2011

Prescription for Fairness: New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers

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PRESCRIPTION FOR FAIRNESS: A NEW APPROACH TO TORT LIABILITY OF BRAND-NAME AND GENERIC DRUG MANUFACTURERS

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ABSTRACT

Over the past two decades, courts have consistently ruled that the manufacturer of a brand-name prescription drug cannot be liable for injuries suffered by those taking generic imitations of its product. This meant that a patient injured by a generic drug could have no remedy at all because in many instances the generic drug manufacturer would escape liability on the ground that it did not produce any information on which the patient's doctor relied. It was a perplexing dilemma. The generic drug manufacturer made the product that the plaintiff received, the brand-name manufacturer produced all of the information the patient's doctor saw, and neither manufacturer could be held liable even if each acted negligently.

The California Court of Appeal recently issued a stunning decision in which it concluded that a brand-name drug manufacturer could be liable to a plaintiff who took a generic version of its product. The reaction to the decision has been overwhelmingly negative. Commentators have condemned the decision as one of the worst rulings made by any court in recent years. Judges around the country have dismissed it as a misguided aberration from the otherwise strong judicial consensus on the issue.

Although the decision has been the subject of scathing criticism, this Article argues that the California court's ruling actually represents

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the first time that a court has properly examined this issue. In addition, the Article points out some weaknesses in the California court's reasoning and proposes a novel general framework for analyzing the liability of brand-name and generic drug manufacturers.

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INTRODUCTION

Imagine that a person goes to see her doctor about a minor health problem. The doctor writes a prescription for a drug that should help the patient. The doctor has seen advertisements for the drug in medical journals, heard about the drug during visits from its manufacturer's sales representatives, and read all of the instructions and warnings provided in the drug's labeling. Based on this

information, the doctor has every reason to believe the drug will be safe and effective, but the drug turns out to have a terrible adverse effect on the patient. The doctor was unaware of this risk because the manufacturer did not mention it in the drug's labeling, advertising, or other promotional efforts. If the manufacturer had done so, the doctor would not have written the prescription. The patient suffers severe, permanent harm from using the drug. Hoping to obtain fair compensation for her injuries, the patient retains a lawyer who investigates and finds proof that the drug's manufacturer should have known about the risk and was extremely negligent in not providing warnings about it.

Under these circumstances, the drug's manufacturer will be liable for the harm resulting from its negligence. If the story changes in one small way, however, controversy and doubt will surround the patient's case. Imagine that several companies manufacture the drug in question. One of them invented the drug, first brought it to market, and still sells it under a unique brand name. When that company's patent on the drug expired, other companies began making and selling generic duplicates. In addition to reproducing the drug itself, the generic drug manufacturers copied verbatim all the warnings and other information on the brand-name drug's labeling. When the hypothetical patient took her doctor's prescription to a pharmacy, the pharmacist gave her one of the generic versions of the drug rather than the brand-name product.

Assuming again that each of the drug makers should have known about the risk and that each acted unreasonably in not providing warnings about it, one might think the plaintiff would still have some legal remedy for her injuries. The fact that the patient received the generic drug, however, will drastically complicate her case and may prevent her from recovering compensation from anyone. If the patient sues the manufacturer of the brand-name drug, that manufacturer will insist it cannot be liable because the patient did not consume its product. If the patient sues the manufacturer of the generic drug she received, that manufacturer will insist it cannot be liable because the patient's doctor did not look at or rely upon the generic product's labeling or any other information disseminated by the generic manufacturer. In other words, one manufacturer supplied the drug that the patient received but not the information that her doctor saw; the other manufacturer provided the information but not the drug. According to the drug companies, this means neither manufacturer can be held responsible for the patient's injuries.

Courts have confronted this sort of situation many times over the past two decades. Until recently, precedent almost uniformly favored defendants. The U.S. Court of Appeals for the Fourth Circuit rendered the seminal decision on the issue in 1994, ruling in *Foster v. American Home Products Corp.*[1] that a brand-name drug manufacturer could not be held liable for injuries suffered by a patient who took the generic equivalent of the manufacturer's product.[2] Other courts around the country consistently followed the Fourth Circuit's lead, rejecting various types of claims asserted against brand-name manufacturers by plaintiffs who took generic drugs.[3] Although these decisions did not completely rule out the possibility that the generic drug's manufacturer could be held liable, they left plaintiffs with the difficult task of finding a way around the fact that doctors rarely see or otherwise rely directly upon any information produced by the generic manufacturer.

The issue seemed settled until the California Court of Appeal's startling 2008 decision in *Conte v. Wyeth, Inc.*[4] Rejecting the reasoning of *Foster* and the long line of cases that followed it, the California court held that a brand-name manufacturer could be liable when the plaintiff took the generic version of the drug but alleged that her doctor relied on negligent misrepresentations made by the brand-name manufacturer.[5] Despite ruling in the plaintiff's favor on the claim against the brand-name drug maker, the court held that the generic manufacturer could not be held liable because the plaintiff's doctor did not rely upon any information from that company.[6] The *Conte* opinion thus reached the seemingly odd conclusion that the only manufacturer that could be held liable for plaintiff's injuries was one that did not make the drug that the plaintiff received.

Virtually all of the reaction to the *Conte* decision has been intensely negative. Commentators have mercilessly lambasted the California court for concluding that a drug manufacturer could be liable for injuries suffered by someone who took another company's product.[7] Lawyers who represent drug companies put *Conte* at the

1. Foster v. Am. Home Prods. Corp., 29 F.3d 165 (4th Cir. 1994).

2. *Id.* at 171–72. For a more detailed account of the case, see *infra* Part II.A.

3. *See infra* Part II.B.

4. Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Ct. App. 2008). For a more detailed account of the case, see *infra* Part II.C.

5. *Conte*, 85 Cal. Rptr. 3d at 307–18.

6. *Id.* at 318–20.

7. *See infra* Part II.D.

head of the list of "worst drug and medical device product liability decisions of the year,"[8] and tort reform advocates condemned it as "bad law, bad public policy and a national embarrassment."[9] Likewise, other courts, now facing a split of authority on the issue, have been nearly unanimous in condemning *Conte*'s reasoning, siding with the older precedent of *Foster* and its progeny, and rejecting any attempts to hold brand-name drug manufacturers liable for generic drug injuries.[10]

The issue has seized the attention of lawyers who represent plaintiffs and those who represent defendants in prescription drug litigation. Moreover, the ways in which courts think about and resolve the issue could have profound implications that extend well beyond the pharmaceutical context to cases involving other sorts of products. Despite its intricacy and importance, the issue has received very little scholarly attention to date.[11]

This Article argues that plaintiffs who took generic drugs should be able to hold brand-name drug manufacturers liable in some circumstances. Although courts and commentators have overwhelmingly sided with the drug manufacturers, treating the *Conte* decision as a lonely and misguided deviation from past precedents and sound principles of products liability law, I contend that *Conte* should instead be seen as the first case in which a court finally got this issue right. The *Conte* court saw through distracting mischaracterizations of the issue that plagued judicial analysis in

8. James M. Beck & Mark Herrmann, *Top Ten Best and Worst Prescription Drug/Medical Device Decisions of 2008—The Worst*, DRUG & DEVICE L. (Dec. 23, 2008, 8:00 AM), http://druganddevicelaw.blogspot.com/2008/12/top-ten-best-and-worst-prescription.html.

9. Lawrence J. McQuillan & K. Lloyd Billingsley, *Opinion: Don't Hold Drugmakers Liable for Competitors' Generics*, SAN JOSE MERCURY NEWS, Feb. 15, 2009, at 13A.

10. *See infra* Part II.D.

11. The discussion in law journals by legal academics and students has been limited. *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 (2010) (criticizing the *Conte* decision); Jean A. Brodie, Casenote, Foster v. American Home Products Corp.*: Tort Liability for Injuries Caused by Someone Else's Product?*, 12 T.M. COOLEY L. REV. 431 (1995) (arguing that the *Foster* case was rightly decided); Beatrice Skye Resendes, Note, *The Extinct Distinction of Privity: When a Generic Drug Label Fails to Warn, the Drug's Pioneer Should Be Liable as Component Part Supplier of the Warning Label*, 32 T. JEFFERSON L. REV. 95 (2009) (arguing that brand-name drug makers should be subject to strict liability on the ground that a generic drug's warning label is essentially a component supplied by the brand-name product's manufacturer). Lawyers who represent drug companies have also argued that *Conte* was wrongly decided. *See* Bridget M. Ahmann & Erin M. Verneris, *Name Brand Exposure for Generic Drug Use: Prescription for Liability*, 32 HAMLINE L. REV. 767 (2009).

Foster and other past cases. Applying basic rules of liability for negligence, the court correctly recognized that a manufacturer may be liable in some instances for tortious conduct other than having made or sold the product that inflicted plaintiff's injuries. Although all questions about liability for prescription drugs should be handled with special care because of the unique difficulty of developing new drugs and their immense potential benefits for consumers, the *Conte* court soundly concluded that fairness and policy considerations ultimately weigh against giving brand-name manufacturers complete immunity from liability for generic drug injuries.

At the same time, the *Conte* court erred in concluding that only the brand-name drug maker, and not the manufacturer of the generic drug that the plaintiff received, could be liable. The court allowed the generic manufacturer to escape liability on the ground that it did not supply any of the information the plaintiff's doctor considered in deciding to prescribe the drug. Given that doctors seldom see generic drug labeling or other information disseminated by generic manufacturers, this approach essentially amounts to absolving generic manufacturers of all liability for inadequate warnings or misrepresentations about their products. This creates far too much of an imbalance between the potential liability of the brand-name manufacturer and its generic counterparts, with the former bearing a disproportionate share of the burden of liability when brand-name and generic manufacturers alike provided inadequate or inaccurate information about the drug.

Drawing on these critical assessments of *Conte* and previous court decisions, this Article proposes a new general framework for drug manufacturer liability. The proposed scheme recognizes that in some instances a plaintiff can assert viable claims against both the brand-name and generic drug producers. For example, when the brand-name manufacturer caused the plaintiff's injuries by negligently designing the product or failing to give adequate warnings about its dangers, but the plaintiff took a generic version of the drug, sufficient grounds exist for imposing liability on both the brand-name and generic manufacturers. At the same time, the framework outlined here accepts the possibility of imposing liability on multiple manufacturers but strives to achieve a fair distribution of the responsibility among the manufacturers. The generic manufacturer in the above example profited from selling the product taken by the plaintiff, and its connection to the plaintiff's injuries is even stronger and more direct than that of the brand-name manufacturer. As a

result, the generic manufacturer should bear primary liability for the plaintiff's injuries, with the brand-name manufacturer having only secondary liability in the event that the generic drug maker has gone out of business or is otherwise unable to pay the damages. With its pivotal distinction between primarily and secondarily liable tortfeasors, this framework can be applied in other complex torts scenarios and therefore has implications far beyond the context of prescription drug liability.

Part I of this Article provides an overview of the federal regulatory scheme governing brand-name and generic drugs. It focuses on the regulations concerning changes to drug labeling because the ability of brand-name and generic manufacturers to change their product's labeling is a crucial part of the debate over what liability they should face under tort law. Part I also provides a basic look at the various types of claims that can be asserted in products liability cases. Part II then examines the court decisions regarding liability of brand-name and generic drug manufacturers. It follows the history from the Fourth Circuit's highly influential ruling in the *Foster* case and the long line of cases in which other courts embraced *Foster*'s reasoning to the California Court of Appeal's bold decision in *Conte* to defy that precedent. Part III delves into the complex array of arguments made in these cases by plaintiffs and defendants. Which of the arguments should prevail is a close and difficult question, whether viewed in terms of tort law principles or policy, but the analysis ultimately tips toward plaintiffs. Part III therefore concludes that a brand-name drug manufacturer should be held liable when it negligently causes harm to plaintiffs taking the generic equivalent of its product. Finally, Part IV lays out in more detail a proposed approach to imposing liability on brand-name and generic drug manufacturers.

