1302, 1310 (D. Nev. 2012) (holding, under Nevada law, manufacturers cannot be held liable for products they did not sell); Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114, 1121 (D. Or. 2012) (proclaiming, under Oregon law, manufacturers are only liable for their own products' defects), *appeal docketed*, No. 15-35096 (9th Cir. Jan. 30, 2015); Gross v. Pfizer, Inc., No. 10-CV-00110-AW, 2010 WL 4485774, at *3 (D. Md. Nov. 9, 2010) (refusing to rely on *Conte* because it is at odds with the majority of case law); Levine v. Wyeth, Inc., 684 F. Supp. 2d 1338, 1344 (M.D. Fla. 2010) (ruling *Conte* ran counter to Florida case law); Meade v. Parsley, No. 2:09-cv-00388, 2009 WL 3806716, at *3 (S.D. W. Va. Nov. 13, 2009) (deeming *Conte*'s negligent misrepresentation theory was not recognized in that jurisdiction); Hardy v. Wyeth, Inc., No. 9:09CV152, 2010 WL 1049588, at *4 (E.D. Tex. Mar. 8, 2010) (following Burke v. Wyeth), *report and recommendation adopted*, No. 9:09-CV-152, 2010 WL 1222183 (E.D. Tex. Mar. 29, 2010); Burke v. Wyeth, Inc., No. G-09-82, 2009 WL 3698480, at *2–3 (S.D. Tex. Oct. 29, 2009) (finding *Conte*'s duty of care based on foreseeability does not comport with Texas law); Moretti v. Wyeth, Inc., No. 2:08-cv-00396-JCM-(GWF), 2009 WL 749532, at *4 (D. Nev. Mar. 20, 2009) (observing *Conte*'s foreseeability analysis is contrary to Nevada law).

70. *See generally* Erie R.R. v. Tompkins, 304 U.S. 64, 78 (1938) (establishing where federal law is silent, federal courts sitting in diversity should apply the laws of the state).

71. *See Germain*, 756 F.3d at 939 (identifying Arkansas, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Washington, and West Virginia would not recognize misrepresentation claims against brand-name manufacturers under their

courts have chosen to follow California's lead in *Conte* and hold brand-name manufacturers liable under various duty to warn theories.[72]

The judicial confusion on this issue is illustrated by the fact that two federal courts analyzed Illinois law and came to opposite conclusions on how the state would handle this issue.[73] In *Dolin*, the Northern District of Illinois held that under Illinois law, a duty to warn extends to "remote and unknown persons" and does not require privity of contract or interest.[74] However, in *Germain v. Teva Pharmaceuticals*,[75] the Sixth Circuit held Illinois law requires a plaintiff to identify the manufacturer and establish causation between the product and the injury.[76]

C. *Changes Being Effected*

It is possible for drug companies to change the warning labels of their products after development through the Changes Being Effected (CBE) process. The U.S. Supreme Court described this process in *PLIVA*.[77] The CBE process provides a way for "drug manufacturers to 'add or

---

respective state laws). *But see Dolin*, 62 F. Supp. 3d at 714 (declaring a brand-name manufacturer owed a duty to warn generic consumers under Illinois law).

72. *See* Sanchez v. Boston Sci. Corp., 38 F. Supp. 3d 727, 734 (S.D. W. Va. 2014) (recognizing a plaintiff can prevail under the learned intermediary doctrine if the plaintiff can show the prescribing physician would have acted differently with adequate warnings from the brand-name manufacturer); Niebuhr v. Xanodyne Pharm., Inc. (*In re* Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.), No. 2:11-md-2226-DCR, 2012 WL 3842271, at *5–6 (E.D. Ky. Sept. 5, 2012) (relying on *Conte* when applying California law); *see also* Rosa v. Taser Int'l., Inc., 684 F.3d 941, 946 (9th Cir. 2012) (following *Conte*'s holding and stating brand-name manufacturers can be held liable if defects are "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution" (quoting *Conte*, 85 Cal. Rptr. 3d at 310, 315)); Thomas v. Abbott Labs., No. CV-12-07005-MWF (CWX), 2014 WL 4197494, at *6–7 (C.D. Cal. July 29, 2014) (applying *Conte*'s use of the learned intermediary doctrine); Catanho v. United States, No. CV 06-2496 CAS (JTLx), 2009 WL 1160256, at *9 (C.D. Cal. Apr. 28, 2009), *aff'd sub nom.* Estate of Cerros v. United States, 401 F. App'x 284 (9th Cir. 2010) (maintaining *Conte*'s use of California law, which states that everyone has a duty of care in preventing injuries to others that would result from their conduct).

73. *Compare Dolin*, 62 F. Supp. 3d at 714 (establishing a duty to warn does not require privity of contract or interest, but under Illinois law extends to remote and unknown individuals), *with Germain*, 756 F.3d at 944 ("Under Illinois law, a plaintiff must 'identify the supplier of the product and establish a causal connection between the injury and the product.'" (quoting York v. Lunkes, 545 N.E.2d 478, 480 (Ill. App. Ct. 1989))).

74. *See Dolin*, 62 F. Supp. 3d at 714 (finding a duty to warn does not require privity of contract or interest).

75. Germain v. Teva Pharms., USA, Inc. (*In re* Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.), 756 F.3d 917 (6th Cir. 2014).

76. *See id.* at 944 (holding, under Illinois law, a plaintiff must identify the manufacturer and establish a causal connection between the injury and the product).

77. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575 (2011) (examining the CBE process).

strengthen a contraindication, warning, [or] precaution' . . . or to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.'"[78] Drug manufacturers do not need to wait for approval by the FDA when making label changes using the CBE process.[79] They are only required to file, simultaneously, a supplemental application with the FDA.[80]

Unfortunately, only brand-name manufacturers are able to take advantage of this process because Hatch–Waxman requires generic manufacturers to maintain identical labels.[81] The different responsibilities created by the CBE process have led to vastly different treatments of brand-name and generic manufacturers with regard to preemption analysis of a manufacturer's duty to warn.[82]

The application of preemption to insulate generic manufacturers from all duty to warn claims may be premature because the FDA does charge generic manufacturers with a duty to monitor the safety of their products and submit any new safety information to the FDA for consideration.[83] Unfortunately, this process is circuitous and may take a great deal more time for the new information to get from the generic manufacturers to doctors and consumers than it would under the process used by brand-name manufacturers.[84] Whereas the CBE process allows a brand-name manufacturer to unilaterally change its label as soon as it deems necessary, a label change initiated by a generic manufacturer may take as long as a year before the FDA considers the change.[85]

---

78. *Id.* (citations omitted).

79. *See id.* (recognizing an essential step to changing a label).

80. *See id.* (outlining the procedure for bypassing FDA approval using the CBE process).

81. *See id.* (noting the current FDA interpretation of CBE regulations allows changes to generic drug labeling only when a generic manufacturer must change its label to conform with an update by a brand-name manufacturer or comply with FDA instructions).

82. *See* Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 582–83 (6th Cir. 2013) (explaining how federal law preempts state tort claims against generic manufacturers under the impossibility doctrine because generic manufacturers cannot change their labels without violating federal law and noting how the impossibility doctrine does not apply to brand-name manufacturers because they can make unilateral changes to their labels). *Compare* Wyeth v. Levine, 555 U.S. 555, 573 (2009) (rejecting a brand-name manufacturer's claim of preemption under the impossibility doctrine), *with PLIVA*, 131 S. Ct. at 2575 (acknowledging a generic manufacturer's duty of sameness triggers the impossibility doctrine because it cannot unilaterally change its label without violating federal law).

83. *See PLIVA*, 131 S. Ct. at 2585 (Sotomayor, J., dissenting) (arguing the FDA construes federal regulations as requiring generic manufacturers to keep the FDA apprised of any new safety information).

84. *See id.* at 2587 (explaining generic manufacturers can effect a change to their labels by informing the FDA of a need for a label change, who will in turn decide if the brand-name label should be changed, thus requiring the generic label to change as well).

85. *See* 21 C.F.R. § 314.81(b)(2)(i) (2015) (mandating a generic manufacturer must present to

A simpler process would be to allow generic manufacturers to strengthen their labels for good cause.[86] If a generic manufacturer changed its label, then the brand-name manufacturer would also be compelled to change its label or repudiate the new warning through a "Dear Doctor" letter.[87]

A Dear Doctor letter is an alternative to the CBE process whereby a drug manufacturer can send a letter to health care providers concerning new information about a drug.[88] A Dear Doctor letter could be an effective way for generic manufacturers to disseminate information; but generic manufacturers are prevented from this option as such communication is considered labeling.[89]

III. EFFECT ON INNOVATION

The majority rule that brand-name manufacturers cannot be held liable for generic warning labels developed because courts recognized that to do otherwise would stifle innovation by forcing brand-name manufacturers to subsidize their competitors' litigation.[90]

The decision in *Dolin*, and those like it, will increase the cost of commercializing new drugs, thereby harming consumers in one of two ways: brand-name manufacturers will increase the cost of their products or

---

the FDA an annual report detailing "[a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product").

86. Ironically, such a solution would alleviate much of the confusion regarding who is responsible for generic warning label defects, but it may open both brand-name and generic companies to more products liability litigation because in many states, like Texas, it would make it easier to prove "a safer alternative design existed." *See* Timpte Indus. v. Gish, 286 S.W.3d 306, 311 (Tex. 2009) (listing the elements of product liability in Texas); *see also* Kelleher v. Marvin Lumber & Cedar Co., 891 A.2d 477, 492 (N.H. 2005) (holding plaintiffs are not required to prove a safer alternative design existed to recover under New Hampshire product liability law).

87. *See* 21 C.F.R. § 201.57(c)(6) (2015) ("[L]abeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established.").

88. *See* James W. Huston et al., *Dear Doctor Letters: Lessons in Statutory Interpretation, Preemption, Proximate Causation, and Subsequent-Remedial Measures*, 22 ANN. HEALTH L. 445, 445 (2013) (recounting Dear Doctor letters, also known as Dear Healthcare Provider letters, were created as an alternative to labeling for drug manufacturers to effectively and quickly deliver new drug information to healthcare providers).

89. *See PLIVA*, 131 S. Ct. at 2576 (citing the amicus curie brief from the FDA characterizing Dear Doctor letters as a form of labeling that if sent by a generic manufacturer would be impermissible because doing so would imply a difference between the generic drug and its brand-name counterpart).

90. *See* Foster v. Am. Home Products Corp., 29 F.3d 165, 170 (4th Cir. 1994) (recognizing "[t]his would be especially unfair when . . . 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").

they will simply cease production.[91] Which option manufacturers choose to take will depend largely on the price elasticity of the individual drugs. Where large markets exist, prices will probably increase and where only small markets exist, the companies may choose to terminate sales rather than incur losses or become more dependent on government subsidies.[92]

Ultimately, well-meaning courts seeking justice for a few may harm far more people by litigating future drugs out of the market place.[93] In fact, there is evidence this is already happening.[94] For example, AstraZeneca has completely abandoned the psychiatric drug market.[95] Additionally, health care providers are increasingly dealing with drug and vaccine shortages, and many manufacturers simply cannot maintain a market presence with current costs.[96]

Drug shortages are increasingly likely to occur if strategic decisions force brand-name manufacturers, or even generics for that matter, out of the marketplace. Anti-trust regulations prevent a drug manufacturer from signaling a competitor to ramp up production when it leaves a market.[97] Amazingly, a drug manufacturer is only required to inform the FDA it is leaving a market if it is a sole supplier—something that is not an issue for drugs with generic options.[98] It is reasonable to conclude that if brand-name manufacturers decide to exit their respective markets as soon as generics make their products unprofitable, the generic manufacturers may not have enough notice or manufacturing capacity to compensate for the loss of supply.[99] Other generic manufacturers may enter the market to fill

91. *See* Parchomovsky & Stein, *supra* note 62, at 306 (identifying the two ways in which consumers will be harmed by the commercialization of drugs).