I. BACKGROUND

The issues raised by cases like *Foster* and *Conte* lie at the intersection of two intricate and often controversial bodies of law. This Part begins with an overview of the first of those areas, the federal regulatory scheme governing prescription drugs, and focuses in particular on how federal law enables generic and brand-name manufacturers to exercise control over a drug's labeling. It then introduces the basic principles of state tort law that govern products liability claims.

A. Brand-Name and Generic Drugs

Federal law requires pharmaceutical companies to obtain approval from the U.S. Food and Drug Administration (FDA) before distributing any new drugs.[12] A manufacturer submitting a new drug application to the FDA must provide extensive test data and other information to show that the drug is both safe and effective.[13] The manufacturer also must provide the labeling it proposes to use for the drug, including the instructions and warnings about the drug's potential dangers.[14]

The FDA approval process is expensive, time consuming, and unpredictable.[15] A manufacturer faces an average wait of approximately eight and one-half years between the time it synthesizes a new drug and the point when the FDA approves the drug for sale.[16] Developing a new drug and obtaining FDA approval

12. 21 U.S.C. § 355(a) (2006). Federal law technically applies only to drugs "introduce[d] or deliver[ed] for introduction into interstate commerce," *id.*, but the FDA's jurisdiction has been interpreted broadly so that it essentially covers all business that drug companies conduct in the United States, *see, e.g.*, FDA, COMPLIANCE POLICY GUIDE § 100.200 (2009), http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073820.htm (asserting that the FDA has jurisdiction over any pharmaceutical product containing an ingredient that was shipped in interstate commerce).

13. 21 U.S.C. § 355(b)(1).

14. *Id.* § 355(b)(1)(F). Detailed specifications for a drug's labeling can be found at 21 C.F.R. § 201.80 (2010).

15. *See, e.g.*, James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs* Are *Different*, 111 YALE L.J. 151, 164–66 (2001) (describing the FDA drug approval process—which requires animal testing and three phases of human clinical testing, during each of which the FDA can request further testing or studies).

16. Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVS. DRUG DISCOVERY 417, 418 fig.1 (2004) (estimating that research, development, testing, and FDA review of a new drug takes a minimum of three years, an average of eight and one-half years, and sometimes as long as twenty years).

for it can cost hundreds of millions of dollars.[17] Most drugs never receive FDA approval.[18]

The financial rewards for obtaining FDA approval of a new drug can be substantial. The drug's developer typically obtains a patent that gives it the exclusive right to make and sell the drug for a limited time. Though a patent is generally effective for twenty years after filing of the patent application,[19] much of that time could be consumed by the process of obtaining FDA approval to begin selling the drug.[20] A special provision in federal law therefore permits drug companies to seek up to a five-year extension of a patent's lifespan.[21] Drug companies have a number of other tactics for attempting to stretch the duration of their patents,[22] but the manufacturer's monopoly over any drug eventually will come to an end. For any profitable drug, a host of other pharmaceutical companies will be waiting to pounce and begin selling generic versions when patent protection expires.[23]

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17. The average cost of developing a new drug is often estimated to be over $800 million. *E.g.*, Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 510–11 (2009). Skeptics contend that the $800 million figure is a gross exaggeration, but concede that the average cost of developing a new drug is at least $100 million. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 37–41 (2004) (estimating that the cost of research and development before taxes was approximately $265 million per drug in 2000 and $455 million per drug in 2001); MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS 236–46 (2004) (noting that studies by the Public Citizen and Global Alliance estimated that the cost of developing a new drug is between $115 million and $240 million).

18. Henderson & Twerski, *supra* note 15, at 163 n.46 ("An estimated three-fourths of all drugs for which drug manufacturers seek marketing approval fail to reach the market due largely to concerns regarding safety and efficacy, as well as undercapitalization of manufacturers.").

19. 35 U.S.C. § 154(a)(2) (2006).

20. Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 52 (2003).

21. 35 U.S.C. § 156(g)(6)(A).

22. *See* Melody Wirz, *Are Patents Really Limited to 20 Years?—A Closer Look at Pharmaceuticals*, 1 OKLA. J.L. & TECH. 5, 3–7 (2003), http://www.okjolt.com/images/pdf/2003okjoltrev5.pdf (describing four ways that brand-name drug manufacturers effectively extend the life of their patents: using legislative loopholes and lobbying, initiating litigation alleging patent infringement, layering patents and combining drugs to create new patents, and advertising and developing brand names to increase barriers to generic entry).

23. A generic manufacturer that successfully challenges the validity of the brand-name manufacturer's patent, rather than waiting for the patent to expire, may be rewarded with a 180-day exclusivity period during which no one else can sell a generic version of the product. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006) (allowing the first generic applicant to file an abbreviated new

Generic drug makers are not required to go through the same arduous application process as the drug's original manufacturer. They can instead submit "[a]bbreviated new drug applications" to the FDA,[24] a shortcut that saves time and money because it does not require any independent proof that the drug is safe or effective. In essence, the manufacturer seeking to begin selling a generic drug must show that its product will be a mere replica of the brand-name or "listed" drug already approved by the FDA. The generic drug maker must certify that the generic product will have the same active ingredient or ingredients as the listed drug; that its route of administration and strength will be the same as the listed drug; and that its instructions, warnings, and other labeling also will be identical to those of the listed drug.[25] Moreover, the generic and brand-name drugs must be "bioequivalent,"[26] meaning that the two drugs would have essentially the same effect on a person taking them.[27] This shortcut to FDA approval benefits consumers by speeding generic drugs to the market as soon as patent protection of the listed brand-name drug expires.[28]

Many doctors continue to prescribe a drug by its familiar brand name even after generic versions of the drug have become available. State laws give pharmacists the option to fill such prescriptions with the cheaper generic equivalent unless the doctor prohibited the pharmacist from doing so by including a specific notation such as "do not substitute" or "dispense as written" on the prescription.[29]

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drug application (ANDA) to sell its drug without competition from later ANDA applicants for 180 days).

24. *Id.* § 355(j).

25. *Id.* § 355(j)(2)(A). The regulations contain some narrow exceptions to these requirements, such as provisions under which differences between the generic drug and the listed drug can be specially approved by the FDA. *Id.* § 355(j)(2)(C); 21 C.F.R. § 314.93 (2010).

26. 21 U.S.C. § 355(j)(2)(A)(iv).

27. *Id.* § 355(j)(8)(B); 21 C.F.R. § 320.1(e) (defining "[b]ioequivalence" as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions").

28. If generic drug makers file ANDAs before the listed drug's patent protection expires, the FDA's approval to start marketing the generic drugs becomes effective as soon as the patent expires. 21 U.S.C. § 355(j)(2)(A)(vii)(III), (j)(5)(B)(ii).

29. *See* Thomas P. Christensen, Duane M. Kirking, Frank J. Ascione, Lynda S. Welage & Caroline A. Gaither, *Drug Product Selection: Legal Issues*, 41 J. AM. PHARM. ASS'N 868, 869 (2001) (noting that all states now have drug product-selection laws). For examples of typical state laws, see CAL. BUS. & PROF. CODE § 4073 (West 2007); N.Y. EDUC. LAW § 6810(6) (McKinney 2003); and TEX. OCC. CODE ANN. § 562.008 (West 2001).

Brand-name drug manufacturers spend billions of dollars every year to promote their products.[30] In addition to running advertisements and sending sales representatives to visit doctors, manufacturers pay to have information about brand-name drugs included in the *Physicians' Desk Reference*,[31] an annual publication that has become most doctors' primary source of information about drugs. The book is distributed to physicians free of charge, and it can be found in virtually every doctor's office, pharmacy, and clinic.[32] The entry for each drug in the *Physicians' Desk Reference* includes a verbatim reproduction of the product's FDA-approved labeling.[33]

Manufacturers sometimes continue to promote brand-name drugs aggressively even after generic versions have entered the market.[34] The brand-name manufacturers' hope is that doctors' familiarity with the brand names will continue to give their products an edge over the generic equivalents.[35]

Generic manufacturers, on the other hand, typically do not spend money to promote their products. Indeed, generic drug manufacturers' business model is to keep costs and prices low by spending nothing on advertising or other marketing, and instead to rely on the brand-name drug manufacturers' promotional efforts to generate sales of the product.[36] Though brand-name drug makers typically pay to have their products included in the *Physicians' Desk Reference*, for example, generic drug makers do not.[37]

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30. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 31–32 (2008) (estimating that drug companies spent $57.5 billion on promotional efforts in the United States in 2004, almost twice as much as they spent on research and development).

31. PHYSICIANS' DESK REFERENCE (64th ed. 2010).

32. Morlino v. Med. Ctr. of Ocean Cnty., 684 A.2d 944, 945 n.1 (N.J. Super. Ct. 1996).

33. Brief of Appellant at 5, Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Ct. App. 2008) (Nos. A116707, A117353), 2007 WL 3032224.

34. *See* Sarah P. Bryan & Thomas L. Hafemeister, *Beware Those Bearing Gifts: Physicians' Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 U. KAN. L. REV. 491, 505–06 (2009) ("Because manufacturers of generic drugs spend significantly less on marketing than their brand-name counterparts, doctors are probably 'less likely to think of generic alternatives' when writing prescriptions." (quoting Benjamin P. Falit, *Curbing Industry Sponsors' Incentive to Design Post-Approval Trials that Are Suboptimal for Informing Prescribers but More Likely than Optimal Designs to Yield Favorable Results*, 37 SETON HALL L. REV. 969, 1001 (2007))).

35. *Id.*

36. *See* Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1500–03 (2008) (describing how generic manufacturers free ride on brand-name manufacturers' extensive promotional efforts).

37. Brief of Appellant, *supra* note 33, at 5.

Generic drug manufacturers thus have the chance to earn substantial profits by riding on the coattails of brand-name manufacturers' efforts. With no new research or testing to be done, a generic manufacturer typically incurs relatively low costs in obtaining FDA approval to begin marketing a generic version of an existing drug.[38] The generic drug makers' share of the overall prescription drug market has been steadily rising, with pharmacists now turning to generic products to fill about two out of three prescriptions.[39]

Prescription drugs continue to be a booming business for brand-name as well as generic manufacturers. Total revenue from sales in the United States reached $234.1 billion in 2008, up from just $40.3 billion in 1990 and $120.6 billion in 2000.[40] Although drug companies' financial fortunes have slipped from the heights they reached a few years ago, when pharmaceutical manufacturing consistently topped lists of the nation's most profitable industries,[41] drug makers still enjoy a spot near the top of the most recent rankings with a robust 19.3 percent return on revenues and a 23 percent profit for shareholders.[42]

Drug makers, whether on the brand-name or generic sides of the business, believe claims brought against them under state tort law should be preempted by the federal laws that regulate drugs,[43] but those arguments have not been faring well in courts. In its 2009 ruling in *Wyeth v. Levine*,[44] the U.S. Supreme Court dealt a crushing blow to the argument that the FDA's approval of a drug and its labeling shields the manufacturer from state-law tort liability for failing to

38. Roin, *supra* note 17, at 510–11 (reporting estimates that the average cost of introducing a generic drug is only $2 million, compared to over $800 million for an original brand-name drug).

39. Micah Hartman, Anne Martin, Patricia McDonnell, Aaron Catlin & Nat'l Health Expenditure Accounts Team, *National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998*, 28 HEALTH AFF. 246, 250 (2009).

40. Micah Hartman, Anne Martin, Olivia Nuccio, Aaron Catlin & Nat'l Health Expenditure Accounts Team, *Health Spending Growth at a Historic Low in 2008*, 29 HEALTH AFF. 147, 148 exhibit 1 (2010).

41. GOOZNER, *supra* note 17, at 233.

42. *Top Industries: Most Profitable*, FORTUNE (May 4, 2009), http://money.cnn.com/magazines/fortune/fortune500/2009/performers/industries/profits.

43. For more detailed discussions of the drug industry's federal preemption arguments, see Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1095 (2007); Christina Marie Martin, Note, *Hugs and Drugs: Research Ethics, Conflict of Interest, and Why the FDA's Attempt to Preempt Pharma Failure-to-Warn Claims Is a Dangerous Prescription*, 6 AVE MARIA L. REV. 587, 593 (2008).

44. Wyeth v. Levine, 129 S. Ct. 1187 (2009).

provide adequate warnings.[45] That case involved a brand-name drug, so generic manufacturers maintained some hope that they could distinguish it by emphasizing the unique restraints that federal law imposes on them, such as the requirement that a generic drug have the same labeling as the brand-name product.[46] Federal district courts split over the issue,[47] federal appellate courts ruled against the generic manufacturers' preemption arguments, and the Supreme Court recently agreed to decide the issue.[48] Without a federal preemption defense, the proper scope of tort liability will continue to be a major issue for generic and brand-name drug makers alike. And if the Supreme Court should find that federal law preempts claims against generic drug manufacturers, the question of whether brand-name drug makers can be liable to those who took generic drugs will take on greater significance than ever before.

B. Labeling Requirements

One specific aspect of the federal regulation of prescription drugs is particularly relevant to the issue of how tort law should apply to brand-name and generic drug manufacturers: if a drug's labeling is dangerously inadequate or misleading, who can correct that problem? Despite some debate and disagreement surrounding this question, the bottom-line answer is that both the brand-name manufacturer and the generic producers of the drug have the ability and responsibility to fix flaws in drug labeling.

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45. *See id.* at 1204 ("Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.").

46. *See supra* note 25 and accompanying text.

47. *See* Kim M. Schmid & Shane V. Bohnen, *Generic Drugs and Preemption After* Wyeth v. Levine, 22 HEALTH LAW. 35, 36 & n.17 (2009).

48. *See* Demahy v. Actavis, Inc., 593 F.3d 428, 449 (5th Cir. 2010) ("Because state imposition of duties to warn on generic drug manufacturers neither renders compliance with federal regulation impossible nor obstructs the goals of that regulation, we affirm the district court's finding that the Demahy's state-law failure-to-warn claims are not preempted."), *cert. granted*, 78 U.S.L.W. 3745, 79 U.S.L.W. 3017, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-1501); Mensing v. Wyeth, Inc., 588 F.3d 603, 605–12 (8th Cir. 2009) ("[W]e decline to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this country and leave injured parties like Mensing no legal remedy."), *cert. granted sub nom.* PLIVA, Inc. v. Mensing, 78 U.S.L.W. 3522, 79 U.S.L.W. 3014, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-993), *and* Actavis Elizabeth, LLC v. Mensing, 78 U.S.L.W. 3523, 79 U.S.L.W. 3014, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-1039).

After it begins to sell a drug, a manufacturer has continuing obligations with respect to the drug's safety.[49] These include an obligation to add an additional warning to the label "as soon as there is reasonable evidence of a causal association" between a drug and a clinically significant hazard.[50] Indeed, pursuant to a regulatory measure known as the "Changes Being Effected" provision, a manufacturer can immediately revise a drug's label, without first obtaining FDA approval, if the change gives doctors reason to be more cautious about the drug.[51] This includes deleting from the label any "false, misleading, or unsupported indications" about the drug's use or effectiveness, as well as adding or strengthening statements on the label about "a contraindication, warning, precaution, or adverse reaction" or "an instruction about dosage and administration that is intended to increase the safe use of the drug product."[52]

The FDA has made clear that the obligation to seek labeling changes when safety concerns arise extends to generic drug makers.[53] When a generic drug manufacturer believes additional or

49. Federal law requires drug manufacturers to submit certain "postmarketing reports" to the FDA, including prompt reports of any serious and unexpected adverse experience suffered by a user of the drug, 21 C.F.R. § 314.80 (2010), and annual reports describing any other significant new information that might affect the safety, effectiveness, or labeling of the product, *id.* § 314.81. These reporting requirements are the same for generic drug makers as they are for brand-name drug producers. *Id.* § 314.98.

50. *Id.* § 201.57(c)(6) (subjecting drugs approved by the FDA after June 30, 2001, to the new rule); *see also id.* § 201.80(e) (providing the same rule for older drugs approved by the FDA before June 30, 2001).

51. *Id.* § 314.70(c)(6)(iii).

52. *Id.* § 314.70(c)(6)(iii)(A), (C)–(D). The FDA also has emphasized that adding text to the packaging and other materials provided with the drug is not the sole means by which a drug maker can seek to inform doctors of concerns about the safety of a product. In addition to warnings provided with the product itself, a manufacturer may opt to send additional information directly to physicians by issuing "Dear Doctor" letters containing new precautionary information about a drug. Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979); *see also* Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 686 (E.D. Pa. 2006) ("The FDA has made clear that warnings other than labeling changes, such as letters to health care professionals, are permissible and the labeling regulations do not bar them."). Such mailings may be considered part of the drug's labeling for FDA regulatory purposes. 21 C.F.R. § 202.1(l)(2).

53. *See* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992) ("If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.").

strengthened warnings should be given, or an erroneous or misleading statement should be corrected, the manufacturer must inform the FDA so that the FDA can determine whether the labeling for the drug should be revised.[54]

The tricky and controversial question is whether a generic drug manufacturer can unilaterally add or strengthen its warnings without prior FDA approval. Although a brand-name manufacturer can add or strengthen warnings without FDA approval pursuant to the "Changes Being Effected" regulation, the FDA has taken the position that generic drug manufacturers do not have the same power.[55] Many courts, however, have suggested that the "Changes Being Effected" regulation does allow generic manufactures to add or strengthen warnings without prior FDA approval.[56]

Uncertainty thus exists about whether a generic drug manufacturer can ever unilaterally change a drug's labeling, but there is no doubt that a generic drug manufacturer can ask the FDA for permission to add or strengthen the warnings in its labeling.[57] And as a result, any change to a drug's labeling will be synchronized, through FDA coordination, so that the change applies to both brand-name and generic versions of the drug, regardless of which manufacturer may have initiated the change. When the brand-name manufacturer modifies its labeling, the FDA will track the changes and notify generic drug makers that they must revise their labeling as well.[58] And when the FDA approves a labeling change requested by a generic manufacturer, the FDA will direct the brand-name manufacturer to make the same change so that the labeling for all versions of the drug remains consistent.[59] All manufacturers of a drug, including those producing it in generic form, thus share responsibility for identifying and eliminating dangers posed by insufficient or inaccurate labeling.

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54. *Id.*

55. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2,848, 2,849 n.1 (Jan. 16, 2008).

56. *E.g.*, Demahy v. Actavis, Inc., 593 F.3d 428, 439–44 (5th Cir. 2010), *cert. granted*, 78 U.S.L.W. 3745, 79 U.S.L.W. 3017, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-1501); Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169–70 (4th Cir. 1994); Stacel v. Teva Pharm., USA, 620 F. Supp. 2d 899, 905–07 (N.D. Ill. 2009).

57. *See* 21 C.F.R. § 314.70 (providing a mechanism for requesting FDA approval to make changes to labeling); *id.* § 314.97 (stating that generic drug manufacturers can seek permission, pursuant to 21 C.F.R. § 314.70, to make labeling changes).

58. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,961.

59. *Id.*

C. Products Liability

Having drawn this basic portrait of the federal regulatory scheme that governs prescription drugs, a brief sketch of products liability law is the next element that must be added into the picture. Products liability is a broad term that describes an entire field of law rather than a single cause of action.[60] It is largely a species of tort law, although it also has a significant vein of contract law embedded within it because the sale of a product is a contractual relationship.[61]

Products can be dangerous in an endless variety of ways, but four basic categories of problems dominate the field: manufacturing defects, design defects, inadequate warnings, and misrepresentations. Manufacturing defects result from errors made during production, such as the misplacement of a part by an assembly line worker in a factory.[62] A design defect, on the other hand, renders every unit of the product dangerous because of some flaw in the blueprints, recipe, or other design specifications originally developed for the product.[63] Other products liability claims relate to information about the product, rather than a flaw in the actual product itself. The warnings and instructions accompanying a product may be insufficient to protect users from the product's dangers,[64] and a misrepresentation or false statement about the product also may lead to accidents and injuries.[65]

To complicate matters, a plaintiff may assert each of these four basic types of products liability claims under any of three different legal theories—negligence, strict tort liability, and breach of warranty.[66] For example, a plaintiff injured by a product may simultaneously claim that the product's manufacturer acted negligently, assert that the manufacturer is subject to strict tort liability because the product was in a "defective" and "unreasonably dangerous" condition,[67] and argue that the manufacturer is liable for

60. DAVID G. OWEN, PRODUCTS LIABILITY LAW § 1.1, at 1, 3 (2d ed. 2008).

61. Professor William Prosser famously and vividly described breach of warranty, a type of products liability claim, as "a freak hybrid born of the illicit intercourse of tort and contract." William L. Prosser, *Assault upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1126 (1960).

62. OWEN, *supra* note 60, § 7.1, at 446.

63. *Id.* § 8.1, at 499.

64. *Id.* § 9.1, at 581.

65. *Id.* § 3.1, at 113–14.

66. *Id.* § 1.3, at 29–34.

67. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

breaching an implied warranty that the product would be "fit for the ordinary purposes for which such goods are used."[68] Although negligence is the "classic products liability claim" and continues to have an important role in products liability law, it has been overshadowed in recent decades by strict tort liability and breach of warranty.[69] A negligence claim requires proof that the defendant failed to exercise reasonable care; strict tort liability and breach of warranty claims do not necessarily require any proof of carelessness or other fault.[70] Strict tort liability and breach of warranty therefore are two theories under which strict or no-fault liability could be imposed.[71] As a result, these claims are often easier to prove than negligence claims and may be the most potent weapons for plaintiffs in products liability cases and the most severe threat to defendants.[72]

Although no-fault liability theories have advantages for plaintiffs, they also come with a variety of important limitations that

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68. U.C.C. § 2-314(2)(c) (1978).

69. OWEN, *supra* note 60, § 2.1, at 60–61.

70. *See* Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 900–01 (Cal. 1963) (describing how strict liability had been imposed on manufacturers via breach of warranty claims and concluding that strict liability should be imposed under tort law as well).

71. OWEN, *supra* note 60, § 5.9, at 329–31 (discussing the distinction between strict liability and negligence). Intense controversy exists about the extent to which courts truly impose strict liability in products cases. Many contend that strict liability has been more of an illusion than a reality, with courts paying lip service to the notion of strict liability even when actually using a negligence or fault-based approach. *See* Sheila L. Birnbaum, *Unmasking the Test for Design Defect: From Negligence (to Warranty) to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 643–49 (1980) ("Imposing a negligence standard for design defect liability is in many cases only to define in a coherent fashion what litigants are in fact arguing and what jurors are in essence analyzing."); James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 271–73 (1990) (asserting that, in attempting to reconcile the "rhetoric" of strict liability with "traditional negligence balancing," some courts have "create[d] verbal distinctions that have little practical consequence other than to confuse litigants and commentators"); David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth*, 1996 U. ILL. L. REV. 743, 785–86 ("As courts and commentators have come to recognize the inherent unworkability, illogic, and even incomprehensibility of such a doctrine in design and warnings cases, the very idea that liability in these central contexts is 'strict' has been viewed increasingly as a myth."); Ellen Wertheimer, *Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes Back*, 60 U. CIN. L. REV. 1183, 1269–71 (1992) ("Strict products liability has been abolished by judicial decisions . . . that were faithless to the goals and purposes for which strict products liability was adopted.").