92. *See id.* (explaining when demand is highly inelastic, as is the case with life-saving innovations, consumers will bear the extra costs, and when demand is elastic, producers will bear the extra cost of the increased legal liability; and if producers are not be able to pass enough of the extra cost to consumers they may simply forego the innovation).

93. *See* Munos, *supra* note 2, at 966 (asserting that focusing short term priorities causes companies to conduct more imitative and less breakthrough research).

94. *See id.* at 965 (showing a twenty year decline in the output of large pharmaceutical companies).

95. *See* Morris, *supra* note 2, at 246 (identifying one brand-name company that has removed itself from particular areas of drug development).

96. *See* Nancy Landis, *Provisional Observations on Drug Product Shortages: Effects, Causes, and Potential Solutions*, 59 AM. J. HEALTH-SYS. PHARM. 2173, 2179 (2002) (noting drug shortages also increase purchase costs for pharmacies and health care organizations).

97. *See id.* at 2180 (contending anti-trust regulations prevent such communication, but some voluntary efforts at public-private partnerships have helped).

98. *See id.* (emphasizing because the FDA has no authority to compel manufacturers to continue producing a product, it relies on voluntary notice of discontinuation from manufacturers, which it posts on its website).

99. *See id.* at 2179 (discussing a factor in many shortages is the difficulty in obtaining the

the void, but additional regulations regarding ANDAs for drugs with discontinued brand-name parents would probably delay their entry.[100]

Dolin argues brand-name manufacturers are already compensated for the added risk of liability under the current regulatory scheme in the form of an extended monopoly period.[101] However, the reverse also holds true for the consumer who receives the benefits of the brand-name drug at the substantially lower cost of the generic drug.[102] While *Dolin* is partially correct that brand-name manufacturers are well compensated through temporary monopolies, it fails to recognize the other half of the equation.[103] Specifically, it ignores the years of free advertising and preferential treatment in prescriptions generic manufacturers enjoy.[104] For example, every state allows or requires pharmacists to fill prescriptions for brand-name drugs with generic substitutes, and Medicare encourages substitution by setting a maximum allowable charge on generics.[105] That maximum allowable charge encourages pharmacists to fill prescriptions with generic drugs because they can capture the difference between the generic price and the brand-name price.[106]

---

reference product information from discontinued brand-name drugs).

100. *See id.* (explaining if the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, describes a parent drug product as discontinued, manufacturers seeking ANDA approval will also need to ask the FDA to determine if the parent drug was removed for safety or efficacy reasons).

101. *See* Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 716 (N.D. Ill. 2014) (adding brand-name manufacturers also maintain complete control over the warning label after generics arrive on the market).

102. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2581 n.9 (2011) (noting generic drug consumers also benefit from substantially safer drugs, in that generics take so long to reach the market, genuinely new information about these drugs occurs rarely).

103. For example, some drug research has incredibly high failure rates, which generic drugs can almost completely avoid. *See* Adams & Brantner, *supra* note 4, at 426 (citing the 16% success rate for asthma drug research).

104. Drug manufacturers have some of the highest marketing to sales cost of any industry. *See* Rahul Guha et al., *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, 1 LANDSLIDE 8, 11 (2008) (claiming the industry benchmark marketing to sales ratio of 14%–15% may actually be an underestimate); *see also Dolin*, 62 F. Supp. 3d at 719 (referencing the fact that even though the patient was prescribed a brand-name drug, the prescription was filled with a generic, in compliance with an Illinois drug substitution law).

105. *See* Danzon & Chao, *supra* note 36, at 316–17 ("[B]y the 1990s[,] all states had repealed antisubstitution laws and authorized pharmacists to substitute generic equivalents unless the physician explicitly writes 'dispense as written.' Managed care plans and Medicaid encourage generic substitution for off-patent drugs by paying a maximum allowable charge . . . for generically equivalent products.").

106. *See id.* (detailing how generic substitution programs will generate high cross-price demand elasticity for generically equivalent products because the pharmacist will be able to capture the difference between the maximum allowable charge, the net of the wholesale margins, and the manufacturer price).

Dolin, thus imbalances this equation by adding the specter of indefinite liability long after a product ceases to be profitable.[107] Indeed, under the reasoning of *Dolin* and its predecessors, like *Conte*, brand-name manufacturers could be held liable even after they leave a market completely.[108] Inevitably, the equation will rebalance in the only way it can under current law—higher consumer prices.[109] Perhaps even more troubling is that there is little to stop this emerging application of limitless vicarious liability on innovators from spreading to every other industry.[110]

Another supposed benefit conferred upon brand-name manufacturers by the Hatch–Waxman Act was longer exclusivity periods, which can extend the initial patent protection by five to fourteen years.[111] This may seem like a long time; however, these numbers are not based on market analysis for a pioneer drug company's return on investment.[112] On average, new brand-name drugs do not produce positive cash flow until their sixth year, and do not recoup fixed costs associated with development and marketing until the sixteenth year.[113] Often, patents do not last long enough to allow brand-name manufacturers to recover their initial investment.[114] Another reason to doubt the effectiveness of the current legal and regulatory model in advancing the second goal of Hatch–Waxman is that, despite the billions of dollars spent by the pharmaceutical

107. *See* Fabian Nehrbass, Comment, *Save Now, Pay Later: The Unfortunate Reality of* PLIVA v. Mensing, 73 LA. L. REV. 1155, 1178 (2013) (arguing since brand-name manufacturers already face unusually high entry costs, fears of indefinite liability would weaken a brand-name manufacture's primary incentive to pursue drug innovation).