72. *But see* Richard L. Cupp Jr. & Danielle Polage, *The Rhetoric of Strict Products Liability Versus Negligence: An Empirical Analysis*, 77 N.Y.U. L. REV. 874, 940 (2002) (suggesting that strict liability theories may not actually provide an advantage to plaintiffs because juries respond more favorably to claims phrased in terms of negligence rather than liability without fault).

do not apply to negligence claims.[73] In particular, both strict tort liability and warranties claims are special, narrow theories that pertain only to a limited set of situations. Strict tort liability applies only to "[o]ne who sells" a product that is defective and unreasonably dangerous.[74] Likewise, liability for breach of warranty can be imposed only on those who sold the product that harmed the plaintiff.[75] Negligence, on the other hand, is a far more general, universal theory of liability. It applies to situations within the field of products liability law that the no-fault theories do not reach, and it also extends far beyond products liability law to a vast array of other situations in which injuries occur. Negligence is essentially the all-purpose tool of tort law, and its scope is much wider than that of more specialized instruments like strict tort liability or warranties.

Determining how this array of potential grounds for liability should apply to prescription drugs is perhaps the single most controversial and confusing area within products liability law.[76] Courts and commentators are virtually unanimous in feeling that "drugs are different" from other products because they offer extraordinary potential benefits to humanity while also posing severe potential dangers, but intense disagreement exists over the implications of those differences.[77] The debate over liability of brand-name and generic drug manufacturers represents another fierce clash on this already "war-weary terrain."[78]

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73. OWEN, *supra* note 60, § 2.1, at 60–61.

74. RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965); *see also id.* § 402B (imposing strict liability on one who makes misrepresentations about a product "sold by him"). The *Third Restatement on Products Liability* also addresses only the liability of those who sold the product in question. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1, 9 (1998) (providing liability rules for "[o]ne engaged in the business of selling or otherwise distributing products").

75. U.C.C. §§ 2-313, 2-314, 2-315 (1978).

76. OWEN, *supra* note 60, § 8.10, at 566–67 ("Whether and how prescription drugs in particular should be treated differently from other types of products has consumed more time and effort, and resulted in the gnashing of more teeth, than about any other particularized issue in all of products liability law.").

77. Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 209–10 (1999); *see also* OWEN, *supra* note 60, § 8.10, at 566–80 (describing the controversy over design-defect claims concerning prescription drugs); *id.* § 9.6, at 627–45 (describing the controversy over inadequate warning claims concerning prescription drugs).

78. OWEN, *supra* note 60, § 8.10, at 568.

II. THE CASES

With this background in mind, this Part turns to the specific problem of injuries suffered by those who take a generic version of a prescription drug. The Fourth Circuit's ruling in *Foster v. American Home Products Corp.* and the California Court of Appeal's decision in *Conte v. Wyeth, Inc.* dominate the landscape examined here.[79] I review the factual background of each case in close detail, both because they are the most significant precedents and also because these decisions concern real problems that have serious consequences for plaintiffs and defendants alike. Though it might be easy to lapse into thinking about the legal issues in more abstract terms, the reality is that very significant interests, with tangible impacts on many people's lives, are at stake on both sides of these cases.

A. Foster v. American Home Products Corp.

Craig and Karen Foster were the parents of infant twins, a girl named Brandy and a boy named Bradley.[80] When the twins were six weeks old, they had a bout of colic,[81] a common condition characterized by irritability, crying, and apparent abdominal pain.[82] The Fosters took the twins to their pediatrician, who prescribed Phenergan syrup,[83] a brand-name antihistamine and sedative drug used to treat allergies and many other medical conditions.[84] The pharmacist who filled the prescription substituted promethazine syrup, the generic version of the prescribed drug.[85] The Fosters gave the generic product to the babies several times over the next few days.[86] On September 11, 1988, the morning after they last gave the drug to the twins, the Fosters found Brandy dead in her crib.[87] Doctors concluded that Brandy died as a result of Sudden Infant Death Syndrome (SIDS) caused by use of the drug.[88]

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79. *See supra* notes 1–6 and accompanying text.

80. Foster v. Am. Home Prods. Corp., 29 F.3d 165, 167 (4th Cir. 1994).

81. *Id.*

82. Russell S. Agnes & Richard L. Mones, *Infantile Colic: A Review*, 4 J. DEVELOPMENTAL & BEHAV. PEDIATRICS 57, 57 (1983).

83. *Foster*, 29 F.3d at 167.

84. *Phenergan*, DRUGS.COM, http://www.drugs.com/phenergan.html (last visited Jan. 5, 2011).

85. *Foster*, 29 F.3d at 167.

86. *Id.*

87. *Id.*

88. *Id.*

The Fosters sued the manufacturer of the brand-name drug their doctor prescribed, as well as the manufacturer of the generic version they actually received from the pharmacy and gave to their daughter before her death.[89] The Fosters pointed to medical studies showing that the drug posed a significant risk of causing SIDS.[90] The Fosters alleged that the brand-name manufacturer had been aware of these studies prior to Brandy's death but ignored them because stronger warnings about the drug's dangers for young children would have reduced sales of the product and interfered with the company's hopes of winning FDA approval to sell the drug as an over-the-counter product.[91] Although the drug's labeling contained statements advising that the product was "not recommended for children under 2 years of age"[92] and "should not be used in children under 2 years of age because safety for such use has not been established,"[93] the Fosters characterized those statements as standard "legalistic" language that merely indicated the manufacturer had not yet done specific studies to document the drug's safety for children.[94] The Fosters argued that these sorts of statements frequently appeared on the labeling of drugs widely prescribed for young children's use, and that doctors interpreted them as meaning that the manufacturer had no reason to think the drug posed any special problems for children.[95] The Fosters further alleged that the brand-name manufacturer had explicitly

89. *Id.* After filing their lawsuit, the Fosters learned that they had sued the wrong generic drug manufacturer. The generic drug taken by their daughter had been manufactured by My-K Laboratories, not Barre-National Corporation, as the Fosters initially believed. The Fosters' claims against Barre-National thus were dismissed, and the Fosters filed a new action against My-K Laboratories. *Id.*

90. Several articles were written before Brandy Foster's death. *See* André Kahn & Denise Blum, *Phenothiazines and Sudden Infant Death Syndrome*, 70 PEDIATRICS 75 (1982) (reporting the findings of a study concluding that phenothiazine is related to SIDS); André Kahn & Denise Blum, *Possible Role of Phenothiazines in Sudden Infant Death*, 314 LANCET 364 (1979) (presenting evidence of a relationship between the administration of a phenothiazine and sleep apnea, which could be related to SIDS); André Kahn, Daniele Hasaerts & Denise Blum, *Phenothiazine-Induced Sleep Apneas in Normal Infants*, 75 PEDIATRICS 844 (1985) (reporting the findings of a study concluding that phenothiazine is related to SIDS). Promethazine, the drug taken by Brandy Foster, is a phenothiazine derivative. Stewart v. Astrue, 551 F. Supp. 2d 1308, 1313 n.7 (N.D. Fla. 2008).

91. Brief of Appellants/Cross-Appellees at 6–7, *Foster*, 29 F.3d 165 (No. 93-1627), 1993 WL 13121590.

92. Brief of Appellee/Cross-Appellant at 35, *Foster*, 29 F.3d 165 (No. 93-1627), 1993 WL 13121591.

93. *Id.* at 5, 35.

94. Brief of Appellants/Cross-Appellees, *supra* note 91, at 17–19, 30.

95. *Id.*

misrepresented the drug's safety for children by claiming in the drug's labeling and *Physicians' Desk Reference* entry that "[c]hildren tolerate this product well."[96] The brand-name manufacturer also promoted Phenergan products with advertisements that featured illustrations of the Seven Dwarfs from the fairy tale Snow White and touted the drug's benefits for kids with coughs, colds, and allergies.[97]

One of the key factual questions in the case was what motivated the Fosters' pediatrician to prescribe the drug, but the evidence on that point was muddled. The doctor stated that he had never seen, and therefore had never relied upon, any information from the drug's generic manufacturers.[98] The extent to which he relied on labeling, advertising, or other information generated by the brand-name manufacturer was much less clear. In a deposition, the doctor testified that he had been familiar with Phenergan since he received his initial medical training, and that he had used it many times in treating patients throughout his career as a pediatrician.[99] He said that Phenergan had been so widely used, for so many years, that he considered it to be "like using Tylenol or things of that nature."[100] The doctor further testified that he generally relied on manufacturers to advise him of a drug's potential dangers, and that he obtained information about Phenergan from the manufacturer's advertising and from reading newsletters and other medical literature.[101] The doctor added that he would not have prescribed Phenergan for the Foster children if he had been warned about the studies linking the drug to SIDS.[102] Indeed, after Brandy Foster's death made him aware of the drug's dangers, the doctor stopped prescribing the drug for children less than two years of age.[103]

After his deposition, however, the doctor agreed to sign an affidavit in support of the brand-name manufacturer's motion for summary judgment.[104] In the affidavit, the doctor denied that he had

96. *Id.* at 6, 11–12.

97. Brief of Appellee/Cross-Appellant, *supra* note 92, at 37.

98. Brief of Appellants/Cross-Appellees, *supra* note 91, at 8–9.

99. *Id.* at 16; Brief of Appellee/Cross-Appellant, *supra* note 92, at 32.

100. Brief of Appellee/Cross-Appellant, *supra* note 92, at 38.

101. Brief of Appellants/Cross-Appellees, *supra* note 91, at 15–16, 19–20.

102. *Id.* at 9, 15–17.

103. *Id.* at 17–18.

104. *See* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 168 (4th Cir. 1994) ("With its motion Wyeth filed an affidavit signed by Dr. Berger stating that he prescribed Phenergan for

relied on any information from the manufacturer and instead stated that in prescribing the drug for the Foster children, he had "relied upon [his] many years of positive experience in using Phenergan to treat patients."[105] The doctor added that his decision to prescribe the drug was not influenced by the *Physicians' Desk Reference*, and that he could not remember how long it had been since he had read that book's entry on the drug.[106] Although he had been visited periodically by the brand-name manufacturer's sales representatives, he could not remember what they talked about with him, and their conversations did not influence his decision to prescribe the drug.[107] Likewise, although he had seen numerous advertisements for the brand-name drug over the years, he could not remember much about their contents, and he had not relied on them in prescribing the drug.[108]

The doctor's affidavit did not directly contradict his deposition testimony, but it put a very different spin on the situation. The affidavit focused narrowly on the doctor's specific thoughts at the moment he prescribed the drug for the Fosters' children, whereas the deposition more broadly addressed the sources of information that, over time, had shaped the doctor's perceptions of the drug, its safety, and its appropriate uses.

The Fosters faced a devilish legal dilemma. Their doctor had prescribed a brand-name drug, but their pharmacist had given them a generic substitute made by another company. The doctor affirmed that he would not have prescribed the drug if he had been adequately warned about its dangers, and yet the doctor vowed that in prescribing the drug he had not relied on anything the drug companies had ever said about their products. One manufacturer was responsible for promoting the drug and crafting its allegedly inadequate warnings; another was responsible for actually concocting the syrup that Brandy received. And in the manufacturers' view, this meant neither could be held legally responsible for her death.

The Fosters ultimately were unable to prevail on any of their claims. Applying Maryland law, the trial judge threw out all but one of the claims against the brand-name manufacturer, concluding that

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Brandy based only on his own experience with the drug and did not rely on any representations made by Wyeth.").

105. Brief of Appellee/Cross-Appellant, *supra* note 92, at 32–33.

106. Brief of Appellants/Cross-Appellees, *supra* note 91, at 9; Brief of Appellee/Cross-Appellant, *supra* note 92, at 32–33.

107. Brief of Appellee/Cross-Appellant, *supra* note 92, at 33.

108. *Id.* at 33, 37–38.

negligent misrepresentation was the only potentially viable cause of action against that defendant because the plaintiffs' other claims were all products liability theories that could not be asserted against a company that did not manufacture or sell the drug that Brandy consumed.[109] While discovery was underway, the Fosters voluntarily agreed to dismiss their suit against the generic drug manufacturer for reasons not revealed by the record,[110] leaving their case focused entirely on their negligent misrepresentation claim against the brand-name drug manufacturer. The trial judge soon tossed that claim as well, concluding that the Fosters could not prove that their doctor had relied on any misrepresentations made by the brand-name manufacturer.[111]

The U.S. Court of Appeals for the Fourth Circuit affirmed the dismissal of the case, but rather than reach a narrow conclusion that the Fosters lacked sufficient evidence, the court issued a more sweeping pronouncement that a brand-name drug maker can never be liable for harm suffered by a person who takes a generic version of its drug.[112] The court declared that products liability claims can only be brought against those who manufactured or sold the product that caused the injury in question, and that plaintiffs cannot circumvent that limitation by cloaking their case in the guise of a negligent misrepresentation theory.[113] The court emphasized that the Fosters cited no previous cases in which a manufacturer had been held liable for injuries resulting from use of another manufacturer's product.[114] This demonstrated nothing more than the novelty of the issue, for apparently neither the defendant nor the court had found any past decisions specifically rejecting claims like those asserted by the Fosters. The court nevertheless concluded that precedent was on the defendant's side, citing irrelevant cases in which products liability claims failed because plaintiffs had no proof of any connection between the defendant and the plaintiff's injuries.[115] The Fourth

109. *Foster*, 29 F.3d at 167. The trial court thus rejected negligence, strict liability, and breach of warranty claims. *Id.*

110. Brief of Appellee/Cross-Appellant, *supra* note 92, at 11 n.8. The Fosters apparently did not sue their doctor. *Id.*

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

112. *Id.* at 168–72.

113. *Id*. at 168.

114. *Id.* at 170.

115. The *Foster* court cited *Tidler v. Eli Lilly & Co.*, 851 F.2d 418, 424 (D.C. Cir. 1988), and noted that the case held that Maryland does not recognize nonidentification theories such as

Circuit's opinion went on to suggest a litany of other reasons why the brand-name manufacturer should not be held liable: a brand-name manufacturer has no relationship with those who take generic versions of its products;[116] a brand-name manufacturer has no control over generic drug makers;[117] and a brand-name manufacturer already bears the immense cost of developing and promoting new drugs, from which generic competitors then profit by copying.[118]

In a curious bit of dicta, the court suggested that the generic drug maker, which was no longer a party in the case, could have been held liable for Brandy's death,[119] but the judges did not explore the ramifications of this suggestion. The court insisted that a generic drug company could be held liable for negligent misrepresentation even if all the statements it ever made about the drug were simply copied from the brand-name drug's labeling.[120] This observation, however, overlooked the more difficult issue of whether the generic drug manufacturer could be held liable even if the plaintiff's doctor never looked at the generic drug's labeling or received any other information from the generic drug maker. In other words, the Fourth Circuit judges felt that a generic manufacturer could not escape liability by pointing out that it did not write its own labeling. It is unclear what the court felt should happen when the generic manufacturer also asserts that nobody relied on its labeling.

A decade after the Fourth Circuit's decision, the FDA announced that a boxed warning would be added to the drug to bar it

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market share liability. *Foster*, 29 F.3d at 168. The *Foster* court also cited *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1163–64 (4th Cir. 1986), and noted that the case rejected claims where the plaintiff could not prove who manufactured the asbestos that allegedly caused his injuries. *Foster*, 29 F.3d at 168. The irrelevance of these nonidentification or indeterminate tortfeasor scenarios is discussed in further detail below. *See infra* Part III.B. The *Foster* court also quoted some broad, general dicta from *Jensen v. American Motors Corp.*, 437 A.2d 242 (Md. Ct. Spec. App. 1981), suggesting that every products liability claim requires "attribution of the defect to the seller" of the product. *Foster*, 29 F.3d at 168 (quoting *Jensen*, 437 A.2d at 247). The *Jensen* case had nothing to do with issues resembling those in the *Foster* case, and the dicta was based on authorities that likewise addressed unrelated issues. *See Jensen*, 437 A.2d at 247 (citing Edward S. Digges, Jr., *Product Liability in Maryland Revisited*, 7 U. BALT. L. REV. 1, 14 (1977)).

116. *Foster*, 29 F.3d at 171.

117. *Id.* at 170.

118. *Id.*

119. *Id.* at 169–70.

120. *Id.*

from being given to children less than two years of age.[121] A boxed warning, also known as a "black box warning,"[122] is the strongest type of warning that the agency can require.[123] The FDA called for adding this warning to promethazine after it reviewed reports it had been receiving since 1969 about children, like Brandy Foster, suffering respiratory depression and other serious adverse effects from taking the drug. The reports attributed the deaths of seven infants to the drug.[124]

B. Case Law after Foster

Foster proved to be an immensely valuable precedent for the drug industry. The Fourth Circuit's position became the prevailing view as courts all over the country followed its reasoning in rejecting claims brought by plaintiffs who tried to sue brand-name drug manufacturers despite having taken generic equivalents.[125] The judges

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121. Peter R. Starke, Joyce Weaver & Badrul A. Chowdhury, *Boxed Warning Added to Promethazine Labeling for Pediatric Use*, 352 NEW ENG. J. MED. 2653, 2653 (2005).

122. Raymond A. Mullady Jr., *Everything You Needed and Wanted to Know About Black Box Warnings*, 68 DEF. COUNSEL J. 50, 51 (2001).

123. *See* 21 C.F.R. § 201.57(c)(1) (2010) ("Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box.").

124. Starke et al., *supra* note 121, at 2653.

125. Smith v. Wyeth, Inc., No. 5:07-CV-18-R, 2008 WL 2677051, at *3–4 (W.D. Ky. June 30, 2008); Pustejovsky v. Wyeth, Inc., No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008); Barnhill v. Teva Pharm. USA, Inc., No. 06-0282-CB-M, 2007 WL 5787186, at *1 & n.2 (S.D. Ala. Apr. 24, 2007); Goldych v. Eli Lilly & Co., No. 5:04-CV-1477, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 538–43 (E.D. Pa. 2006), *aff'd in part and rev'd in part on other grounds*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009); Possa v. Eli Lilly & Co., No. 05-1307-JJB-SCR, 2006 WL 6393160, at *1 (M.D. La. May 10, 2006); Tarver v. Wyeth, Inc., No. Civ.A.3-04-2036, 2006 WL 1517546, at *2–3 (W.D. La. Jan. 26, 2006); Tarver v. Wyeth, Inc., No. Civ.A.3-04-2036, 2005 WL 4052382, at *2–3 (W.D. La. June 7, 2005); Sheeks v. Am. Home Prods. Corp., No. 02CV337, 2004 WL 4056060, at *2 (D. Colo. Oct. 15, 2004); Doe v. Ortho-Clinical Diagnostics, Inc., 335 F. Supp. 2d 614, 626–30 (M.D.N.C. 2004); Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368, 1376–77 (N.D. Ga. 2003); Block v. Wyeth, Inc., No. Civ.A.3:02-CV-1077, 2003 WL 203067, at *2–3 (N.D. Tex. Jan. 28, 2003); Beutella v. A.H. Robins Co., No. 980502372, 2001 WL 35669202, at *3 (D. Utah Dec. 10, 2001); Reynolds v. Anton, No. 01A-76719-3, slip op. at 14 (Ga. Super. Ct. Oct. 28, 2004), 2004 WL 5000272; Stanley v. Wyeth, Inc., 991 So. 2d 31, 34–35 (La. Ct. App. 2008); Kelly v. Wyeth, No. Civ.A.MICV200303314B, 2005 WL 4056740, at *2–5 (Mass. Super. Ct. May 6, 2005); Sloan v. Wyeth, No. MRS-L-1183-04, slip op. at 2–5, 10 (N.J. Super. Ct. Oct. 13, 2004), 2004 WL 5767103; *cf.* DaCosta v. Novartis AG, No. CV 01-800-BR, 2002 WL 31957424, at *9 (D. Or. Mar. 1, 2002) (holding that an individual sales representative of a pharmaceutical manufacturer could not be held liable when he did not promote the particular drug taken by the plaintiff); Flynn v. Am. Home Prods. Corp., 627 N.W.2d 342, 350–52 (Minn. Ct. App. 2001) (rejecting

in these cases did not seem to regard the issue as a close one. An appellate court in Florida, for example, rejected a plaintiff's claims against a brand-name drug manufacturer with an opinion consisting of nothing more than a citation of the *Foster* case.[126]

A few judges challenged the orthodox view, but their rulings could be brushed aside as minor deviations from the otherwise unanimous national consensus on the issue. For example, in *Easter v. Aventis Pasteur, Inc.*,[127] a federal judge in Texas held that the original designer of a pharmaceutical product could be held liable for harm resulting from a patient's use of other manufacturers' versions of the same product.[128] The case concerned a child allegedly exposed to harmful levels of mercury contained in thimerosal, a preservative used in pediatric vaccines.[129] The child's mother sued Eli Lilly & Co., even though that company had not manufactured the thimerosal in the vaccines received by her child.[130] The mother alleged that "for many years, Lilly, as the original designer of thimerosal, distorted published medical literature and deceived health regulators and physicians about the safety of thimerosal,"[131] and that thimerosal had become a widely used product because doctors, government regulators, and other manufacturers had relied on Lilly's misrepresentations.[132] Although Lilly insisted that it could not be held liable for harm suffered via use of products it played no part in manufacturing, the court held that Lilly knew other manufacturers had copied its design, was in the best position to know about the potential hazards of that design, and thus had a duty to warn about those risks.[133]

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misrepresentation claims against a brand-name drug manufacturer on the alternative grounds that federal law preempted the claims and that the manufacturer could not be liable for injuries suffered by a patient who consumed a generic version of the drug).

126. Sharp v. Leichus, 952 So. 2d 555, 555 (Fla. Dist. Ct. App. 2007), *aff'g* No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006).

127. Easter v. Aventis Pasteur, Inc., No. 5:03-CV-141(TJW), 2004 WL 3104610 (E.D. Tex. Feb. 11, 2004).

128. *Id.* at *10.

129. *Id.* at *1.

130. *Id.* at *2, 8.

131. *Id.* at *8.

132. *Id.*

133. *Id.* at *9.