108. *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) (examining the possibility that courts following the *Conte* decision would permit plaintiffs harmed by generic drugs to sue brand-name manufacturers even after the brand-name drug has been pulled off the market).

109. *See* Landis, *supra* note 96, at 2180 (recognizing drug pricing depends on competition).

110. *See* Wyeth, Inc. v. Weeks, 159 So. 3d 649, 707 (Ala. 2014) (Murdock, J., dissenting) (contending when courts begin applying foreseeability without requiring a relationship, the line between the pharmaceutical industry and other industries becomes arbitrary and will exist only as long as courts say it should exist); *see also* Alissa J. Strong, *"But He Told Me It Was Safe!": The Expanding Tort of Negligent Misrepresentation*, 40 U. MEM. L. REV. 105, 142 (2009) (asserting *Conte*'s reasoning could be used to advance negligent misrepresentation claims against manufacturers in any industry).

111. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 190 (1999) (pointing out the total market exclusivity period under Hatch-Waxman cannot be longer than fourteen years).

112. *See id.* ("The length of the exclusivity periods are strictly arbitrary legislative numbers pulled out of the air.").

113. *See* Morris, *supra* note 2, at 267–68 (recounting factors that limit the effectiveness of patent drugs in the pharmaceutical industry).

114. *See id.* at 249–51 (describing the situation in which the low costs for generic market entry diminishes the incentives for brand-name manufacturers to innovate and develop new drugs).

industry, the rate of new drug approvals is essentially the same as it was fifty years ago.[115]

What happens if a brand-name drug company cannot recoup its investment in less than the five-to-fourteen year extensions arbitrarily allowed? Most likely, the company will either sell the rights to develop the nascent drug to another company, thus extending even further the time to market, or simply cut its losses and give up developing the drug.[116] If the minority view persists, brand-name manufacturers will have to factor in this potential for unlimited liability.

Logically, it is difficult to argue increased litigation will not increase costs for drug manufacturers.[117] However, a scenario even worse than more expensive drugs is one where the drugs are simply not developed at all. Research analysts at the Federal Trade Commission's Bureau of Economics found the average cost of bringing a new drug to market is $868 million.[118] While that number alone may be staggering, it is less than half the $2.12 billion spent by one drug manufacturer in that study.[119] The analysis attributes the wide variation in drug costs partly to strategic decisions made by the drug companies.[120] However, as noted above, increased costs increase the risk that companies will make the strategic decision to leave the market.[121]

Tort law is, by nature, an inefficient and unreliable way to encourage innovation.[122] Tort liability acts as a negative incentive for innovation because, as the threat of tort liability grows, medical practitioners and drug manufacturers are more likely to embrace the comfort and protection of accepted customs than to expand into the potentially dangerous waters of

115. *See* Munos, *supra* note 2, at 959 (stating new drug development has not improved in fifty years and 2008 saw only twenty-one new drugs brought to market, a number well below average).

116. *See id.* at 966 (positing a focus on short-term priorities causes companies to eschew blockbuster innovation in favor of the higher rates of return on marginal innovation).

117. *But see id.* at 963–64 (arguing increased regulation has forced companies to be more selective in the chemicals they pursue, thus increasing the success rate of innovation).

118. *See* Adams & Brantner, *supra* note 4, at 427 (estimating the average costs for drug development to be $868 million).

119. *See id.* (contrasting the wide range of costs endured by various drug companies).

120. *See id.* (suggesting the range of development costs between $521 million and $2.12 billion is the result of variations in strategic decision-making).

121. *See* Nehrbass, *supra* note 107, at 1178 (arguing since it already faces unusually high entry costs, fears of indefinite liability would weaken a brand-name manufacture's primary incentive to pursue drug innovation).

122. *See* Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J. L. & MED. 7, 15 (2011) ("The common law proceeds in a decentralized, amorphous fashion as development is informed by uncoordinated and self-interested advocates.").

innovation.[123] Even if tort liability was an effective way of spurring innovation, courts simply cannot keep up with the potential pace of innovation.[124]

Increased tort liability exposure may also harm the consumer in a stealthier way. Brand-name manufacturers faced with a nearly unlimited tort burden for a product, due to generic competition, are more of a liability than an asset because these manufacturers could simply pile on warnings for every conceivable adverse reaction, no matter how remote the odds.[125] This would have the effect of protecting the brand-name drug companies from the 20/20 hindsight of juries.[126] However, piling on warnings could also overwhelm patients with adverse consequences and could cause at least some patients to forego potentially lifesaving drug treatment for fear of consequences that almost certainly would not occur.[127] Ultimately, the increased tort liability on brand-name manufacturers created by the new minority view undermines the Hatch–Waxman policy goals of proliferating cheap and effective drugs by disrupting the free-market forces that have spurred so much innovation over the last fifty years.[128] Congress must change the current legal framework to resolve the problem of affixing liability in a manner that is fair to brand-name and generic manufacturers without removing the ability of consumers, who have been truly harmed, to recover for their injuries.

IV. FIXING THE PROBLEM

Critics argue gradual acceptance of the minority rule runs the serious

123. *See* Parchomovsky & Stein, *supra* note 62, at 304 (explaining how under a product liability regime, manufacturers can defeat defective design claims through the risk-utility and consumer-expectation tests, but open themselves to liability through those same tests when they attempt to innovate); *see also* Avraham, *supra* note 122, at 15 ("[S]ince following current industry custom is still the best way to prevent potential medical malpractice liability, doctors are often reluctant to embrace medical innovations, and consequently there is substantially sub-optimal incentive to innovate.").

124. *See* Avraham, *supra* note 122, at 25 (emphasizing medical advances outpace legal remedies because the latter requires a long process of generalizing and rationalizing disparate outcomes by uninformed and self-interested advocates).