A few years later, in *Clark v. Pfizer Inc.*,[134] a Pennsylvania trial court reached a similar conclusion in a case that involved only economic harm, not personal physical injuries.[135] The case concerned a drug approved by the FDA for treatment of epilepsy and neuralgia.[136] The plaintiffs accused the drug's brand-name manufacturer of illegally promoting the drug for other, unapproved uses.[137] The suit was brought as a class action on behalf of everyone who had purchased the drug, in its brand-name or generic form, with prescriptions written for off-label uses.[138] The plaintiffs did not claim to have been physically harmed by taking the drug; they simply sought refunds of the money they paid for it.[139] Insisting that it had no duty to consumers who purchased other companies' products, the brand-name manufacturer sought summary judgment on the claims of all class members who received the generic rather than the brand-name version of the drug.[140] The trial judge denied the motion, rejecting the argument that a brand-name manufacturer has no duty to those who receive the generic version of its product.[141] The judge reasoned that if the brand-name manufacturer fraudulently encouraged doctors to believe the drug was suitable for nonapproved uses, some patients would wind up receiving the generic drug for those off-label uses.[142] The judge thus saw no reason to draw a distinction between patients who took the generic drug and those who took the brand-name product, because all were harmed in equally foreseeable ways by the brand-name manufacturer's wrongdoing.[143]

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134. Clark v. Pfizer Inc., No. 1819, 2008 Phila. Ct. Com. Pl. LEXIS 74 (Pa. Ct. Com. Pl. Mar. 14, 2008).

135. *Id.* at *30–32.

136. *Id.* at *1.

137. *Id.* at *2. Indeed, as part of a plea agreement to a criminal charge, one of the drug's manufacturers had agreed to pay a $240 million fine and to stop promoting the drug for off-label use. *Id.*

138. *Id.* at *1.

139. *See id.* at *30 (discussing the validity of plaintiffs' "claims for reimbursement of sums spent").

140. *Id.* at *1.

141. *See id.* at *28–30 (applying a five-factor test to determine that the brand-name manufacturer owed a duty to those who received the generic version of the drug). The judge, however, ruled that the manufacturer could not be held liable for breach of warranty to those who did not purchase its product. *Id.* at *1, *31.

142. *Id.* at *21–22.

143. Much of the brand-name manufacturer's alleged wrongdoing in the *Clark* case occurred while the brand-name drug was still under patent protection and no generic version of the drug was even available. *Id.* at *19–20. This did not deter the judge from ruling that the brand-name

The *Clark* ruling thus made another small dent in the line of precedent after *Foster*, but it drew little attention.[144] The California Court of Appeal was, however, about to deliver a more significant blow.

C. Conte v. Wyeth, Inc.

Elizabeth Conte was about sixty years old when she began to experience problems with food from her stomach backing up into her throat.[145] After about a month of discomfort from this condition, commonly known as heartburn or acid reflux,[146] Conte saw a doctor about the problem.[147] She then began taking metoclopramide,[148] a prescription drug manufactured and sold by Wyeth, Inc. under the brand name Reglan but also produced by a number of generic manufacturers.[149] The drug essentially blocks reception of certain neurotransmitters, thereby stimulating gastrointestinal nerves and muscles to make the stomach empty more rapidly into the intestines.[150]

In 2003, about three years after she started taking the drug, Conte began to experience mild involuntary movements of her mouth.[151] The condition soon worsened, with the uncontrollable movements of her mouth and tongue becoming more severe.[152] Conte's toes began to move involuntarily as well.[153] Conte saw a neurologist who determined that she was suffering from a neurological disorder known as tardive dyskinesia, caused by her

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manufacturer might be liable to those who eventually took the generic drug because the brand-name manufacturer could easily foresee that generic versions of the drug would become available as soon as the brand-name drug's patent expired. *Id.* at *21–22.

144. The judge later decertified the plaintiff class. Clark v. Pfizer Inc., No. 1819, 2009 WL 1725953, at *6 (Pa. Ct. Com. Pl. Apr. 20, 2009), *aff'd in part and vacated in part*, 990 A.2d 17 (Pa. Super. Ct. 2010).

145. *See* Respondent Wyeth's Brief at 4, Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Ct. App. 2008) (Nos. A116707, A117353), 2008 WL 684752.

146. *See generally* John F. Johanson, *Epidemiology of Esophageal and Supraesophageal Reflux Injuries*, 108 AM. J. MED. 99S, 99S (Supp. 4A 2000) (equating individuals suffering from "symptoms of heartburn" with people suffering from gastroesophageal reflux disease).

147. Respondent Wyeth's Brief, *supra* note 145, at 4.

148. *Id.*

149. *Id.* at 1.

150. *See Reglan*, RXLIST, http://www.rxlist.com/reglan-drug.htm (last visited Jan. 5, 2011).

151. Complaint for Damages ¶ 20, Conte v. Wyeth, Inc., No. CGC-04-437382 (Cal. Super. Ct. Dec. 2, 2005), 2005 WL 5168019.

152. *Id.*

153. *Id.*

long-term use of metoclopramide to treat her heartburn symptoms.[154] Tardive dyskinesia produces persistent, repetitive involuntary movements, particularly in the muscles of the lower face. These movements, including facial grimacing and tongue thrusting, "are often severe, distressing, and incapacitating,"[155] and may lead to life-threatening respiratory difficulties.[156] No cure exists for tardive dyskinesia, and little can be done to treat the condition once it has begun.[157]

Conte filed a lawsuit against her doctor, the manufacturer of the brand-name drug, and three companies that produced the drug in generic form.[158] She acknowledged that she consumed only the generic versions of the drug.[159]

Significant confusion soon arose about the facts surrounding Conte's prescriptions for the drug. Conte alleged that she took the drug, which her gastroenterologist prescribed, from about August 2000 until about April 2004.[160] The doctor, however, denied that he had ever prescribed the drug for Conte.[161] Pharmacy records seemed to show otherwise, indicating that Conte had received the drug, pursuant to prescriptions from the doctor, for at least two years.[162] Moreover, the doctor's assistant testified that she authorized a pharmacy to refill Conte's prescription on some occasions.[163]

Given that such confusion existed about the simple issue of whether Conte even received a prescription, it is not surprising that the evidence was also unclear on the more complex question of why

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154. *Id.*

155. M. L'E. Orme & R.C. Tallis, *Metoclopramide and Tardive Dyskinesia in the Elderly*, 289 BRIT. MED. J. 397, 398 (1984).

156. M. Reza Samie, Mary Anne Dannenhoffer & Susan Rozek, *Life-Threatening Tardive Dyskinesia Caused by Metoclopramide*, 2 MOVEMENT DISORDERS 125, 125 (1987).

157. Orme & Tallis, *supra* note 155, at 398.

158. Complaint for Damages, *supra* note 151, ¶¶ 2–14. The brand-name drug was initially produced by A.H. Robins Co., which was later acquired by Wyeth. Brief of Appellant, *supra* note 33, at 2 n.1. In 2001, during the period when Conte was taking the drug, Wyeth sold the rights to produce the brand-name product to another company, Schwarz Pharma, Inc. *Id.* at 3 n.1. Conte therefore asserted claims against both Wyeth and Schwarz Pharma as producers of the brand-name drug. Complaint for Damages, *supra* note 151, ¶¶ 2–4. For simplicity's sake, this Article will discuss the situation as though there was only one brand-name manufacturer of the drug; that there were actually two does not affect the analysis.

159. Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 309 (Ct. App. 2008).

160. Complaint for Damages, *supra* note 151, ¶¶ 17, 19.

161. Brief of Appellant, *supra* note 33, at 9.

162. *Id.* at 8–9, 9 n.6.

163. *Id.* at 9.

Conte's doctor prescribed the drug for her. Conte claimed that the doctor relied on information that the brand-name manufacturer disseminated through the *Physicians' Desk Reference*.[164] In his deposition, the doctor acknowledged that he probably had read the information about the drug in that book at some point during the residency period at the beginning of his medical career, that he believed the information he had read was accurate, and that the *Physicians' Desk Reference* generally was one of the sources he would refer to in prescribing Reglan for his patients.[165] The brand-name manufacturer, however, was able to obtain an affidavit from the doctor stating that he did not rely on the *Physicians' Desk Reference* or any other information from the brand-name manufacturer in deciding on a course of treatment for Conte.[166] It is hard to know what to make of the affidavit, given that the doctor denied even having prescribed the drug. In any event, whatever the doctor knew about the drug appeared to have come from the brand-name manufacturer and not the generic producers. Conte conceded that there was no evidence the doctor ever saw the generic products' labeling or any other information generated by the generic manufacturers.[167]

Whether the drug's labeling contained adequate warnings about the risk of tardive dyskinesia was another hotly disputed issue in the case. As early as 1978, articles in medical journals had raised concerns about a link between metoclopramide and tardive dyskinesia.[168] The evidence of an association between the drug and this disorder quickly accumulated,[169] and in 1985 the FDA required manufacturers of

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164. *Conte*, 85 Cal. Rptr. 3d at 307–08; Brief of Appellant, *supra* note 33, at 9.

165. *Conte*, 85 Cal. Rptr. 3d at 308 & n.6; Brief of Appellant, *supra* note 33, at 9; Respondent Wyeth's Brief, *supra* note 145, at 28.

166. *Conte*, 85 Cal. Rptr. 3d at 308; Brief of Appellant, *supra* note 33, at 9; Respondent Wyeth's Brief, *supra* note 145, at 28.

167. *Conte*, 85 Cal. Rptr. 3d at 318; Brief of Appellant, *supra* note 33, at 10.

168. *See* M. Kataria, M. Traub & C.D. Marsden, *Extrapyramidal Side-Effects of Metoclopramide*, 312 LANCET 1254, 1254 (1978) ("Metoclopramide has been associated with chronic tardive dyskinesia . . . ."); S. Lavy, E. Melamed & S. Penchas, *Tardive Dyskinesia Associated with Metoclopramide*, 1 BRIT. MED. J. 61, 77 (1978) ("Recently, acute facial dyskinesias . . . have been reported . . . shortly after administration of low doses of metoclopramide."); *see also* S. Melmed & H. Bank, *Metoclopramide and Facial Dyskinesia*, 1 BRIT. MED. J. 293, 331 (1975) (reporting two cases of acute or short-term episodes of facial dyskinesia by patients taking metoclopramide, but noting that they "seem to be unique and may signify an individual sensitivity to the drug").

169. *See, e.g.*, J. David Grimes, *Parkinsonism and Tardive Dyskinesia Associated with Long-Term Metoclopramide Therapy*, 305 NEW ENG. J. MED. 1417, 1417 (1981) (noting that "metoclopramide-induced parkinsonism and tardive dyskinesia have become frequent

metoclopramide to add a warning to the drug's labeling about this risk.[170] The warning stated that the drug was to be used as "short-term (4 to 12 weeks) therapy" for patients whose acid reflux failed to respond to other treatments, and that use for periods longer than twelve weeks "has not been evaluated and cannot be recommended."[171] The labeling noted that "approximately 1 in 500 patients" showed symptoms of neurological movement disorders within a short time after beginning to take the drug.[172] It went on to warn that the drug could cause tardive dyskinesia, particularly among elderly women, and that "[b]oth the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose."[173]

According to the drug's manufacturers, these warnings sufficed to apprise doctors of the risk of tardive dyskinesia from long-term use of metoclopramide.[174] Many plaintiffs like Conte have argued otherwise, pointing out that studies actually suggested the risk of developing tardive dyskinesia from long-term use of the drug might be more than one hundred times greater than the one-in-five-hundred figure mentioned on the drug's labeling.[175] Although the label specified that the one-in-five-hundred statistic was for short-term use and that the risk for long-term users was believed to be higher, mentioning the low number and then merely saying that the odds

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diagnoses"); J. David Grimes, Mohamed N. Hassan & David N. Preston, *Adverse Neurologic Effects of Metoclopramide*, 126 CAN. MED. ASS'N J., 23, 23 (1982) (noting "a frequent association between the long-term use of metoclopramide and a parkinsonian syndrome that was often followed by tardive dyskinesia"); Norman A. Leopold, *Prolonged Metoclopramide-Induced Dyskinetic Reaction*, 34 NEUROLOGY 238, 238 (1984) ("A prolonged acute dyskinetic reaction due to metoclopramide . . . is herein described.").