125. *See* Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1150 (1987) (asserting trial lawyers, when faced with a failure-to-warn claim, first see what warnings were given, then tailor their plaintiffs' claims to fit the narrative that the warning was inadequate).

126. *See id.* (stating modern juries have intensified a common law bias toward finding all warnings inadequate through the use of 20/20 hindsight).

127. *See id.* (explaining every warning requires a happy medium, where too severe or too soft warnings would distort the relevant patient and a patient's decision to use the medication).

128. *See* Wyeth, Inc. v. Weeks, 159 So. 3d 649, 706–07 (Ala. 2014) (Murdock, J., dissenting) (forcing brand-name manufacturers to essentially insure their generic competitors will disrupt the free market forces that drive innovation and ultimately lead to fewer medical innovations).

risk of chilling innovation, but in reality, the very existence of a minority rule chills innovation.[129] Brand-name manufacturers do business in every corner of the country and, therefore, are amenable to suit in every jurisdiction.[130] They must make business decisions with an eye on how their actions will be treated under the law in any jurisdiction, and a billion-dollar judgment is just as painful when it comes from a minority jurisdiction as from a majority jurisdiction.[131]

Decisions like *Dolin* may represent the minority rule, but from a pre-litigation business perspective, they essentially rewrite the law for everyone.[132] Therefore, lawmakers must craft a solution that balances the social utility of new drugs and their associated risks against the courts' moral imperative to seek justice between the litigants. Two changes to the current legal scheme must take place to affect this outcome. First, generic manufacturers must be given the same authority as brand-name manufacturers under the CBE process. Second, Congress must expressly preempt state tort law with the new CBE process.

A. *Generic Manufacturers Should Be Responsible for Label Changes*

Balancing these competing demands will require modifying the CBE process to allow generic manufacturers to change their warning labels when they have good cause.[133] This will allow plaintiffs to recover

129. *See* Rostron, *supra* note 2, at 1126–27 ("Lawyers who represent drug companies put *Conte* at the head of the list of 'worst drug and medical device product liability decisions of the year,' and tort reform advocates condemned it as 'bad law, bad public policy and a national embarrassment.'" (footnotes omitted)).

130. *See* Burger King Corp. v. Rudzewicz, 471 U.S. 462, 473 (1985) (holding the Due Process Clause does not restrict the powers of a state to assert personal jurisdiction over a corporation if that corporation "'delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State' and those products subsequently injure forum consumers." (quoting World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980))).

131. The First Circuit opined drug companies can avoid this by simply not selling their products in unfriendly jurisdictions. *See* Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 38 (1st Cir. 2012) (finding a generic manufacturer may have no choice in its labeling, but has full control over the decision to make or market the drug in a particular state), *rev'd*, 133 S. Ct. 2466 (2013). *But see* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2477 (2013) (rejecting this approach as incoherent and incompatible with preemption doctrine because it presumes a corporation trying to satisfy both federal and state obligations is required to discontinue economically beneficial activity altogether, simply to avoid liability).

132. A good analogy would be the prevalence of defensive medicine, defined as excessive care to avoid liability, which externalizes extra costs to the consumer. *See* Avraham, *supra* note 122, at 8 (explaining defensive medicine increases costs to the consumer by as much as $200 billion a year).

133. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575 (2011) (noting the current FDA interpretation of CBE regulations only allows a generic manufacturer to change a generic drug label to either conform to an update by the brand-name manufacturer of its label or comply with FDA

without placing unnecessary legal and financial burdens on brand-name innovators.[134] The most persuasive reason for leaving liability in the hands of the brand-name manufacturers is they are in the best position to discover new problems with a drug.[135] But is this really the case? Generic drugs can take 80% of a brand-name's market share within as little as six months after patent expiration.[136] The sheer volume of sales attributable to generics over brand-name drugs indicates that generic, not brand-name manufacturers are more likely to receive the product complaints that lead to warning label changes.[137]

An easy solution to this problem is to give generic manufacturers the freedom to alter their labels when new safety information is acquired. Indeed, the FDA has already proposed this change.[138] The FDA made this proposal after finding *PLIVA* altered generic manufacturer incentives to conduct meaningful post-marketing reporting as required by regulation.[139]

However, this change may not be enough, as courts have expressed a willingness to charge brand-name manufacturers with warning label liability even if generic manufacturers have the power to change their labels.[140]

---

instructions).

134. *See* Nehrbass, *supra* note 107, at 1157 (fixing the CBE process to allow generic manufacturers to unilaterally alter their labels will relieve brand-name manufacturers of unnecessary liability while retaining proper remedies for generic consumers in failure-to-warn suits).

135. *See* Schwartz et al., *supra* note 21, at 1844–45 (acknowledging the FDA requires brand-name manufacturers to conduct significant post-market analysis of reports and scientific literature to verify the safety of their products even after the patent expires, whereas generic manufacturers are not held to similarly rigorous standards).

136. *See* Epperly, *supra* note 1, at 7 (explaining generics produced in 2010 captured 80% of a brand-name drug's sales six months after the loss of a patent and the pace of market share growth continues to accelerate).

137. Nevertheless, the FDA does not require generic manufacturers to monitor scientific literature or report scientific developments. *See* Schwartz et al., *supra* note 21, at 1844–45 (indicating generic manufacturers' responsibilities only include maintaining adequate records and reporting adverse effects because by the time generic drugs come to market most adverse effects are already known).

138. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,985 (proposed Nov. 13, 2013) (codified at 21 C.F.R. pts. 314 & 601).

139. *See id.* at 67,988–89 (explaining *PLIVA* alters generic manufacturers incentives to comply with robust post marketing surveillance of its products); 5 FRUMER & FRIEDMAN, PRODUCTS LIABILITY § 50.02(2)(m)(iv) (Matthew Bender & Co. rev. ed. 2014) (crediting the Supreme Court's decision in *PLIVA* as the catalyst for the unprecedented reversal in the FDA regulatory scheme).