170. Demahy v. Actavis, Inc., 593 F.3d 428, 430 (5th Cir. 2010), *cert. granted*, 78 U.S.L.W. 3745, 79 U.S.L.W. 3017, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-1501).

171. PHYSICIANS' DESK REFERENCE 2714–15 (55th ed. 2001).

172. *Id.* at 2714.

173. *Id.*

174. *See, e.g.*, McNeil v. Wyeth, 462 F.3d 364, 369–72 (5th Cir. 2006) (reviewing and rejecting the manufacturer's argument that its warnings about tardive dsykinesia were adequate).

175. *See* Linda Ganzini, Daniel E. Casey, William F. Hoffman & Anthony L. McCall, *The Prevalence of Metoclopramide-Induced Tardive Dyskinesia and Acute Extrapyramidal Movement Disorders*, 153 ARCH. INTERN. MED. 1469, 1469 (1993) ("Metoclopramide use is associated with a significantly increased prevalence and severity of several extrapyramidal movement disorders."); Daniel D. Sewell, Angela B. Kodsi, Michael P. Caligiuri & Dilip V. Jeste, *Metoclopramide and Tardive Dyskinesia*, 36 BIOL. PSYCH. 630, 631 (1994) (finding "that [metoclopramide]-associated [tardive dyskinesia] may be frequent, mild to moderate in severity, and persistent").

might be higher for long-term users "does not put a physician on notice that the increase in risk is of a completely different order of magnitude" and therefore could be considered misleading and inadequate.[176] Moreover, plaintiffs like Conte also pointed to evidence showing that drug makers knew that doctors routinely continued to prescribe the drug for long-term use despite the label's statement that it was not recommended for use beyond twelve weeks.[177]

The drug companies in Conte's case did not want to face a jury on those issues. They therefore took the position that even if the drug's labeling was inadequate, no manufacturer could be held responsible because Conte's doctor obtained information about the drug only from the brand-name manufacturer, whereas Conte's pharmacist gave her only the generic versions of the drug.[178] Conte thus found herself in the same dilemma that had snared the Fosters and many other plaintiffs in previous cases.

The trial court dismissed all of Conte's claims against the drug makers. On appeal, she faced the solid wall of precedent following the Fourth Circuit's reasoning in *Foster* and rejecting the idea that a brand-name drug manufacturer could be liable for harm suffered by those taking generic equivalents of its product.[179]

The California Court of Appeal, however, fired a forceful shot at that wall by ruling in favor of Conte on her claims against the brand-name manufacturer.[180] The court began by recognizing that a genuine factual dispute existed about whether Conte's doctor had relied on

176. *McNeil*, 462 F.3d at 370; *see also* Brief of Appellant, *supra* note 33, at 7 ("The information disseminated by Wyeth and the generic defendants, whether through the PDR, in metoclopramide package inserts, or otherwise, was materially false, incomplete, and/or misleading . . . .").

177. *See McNeil*, 462 F.3d at 369 (stating that the drug maker's market data indicated an 84 percent rate of long-term use); Brief of Appellant, *supra* note 33, at 7 (noting the drug maker's internal data and access to independent studies); R.B. Stewart, *Metoclopramide: An Analysis of Inappropriate Long-Term Use in the Elderly*, 26 ANNALS OF PHARMACOTHERAPY 977, 977–78 (1992) (demonstrating that 32.4 percent of surveyed metoclopramide patients had been using it for over one year).

178. Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 305–06 (Ct. App. 2008). The generic manufacturers also argued that federal law preempted the claims against them. *Id.* Indeed, only one of the generic manufacturers actually pressed the argument about not having supplied information to Conte's doctor, although that argument turned out to be the means by which all three ultimately escaped liability for Conte's injuries. *Id.* at 318–20.

179. *See supra* Part II.B.

180. *Conte*, 85 Cal. Rptr. 3d at 309–18.

Wyeth's alleged misrepresentations about its product.[181] The court then held that although Conte could have strict products liability claims only against those who manufactured or sold the product she consumed, no similar limit applied to a negligent misrepresentation claim.[182] The court further found that the brand-name manufacturer owed a duty to Conte because it was foreseeable that the generic drug makers would copy the brand-name drug's labeling and that pharmacists would fill prescriptions for brand-name drugs with their generic equivalents.[183] Concluding that the brand-name manufacturer therefore should not be able to avoid responsibility to someone like Conte who fortuitously happened to receive the generic drug, the court emphasized that its decision was "rooted in common sense and California common law" and was "not marking out new territory."[184]

Although ruling against the brand-name drug manufacturer, the California Court of Appeal went the other way on Conte's claims against the generic drug makers.[185] The court noted that although Conte took the generic versions of the drug, she had no evidence that her doctor ever read or relied upon any labeling or other information generated by the generic drug manufacturers.[186] Even if the generic drug makers' warnings were inadequate, the court reasoned, they could not be the cause of Conte's injuries if her doctor never looked at them.[187] The court therefore concluded that Conte could proceed with her claims against the brand-name manufacturer but not the generic drug producers. The decision was an odd converse of the result in *Foster*, in which the Fourth Circuit rejected the claims against the brand-name manufacturer but suggested the generic producer should have been held liable.[188]

In one respect, however, the *Conte* and *Foster* cases had parallel outcomes. In early 2009, the FDA ordered manufacturers of metoclopramide, the drug taken by Elizabeth Conte, to start putting a

181. *Id.* at 308 ("[T]here are disputed factual issues as to both the accuracy of Dr. Elsen's recollection and, even if he did not specifically refer to the PDR when he formulated Conte's treatment, whether information he had previously garnered from the PDR was a substantial factor in his decision to prescribe Reglan for her.").

182. *Id.* at 309–11.

183. *Id.* at 311–13.

184. *Id*. at 311.

185. *Id.* at 318–20.

186. *Id.* at 318.

187. *Id.* at 319.

188. *See supra* notes 119–20 and accompanying text.

black box warning at the top of their labeling, emphasizing the risk of tardive dyskinesia and advising against long-term use.[189] The FDA found that, despite the weaker warnings previously given, many doctors were still prescribing the drug for periods longer than three months, and that metoclopramide had become the nation's leading cause of drug-induced movement disorders.[190] The FDA's action, like its similar move to require a black box warning about the drug involved in *Foster*,[191] underscores that the plaintiffs in these cases raised genuinely serious questions about the adequacy of the warnings being given by the drug companies.

D. The Reaction to Conte

The California Court of Appeal's decision in *Conte* immediately drew scathing criticism from commentators. An influential blog on legal issues relating to pharmaceutical companies declared that *Conte* "effectively stands product liability law on its head."[192] Others similarly expressed surprise at the California court's decision, calling it a "stunning"[193] and "remarkable"[194] decision that "sen[t] the pharmaceutical defense bar reeling."[195]

Given that it involved a significant issue of first impression in the state and reached conclusions that differed from most precedent in other jurisdictions, the *Conte* decision seemed to be a likely candidate for review by the Supreme Court of California. A slew of amicus filings asked the Supreme Court of California to hear the case and to

189. *See* Elizabeth Mechcatie, *Stronger Warning on Dyskinesia Risk Required for Metoclopramide*, CLINICAL NEUROLOGY NEWS, May/June 2009, at 14, 14 ("The chronic use of metoclopramide therapy should be avoided in all but rare cases . . . ." (quoting Dr. Janet Woodcock, Director, FDA Center for Drug Evaluation and Research)).

190. *Id.*

191. *See supra* notes 121–24 and accompanying text.

192. James M. Beck & Mark Herrmann, *Generic Drug—Pioneer Liability*, DRUG & DEVICE L. (Nov. 7, 2008, 4:10 PM), http://druganddevicelaw.blogspot.com/2008/11/generic-drug-pioneer-liabilty.html.

193. Sheila B. Scheuerman, *Brand Name Manufacturer Liable for Generics Made by Competitor*, TORTSPROF BLOG (Nov. 11, 2008, 11:17 AM), http://lawprofessors.typepad.com/tortsprof/2008/week46/index.html.

194. James R. Phelps, *Am I My (Generic) Brother's Keeper? In California, Yes.*, FDA L. BLOG (Nov. 11, 2008), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/11/am-i-my-generic-brothers-keeper-in-california-yes.html.

195. Melissa Maleske, *Brand-Name Burdens: California Decision on Generic Drug Liability Upends 14 Years of Precedent*, INSIDE COUNSEL, Feb. 2009, at 20, 20.

reverse the lower court's ruling.[196] The California high court nevertheless declined to review the matter, clearing the way for the case to return to the trial court and work its way toward a trial.[197]

The *Conte* case thus created a distinct split of judicial authority. In the years since the *Conte* decision, a multitude of other courts that have faced the issue have followed *Foster* and rejected *Conte*'s conclusion that a brand-name manufacturer could be liable to a patient who took the generic version of the drug.[198] To the extent these courts have mentioned *Conte*, they have dismissed it as "the lone outlier against the overwhelming weight of authority on this point."[199] The *Conte* decision also continues to be roundly condemned by defense lawyers and other commentators. *Conte* is an

196. The organizations filing briefs in support of the brand-name drug manufacturer included the California Health Institute, the California Manufacturers & Technology Association, the Pacific Legal Foundation, the Pharmaceutical Research and Manufacturers of America, and the Product Liability Advisory Council. More complete information about the amicus filings can be found in the docket for the *Conte* case. *Docket (Register of Actions):* Conte v. Wyeth Inc. et al., CAL. APPELLATE CTS.: CASE INFO., http://appellatecases.courtinfo.ca.gov/search/case/dockets.cfm?dist=1&doc_id=534293&doc_no=A117353 (last visited Jan. 5, 2011).

197. Conte v. Wyeth, Inc., No. S169116, 2009 Cal. LEXIS 233, at *1 (Cal. Jan. 21, 2009).

198. Mensing v. Wyeth, Inc., 588 F.3d 603, 612–14 (8th Cir. 2009), *cert. granted sub nom.* PLIVA, Inc. v. Mensing, 78 U.S.L.W. 3522, 79 U.S.L.W. 3014, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-993), *and* Actavis Elizabeth, LLC v. Mensing, 78 U.S.L.W. 3523, 79 U.S.L.W. 3014, 79 U.S.L.W. 3353, 79 U.S.L.W. 3358 (U.S. Dec. 10, 2010) (No. 09-1039); Gross v. Pfizer, Inc., No. 10-CV-00110-AW, 2010 WL 4485774, at *2–3 (D. Md. Nov. 9, 2010); Fullington v. Pfizer, Inc., No. 4:10CV00236 JLH, 2010 WL 3632747, at *2 (E.D. Ark. Sept. 17, 2010); Johnson v. Teva Pharm. USA, Inc., No. 2:10 CV 404, 2010 WL 3271934, at *3 (W.D. La. Aug. 16, 2010); Fisher v. Pelstring, No. 4:09-cv-00252-TLW, 2010 WL 2998474, at *6 (D.S.C. July 28, 2010); Neal v. Teva Pharm. USA, Inc., No. 09-CV-1027, 2010 WL 2640170, at *2 (W.D. Ark. July 1, 2010); Mosley v. Wyeth, Inc., No. 09-0284-KD-C, 2010 WL 2594000, *6 (S.D. Ala. June 28, 2010); Phelps v. Wyeth, Inc., No. 09-6168-TC, 2010 WL 2553619, at *2–3 (D. Or. May 28, 2010); Craig v. Pfizer, Inc., No. 3:10-00227, 2010 WL 2649545, at *4 (W.D. La. May 26, 2010); Finnicum v. Wyeth, Inc., No. 1:09-CV-785, 2010 WL 1718204, at *5–6 (E.D. Tex. Apr. 28, 2010); Howe v. Wyeth, Inc., No. 8:09-CV-610-T-17AEP, 2010 WL 1708857, at *3 (M.D. Fla. Apr. 26, 2010); Couick v. Wyeth, Inc., 691 F. Supp. 2d 643, 646 (W.D.N.C. 2010); Hardy v. Wyeth, Inc., No. 9:09CV152, 2010 WL 1049588, at *5 (E.D. Tex. Mar. 8, 2010); Levine v. Wyeth Inc., 684 F. Supp. 2d 1338, 1343–45 (M.D. Fla. 2010); Morris v. Wyeth, Inc., No. 09-0854, 2009 WL 4064103, at *4 (W.D. La. Nov. 23, 2009); Meade v. Parsley, No. 2:09-cv-00388, 2009 WL 3806716, at *2–3 (S.D. W. Va. Nov. 13, 2009); Burke v. Wyeth, Inc., No. G-09-82, 2009 WL 3698480, at *3 (S.D. Tex. Oct. 29, 2009); Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009); Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1061 (W.D. Ark. 2009); Moretti v. Wyeth, Inc., No. 2:08-cv-00396-JCM-(GWF), 2009 WL 749532, at *4 (D. Nev. Mar. 20, 2009); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1266–67 (W.D. Okla. 2009); Cousins v. Wyeth Pharm., Inc., No. 3:08-CV-0310-N, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009).