140. *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 315 (Cal. Ct. App. 2008) ("[W]e find the conclusion inescapable that Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide

The minority rule can still find fertile ground in which to grow, even in the face of changes to the CBE process, where states follow the dissenting opinion in *Palsgraf v. Long Island Railroad Co.*,[141] which notes "[e]veryone owes to the world at large the duty of refraining from those acts that may unreasonably threaten the safety of others."[142] The California Court of Appeals relied on a variation of this philosophy when holding Wyeth Inc., a brand-name manufacturer, liable for defects caused by its generic substitute's warning label.[143] This doctrine makes it possible for generic drug consumers to recover from brand-name manufacturers, even after the FDA updates the CBE process, as long as it can be shown that the consumer's doctor relied on representations from the brand-name manufacturer in prescribing the generic drug.[144] Considering brand-name manufacturers conduct all research and advertising for their drugs when they are under patent protection, it is difficult to see how a court would not find that they could reasonably foresee reliance by prescribing doctors.[145] This problem persists in large part because Congress has left the question of preemption up to the courts.

B. *Express Preemption as a Necessary Compliment to the New FDA Regulation*

The proposed FDA changes to the CBE process are an important first step toward fixing the tangled mess of drug manufacturer liability; however, they may not be sufficient without complementary legislation that expressly preempts state law.[146] There are three kinds of federal preemption: express, implied, and impossibility.[147] Express preemption is

---

prescribed or dispensed to them."); Schwartz et al., *supra* note 21, at 1849 (citing *Conte*'s reasoning in allowing brand-name liability because the prescribing physician relied on claims by the brand-name manufacturer even though generics were prescribed).

141. Palsgraf v. Long Island R.R., 162 N.E. 99 (N.Y. 1928).

142. *Id.* at 103 (Andrews, J., dissenting).

143. *See Conte*, 85 Cal. Rptr. 3d at 315 (finding California tort law imposes upon everyone a duty to use reasonable care to avoid injury to others); *see also* Boyer v. Weyerhaeuser Co., 39 F. Supp. 3d 1036, 1048 (W.D. Wis. 2014) (suggesting Wisconsin's adoption of the dissenting view in *Palsgraf* could allow generic plaintiffs to sue brand-name manufacturers because of the manufacturers' duty to refrain from any action that may unreasonably endanger the safety of others).

144. *See Conte*, 85 Cal. Rptr. 3d at 315 (holding California law allows liability to be placed on Wyeth whether a consumer was harmed by its drug or a generic copy, as long as Wyeth could reasonably foresee doctors may rely on representations from Wyeth in prescribing either version).

145. *See id.* at 308 (relying on a doctor's vague statement that he probably read the defendant brand-name manufacturer's monograph during residency training as sufficient proof of reliance, even though in a previous deposition the doctor emphatically denied any such reliance).

146. *See id.* at 305 (holding brand-name manufacturers owe a common law duty of care to generic drug consumers if their doctor relied on statements by the brand-name manufacturer).

147. *See* Richard E. Kaye, Annotation, *Federal Preemption of State Common-Law Products Liability*

the only way to ensure the new regulations are applied uniformly in all jurisdictions because the other two types of preemption would leave individual courts to decide Congress's legislative intent.[148] Unless Congress expressly provides the new regulations preempt state tort laws, courts will still be left to decide whether preemption is appropriate when a generic drug consumer chooses to go after the deeper pockets of a brand-name manufacturer under the minority rule.[149]

For example, even though the new regulations promulgated by the FDA will allow generic manufacturers the freedom to change their labels when new drug safety information is discovered, it does not specifically require that they be held solely responsible for their warning labels.[150] Under the foreseeable reliance doctrine used in California, patients could still sue brand-name manufacturers when generic manufacturers harm them, so long as they can show their doctor could have reasonably relied on the statements of the brand-name manufacturer in prescribing the generic drug.[151] This seems even more likely considering brand-name manufacturers shoulder almost the entire burden of advertising, even after generic drugs hit the market.[152]

Historically, brand-name manufacturers have been protected from the state tort claims of consumers of generic drugs because they were viewed to owe no duty of care to individuals who never used their products.[153]

Claims Pertaining to Drugs, 70 A.L.R. Fed. 2d 69, 87 (explaining the three forms of preemption).

148. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (noting the cornerstone of federal preemption is that states' police powers should not be preempted by federal law unless such action was the manifest purpose of Congress because they are independent sovereigns).

149. *See* Kaye, *supra* note 147, at 89 (citing Congress's lack of legislation to explicitly preempt state law as the reason state courts must frequently determine whether state law can be applied); *see also* Kellogg v. Wyeth, 762 F. Supp. 2d 694, 708 (D. Vt. 2010) (stating there is no reason to limit a brand-name manufacturer's duty of care when a pharmacist chooses to fill a prescription for a brand-name drug with a generic equivalent).

150. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,989 (proposed Nov. 13, 2013) (codified at 21 C.F.R. pts. 314 & 601) (proposing ANDA holders be allowed to update their labels to create parity between brand-name and generic manufacturers, but omitting any mention of legal responsibility for the information on the labels).

151. *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 305 (Cal. Ct. App. 2008) (finding since Wyeth knew, or should have known, a significant number of doctors would rely on its product information when prescribing patients generic metoclopramide, Wyeth could be held liable under the doctrine of foreseeability).

152. *See* Rostron, *supra* note 2, at 1133 (describing how the typical generic manufacturer's business model is designed to keep costs low by spending nothing on marketing, instead relying solely on the brand-name manufacturer's marketing to generate product sales).

153. *See* Schrock v. Wyeth, Inc., 727 F.3d 1273, 1281–82 (10th Cir. 2013) (holding a manufacturer cannot be held liable for harm unless there was first a duty of care created through

The new minority rule leverages the doctrine of foreseeability to turn this jurisprudence on its head and hold a brand-name manufacturer liable for harm caused by generic copycats if it can be shown that a doctor might reasonably rely on the brand-name label when prescribing a generic drug.[154]

Generic manufacturers have benefited from the express preemption provisions of the Hatch–Waxman Act.[155] No such provision exists for brand-name manufacturers; therefore, they would be left to rely on implied or impossibility preemption. However, federal rules and Supreme Court jurisprudence would be of little help in this regard. In 1962, when Congress created the FDA's pre-marketing review of prescription drugs, a saving clause was added so the legislation would not be construed to invalidate state law unless a direct and positive conflict exists.[156] In the years since, state common law suits have continued unabated in spite of FDA regulation because Congress never enacted a preemption provision for prescription drugs even as it enacted such provisions for other products governed by FDA regulations.[157]

The FDA's pending updates to the regulatory scheme contemplate allowing generic manufacturers full access to the CBE process will create parity between generic and brand-name manufacturers and will likely eliminate the failure-to-warn preemption protection generic manufacturers

---

selling or distributing its product); Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009) (declaring Wyeth could not be held liable for harm caused by its generic counterpart because under Minnesota law, a direct relationship is required for a duty of care to arise); Foster v. Am. Home Prods. Corp., 29 F.3d 165, 171 (4th Cir. 1994) (rejecting the argument that a duty is created if it is foreseeable misrepresentations regarding one drug could result in personal injury to users of that drug's generic equivalents).

154. *See* Thomas v. Abbott Labs., No. CV-12-07005-MWF (CWX), 2014 WL 4197494, at *5 (C.D. Cal. July 29, 2014) (explaining, under California law, a prescription drug manufacturer's duty is not just to the consumer specifically, but to the medical profession in general); *Conte*, 85 Cal. Rptr. 3d at 305 (discussing the significance of reliance by doctors on the brand-name drug's information when prescribing a generic counterpart).

155. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2579 (2011) (upholding the argument that federal law requiring generic manufacturers to maintain identical labels with brand-name manufacturers preempts state tort claims); *see also* Demahy v. Actavis, 593 F.3d 428, 449 (5th Cir. 2010) (rejecting preemption because it would leave a generic drug consumer without legal recourse); *Mensing*, 588 F.3d at 614 (reversing judgment in favor of generic manufacturers).

156. *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2484 (2013) (Sotomayor, J., dissenting) (explaining the 1962 amendments to the Federal Food, Drug and Cosmetics Act).

157. *See id.* (noting the legislative intent behind the creation of the FDA's pre-market analysis regulation was to supplement, not replace, state common law claims); Wyeth v. Levine, 555 U.S. 555, 578 (2009) (discussing how Congress's decision not to preempt state common law tort suits indicates that the FDA regulations have traditionally been regarded as a complementary form of regulation).

currently enjoy.[158] However, even parity between brand-name and generic manufacturers will not clear up the confusion on how to apply impossibility preemption.

Consider the differing views on how to apply preemption advanced in *PLIVA*. Justice Thomas, delivering the opinion of the Court, described the impossibility doctrine as "whether the private party could independently do under federal law what state law requires of it."[159] The Court essentially found, even though there was an option for PLIVA to warn of the harmful effects of its drug, it required federal regulatory intervention. Therefore, it was impossible for the company to follow independently state and federal law.[160] Justice Sotomayor, writing for the dissent, pilloried this application as "invent[ing] new principles of pre-emption law out of thin air to justify its dilution of the impossibility standard."[161] She described the standard advanced by the majority as preemption through the "mere possibility of impossibility."[162]

Considering the abundance of pharmaceutical product liability litigation and that *PLIVA* was a very contentious 5–4 decision, it is likely we will see further confusion on the issue. For example, even with the parity between drug manufacturers created by the new regulations, a court applying California's standard of duty and Justice Sotomayor's interpretation of preemption could still find a brand-name manufacturer liable for harm caused by a generic substitute because the brand-name manufacturer originally created the label.[163]

---

158. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,989 (proposed Nov. 13, 2013) (codified at 21 C.F.R. pts. 314 & 601) (explaining the proposed regulations are intended to ensure that generic manufacturers cooperate with the FDA and brand-name manufacturers to provide timely, accurate, and complete drug safety labels and, if adopted, it may eliminate federal preemption of state failure-to-warn claims for generic drugs).

159. *See PLIVA*, 131 S. Ct. at 2579 (Sotomayor, J., dissenting) (suggesting if the Court were to accept the plaintiff's argument, conflict preemption would be rendered meaningless because it would make most state and federal law conflicts largely illusory).

160. *See id.* (arguing just because the Court can imagine a scenario where the federal government *might* take some action that makes it lawful for a private party to simultaneously comply with state and federal law does not mean the scenario is sufficiently likely to invalidate the preemption clause of the Constitution).

161. *Id.*

162. *See id.* at 2582 (recognizing the majority's decision effectively rewrote the Court's decision of just two years earlier in *Wyeth v. Levine*).

163. *Cf. PLIVA*, 131 S. Ct. 2567 at 2587 (Sotomayor, J., dissenting) (stating a defendant can only prevail on an impossibility claim if compliance with both state and federal law is a *physical* impossibility); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 304–05 (Cal. Ct. App. 2008) (holding a brand-name manufacturer's duty of care in product warnings extends to consumers of its own product and to consumers of generic products whose doctors could foreseeably rely on the brand-

Therefore, if Congress does not clearly define which manufacturer—brand-name or generic—is responsible for a duty to warn, the new FDA regulation will not protect brand-name manufacturers, but simply add generic manufacturers to a plaintiff's potential list of defendants, thus confusing the issue further.[164]

V. CONCLUSION

The current state of jurisprudence on the issue of prescription drug warning label liability is murky at best. Just a few years ago, there was a clearly defined standard applied in every jurisdiction, but since 2009, *Conte* and its progeny turned the case law on its head.[165]

The major source of confusion comes from the fact the Hatch–Waxman Act disconnects traditional standards of duty to warn from the risk-reward calculus of manufacturers.[166] Under the current law, generic manufacturers cannot be sued for harm caused by their warning label defects in majority jurisdictions due to the federal preemption created by the Hatch–Waxman Act.[167] Additionally, in majority jurisdictions, consumers of generic drugs protect brand-name manufacturers from lawsuits because the consumers never actually used their product.[168] This

---

name manufacturer's information when prescribing a medication).

164. *Compare* Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009) (finding brand-name manufacturers liable for injuries caused by their generic counterparts would be too broad an application of foreseeability), *with Conte*, 85 Cal. Rptr. 3d at 304–05 (holding a brand-name manufacturer's common law duty to use due care in product warnings "extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the brand-name manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug"). *See also* Boyer v. Weyerhaeuser Co., 39 F. Supp. 3d 1036, 1045 (W.D. Wis. 2014) (suggesting Wisconsin's adoption of the dissenting view in *Palsgraf* could allow generic plaintiffs to sue brand-name manufacturers because of their duty to refrain from any action that may unreasonably endanger the safety of others).

165. *See* Schwartz et al., *supra* note 21, at 1849 (describing these courts as side-stepping dozens of other courts and well established rights and responsibilities to create novel new tort claims).

166. Despite enjoying as much as 80% market share for their products, generic manufacturers are incentivized to avoid going out of their way to study the safety of their product because their only legal responsibility is to be identical to the brand-name drug; however, brand-name manufacturers are shouldered with the burden of taking affirmative steps to improve safety for the entire industry, even after their product becomes unprofitable. *See* Schwartz et al., *supra* note 21, at 1844–46 (explaining generic responsibilities only include maintaining adequate records and reporting adverse effects because by the time generics come to market most adverse affects are already known, but brand-name manufacturers must regularly check safety reports and scientific literature, even after they lose patent protection).

167. *See PLIVA*, 131 S. Ct. at 2581 (holding a generic manufacturer could not be held liable for warning label defects under state tort law because federal regulations prevented the manufacturer from taking the necessary actions to conform to state laws).

168. *See* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170–71 (4th Cir. 1994) (finding no

situation is unfair to plaintiffs who have been legitimately harmed by generic drugs because they are left without legal recourse.[169]

Minority jurisdictions have developed a way to allow generic drug consumers to recover for their damages but have done so by placing liability on companies that have no privity with the plaintiffs.[170] This is also unfair in that it forces brand-name manufacturers to indemnify their competition without any compensation for their added costs.[171] This will create disincentives to innovation and ultimately harm consumers either by increasing costs or by restricting the flow of new drugs.[172]

Fixing the problem does not require radical changes to the law, merely adjustments. The FDA is already considering one of these adjustments, allowing generic manufacturers to take part in the CBE process.[173]

---

relationship capable of creating a duty to warn when the plaintiff consumed a generic version of the defendant's product, rather than ingesting the defendant's product itself).

169. *See PLIVA*, 131 S. Ct. at 2581–82 (acknowledging that applying federal preemption of state tort law made it impossible for the plaintiffs, and others similarly situated, to recover for their damages, but noting it was Congress's prerogative to create such an unusual scheme). *But see PLIVA*, 131 S. Ct. at 2589 (Sotomayor, J., dissenting) (arguing Congress did not intend to create such an unusual scheme because the regulatory framework did leave open options for generic manufacturers to change their labels).

170. *See* Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014) (explaining, under Illinois law, the existence of a duty does not require a direct relationship between the parties, contract, privity of interest, or proximity of relationship, and may extend to remote or unknown people); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 311 (Cal. Ct. App. 2008) (relying on California's general rule that everyone has a duty to use reasonable care to avoid injury to others in holding a brand-name manufacturer can be held liable for harm caused to someone who never used its product because the prescribing doctor *may* have relied on assertions by the brand-name defendant in prescribing the generic drug).

171. *See* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 828 (1973) (stating strict liability for products does not make a manufacturer an insurer for the entire industry because, if it did, a plaintiff would need to prove only cause in fact, and thus, "the manufacturer of a match would be liable for anything burned by a fire started by a match produced by him"). *But see* Rostron, *supra* note 2, at 1176 (asserting brand-name manufacturers mislead the courts when discussing fairness by comparing themselves only to the generic manufacturers and leaving the injured plaintiff out of the equation).

172. *See* Epstein, *supra* note 125, at 1153–54 (explaining if aggregate net gains to consumers and pharmaceutical companies are eliminated by the cost of litigation, then manufacturers will discontinue making the product; however, if some net gains still exist, but are reduced, then fewer units will be produced and some marginal consumers will have to do without); W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976–1989*, 24 SETON HALL L. REV. 1418, 1419 (1994) (arguing the net effect of the increase in costs associated with litigation discouraged innovation in the pharmaceutical industry).

173. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,989 (proposed Nov. 13, 2013) (codified at 21 C.F.R. pts. 314 & 601) (proposing to change the FDA regulation to allow generic manufacturers, referred to as ANDA holders, to unilaterally change their warning labels, even though such changes will cause the generic and brand-name labels to differ).

However, Congress has not addressed the second change, establishing express federal preemption of state tort laws.[174] Without this vital last step, the new regulations will simply broaden a plaintiff's choice of defendants rather than bring clarity to the law. Establishing these two changes to the current legal framework will place liability with the proper manufacturers, give generic drug consumers legal recourse for harm in any jurisdiction, and limit the harm to innovation caused by litigation.

174. *See* Wyeth v. Levine, 555 U.S. 555, 581 (2009) (noting because Congress repeatedly declined to apply federal preemption to state law, the FDA's position that state tort suits interfere with its regulatory authority is entitled no weight); Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (explaining courts begin a preemption analysis with the assumption the police powers of a state shall not be superseded by federal law, unless Congress clearly manifests such an intent).