199. Dietrich v. Wyeth, Inc., No. 50-2009-CA-021586 XXX MB, slip op. at 10 (Fla. Cir. Ct. Dec. 21, 2009), 2009 WL 4924722.

"aberration," its critics argue, "which belies the policy and precedent of products-liability law."[200]

The California Court of Appeal does not stand completely alone, however, for a federal district court judge in Vermont has joined it in recognizing that a brand-name manufacturer could be liable for injuries caused by the generic version of its drug.[201] After discussing the *Foster* and *Conte* precedents and acknowledging that they might provide helpful insights, the federal court undertook a careful analysis of Vermont tort law and concluded that "[t]here is no reason, under Vermont law, to limit [a brand-name manufacturer's] duty of care to physicians by the pharmacist's choice of a generic bioequivalent drug to fill the physician's prescription."[202] The federal court's ruling suggests that *Conte* ultimately may turn out to be more influential and less of an aberrational outlier than its critics expected.

III. ASSESSING THE ARGUMENTS ABOUT BRAND-NAME MANUFACTURERS' LIABILITY FOR GENERIC DRUG INJURIES

In turning to the many arguments presented on both sides of the issue, there are some initial areas of basic confusion that have clouded

200. Ahmann & Verneris, *supra* note 11, at 789.

201. Kellogg v. Wyeth, No. 2:07-cv-00082, slip op. at 19–34 (D. Vt. Oct. 20, 2010).

202. *Id.* at 31. Prior to the court's ruling in *Kellogg*, the plaintiff submitted to the court a copy of a pre-publication draft of this Article, and the court ordered the parties to submit supplemental briefs addressing it. The *Kellogg* plaintiff suggested that the Article makes "substantial and positive contributions to the understanding of these cases and the issues presented in them," but "miss[es] the mark" in many ways, particularly with respect to the role of causation and reliance in misrepresentation claims versus failure to warn claims. Plaintiff's Memorandum Concerning Pertinent Aspects of the Rostron Article at 2, *Kellogg*, No. 2:07-cv-00082. In addition, preferring a simple rule of joint and several liability for all defendants responsible for an injury, the plaintiff objected to this Article's proposed framework for allocating liability between brand-name and generic manufacturers. *Id.* at 12–14; *see also infra* Part IV.B. On the other hand, the brand-name manufacturer in *Kellogg* characterized the Article as being concerned primarily with situations where a plaintiff who took a generic drug would be left with no remedy whatsoever if the drug's brand-name manufacturer escaped liability. Wyeth's Supplemental Memorandum Brief in Support of Its Motion for Summary Judgment at 1–3, *Kellogg*, No. 2:07-cv-00082. The manufacturer argued that no need existed for adopting the Article's "novel theories" in a case where the plaintiff might have viable claims against generic drug manufacturers and against her doctor. *Id.* at 4–5. In fact, situations where an injured plaintiff would have no tort remedies against anyone illustrate most starkly the unfairness of letting brand-name manufacturers avoid responsibility for harm caused by their negligence, but the unfairness is by no means limited to those situations. Despite giving careful consideration to both parties' assessments, I was not moved by their critiques. Indeed, taking fire from both sides encouraged me to hope that the approach proposed in this Article balances well the competing interests at stake.

the question and often have prevented litigants, courts, and commentators from zeroing in on equitable and policy considerations that should be the focal points of the debate. Clearing away these preliminary sources of confusion will not resolve the ultimate issue under consideration here, but it will set the stage for a more lucid and productive discussion. After trying to shed light on the matters that have distracted and misled analyses in the past, I turn to the equity and policy considerations that should drive efforts to develop approaches fair to injured plaintiffs, brand-name manufacturers, and generic drug makers.

A. Negligence versus Strict Liability Claims

Determining the proper scope of drug companies' liability requires careful attention to distinctions among the several different causes of action that can be asserted in products liability cases. Products liability is a broad term that covers an entire field of law containing several different types of claims and legal theories.[203] Some products liability claims require proof that the defendant was negligent, but others, like strict tort liability and breach of warranty, do not necessarily require any proof of fault.[204] Those "untutored in the finer points of products liability law sometimes casually interchange the terms 'strict liability' and 'products liability,'" but "[s]uch usage is imprecise and should be avoided, because it equates a single theory of liability with an entire field of law."[205]

Drug manufacturers and other critics of *Conte* often have failed to fully respect these crucial distinctions. They point to judicial decisions that discuss the purposes and limits of strict liability claims but misread the decisions as addressing all tort claims, even those not involving any form of strict liability.[206] For example, when the Supreme Court of California first ruled in *Greenman v. Yuba Power Products, Inc.*[207] that strict tort liability should be imposed on manufacturers of defective products, it stated that "[t]he purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such

203. *See supra* notes 60–69 and accompanying text.

204. *See supra* notes 69–70 and accompanying text.

205. OWEN, *supra* note 60, § 5.1, at 254.

206. *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 310–11 (Ct. App. 2008) (noting the brand-name drug manufacturer's misplaced reliance on numerous strict tort liability cases).

207. Greenman v. Yuba Power Prods., Inc., 377 P.2d 897 (Cal. 1963).

products on the market."[208] Critics of the *Conte* decision contend that this is the "bedrock rationale for product liability" and that *Conte* contradicts it.[209] The court in *Greenman*, however, made very clear that it was talking about strict tort liability, not all tort claims or even all products liability claims.[210] To contend otherwise, critics of *Conte* have engaged in a subtle sleight of hand that improperly equates strict liability with products liability and stretches these terms to cover negligence and all other tort claims that could ever be brought against manufacturers.

Although *Greenman* and countless other cases established that strict liability applies only to the manufacturer and other sellers that put the allegedly defective product on the market,[211] *Conte* does not undercut or contradict that proposition in any way. Indeed, the *Conte* decision did not say anything whatsoever about expanding the reach of strict liability. It instead specifically emphasized that strict liability *cannot* apply to a brand-name manufacturer when the plaintiff took a generic drug made by another company.[212] At the same time, the court recognized that "[n]egligence and strict products liability are separate and distinct bases for liability" and that they "do not automatically collapse into each other" merely because there are some situations in which a plaintiff might be able to assert both types of claims.[213]

Strict liability is unusual. Tort law generally imposes liability only on those who were at fault, either through negligence or intentional wrongdoing.[214] Strict liability is thus a rare and exceptional condition, whereas being liable for injuries caused by one's negligence is the norm. The limits on the reach of strict liability claims should be carefully respected, but when a situation is outside those limits, it does not fall into some sort of bizarre twilight zone in which defendants have immunity from all liability. Instead, the normal rules of tort law apply, including the principles providing that defendants

208. *Id.* at 901.

209. *E.g.*, James M. Beck & Mark Herrmann, *More Thoughts on* Conte v. Wyeth, DRUG & DEVICE L. (Nov. 13, 2008, 4:52 PM), http://druganddevicelaw.blogspot.com/2008/11/more-thoughts-on-conte-v-wyeth.html.

210. *Greenman*, 377 P.2d at 901.

211. *See supra* notes 74–75 and accompanying text.

212. *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 311 (Ct. App. 2008) ("[T]he defendant would not be liable in strict products liability because it did not manufacture or sell the product.").

213. *Id.* at 310.

214. DAN B. DOBBS, THE LAW OF TORTS § 112, at 263–66 (2000).

who cause foreseeable harm through unreasonably careless behavior generally can be held liable for their negligence. Though a brand-name drug manufacturer may not be held strictly liable for harm to patients who took its product's generic counterpart, the manufacturer's potential liability for negligence is a separate matter that must be resolved through careful analysis.

B. Indeterminate Tortfeasor versus Additional Tortfeasor Scenarios

The other major point of confusion that has plagued the debate over these issues is a failure to distinguish between two different types of situations in which a plaintiff might assert claims against more than one manufacturer. In some instances, a plaintiff sues multiple manufacturers simply because the true identity of a product's manufacturer is in doubt. In other instances, the identity of the product's manufacturer is well known, but the plaintiff sues multiple manufacturers because one engaged in some conduct, other than manufacturing the product, that was tortious and contributed to causing plaintiff's injury. These two different situations have been continually conflated and confused with one another in the debate over brand-name and generic drug manufacturer liability.

Consider a scenario that does not involve products. Suppose several people fired guns in a plaintiff's direction, and the plaintiff wound up being struck by one bullet. To recover damages, the plaintiff would generally need to identify the person who shot her. The plaintiff would figure out whose bullet hit her, and then simply sue that person. If the plaintiff could not determine which person shot her, she might still be able to recover under one of several special tort theories. For example, if the people firing guns engaged in a concerted effort to harm the plaintiff, then all of them would be jointly liable for the harm no matter who fired the bullet that actually found its target.[215] Even absent such concerted or joint action, the theory of alternative liability could enable the plaintiff to sue and to hold liable all who negligently fired the shots toward her.[216]

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215. *See* RESTATEMENT (SECOND) OF TORTS § 876(a) (1979) ("For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he does a tortious act in concert with the other or pursuant to a common design with him . . . .").

216. Invented by the Supreme Court of California, alternative liability has been widely embraced by other courts. *See* Summers v. Tice, 199 P.2d 1, 3–5 (Cal. 1948) (shifting the burden of proof to the defendants and concluding that each defendant would be liable unless he is able to prove it was not his shot that caused the plaintiff's injury); RESTATEMENT (SECOND) OF TORTS § 433B(3) (1965) ("Where the conduct of two or more actors is tortious, and it is proved

Those situations in which the plaintiff cannot determine the identity of the person whose bullet struck her must be carefully distinguished from situations in which the plaintiff has no doubts about whose bullet hit her body, but she nevertheless has grounds for asserting tort claims against more than one person. Assume, for example, that the evidence makes clear that John fired the shot that hit the plaintiff. In addition to whatever claims she may have against John, the plaintiff may have claims against David as well if she can prove that David engaged in some sort of tortious conduct that was a cause of the injury. For example, if David should have known that John was mentally unstable and violent, but nevertheless gave him the gun used to shoot the plaintiff, David might be liable for negligent entrustment of the firearm.[217] If David negligently mistook the plaintiff for a deer and then convinced John to shoot in the plaintiff's direction, David could be liable even though he did not fire the bullet that hit the plaintiff.[218] Likewise, if David negligently told the plaintiff that it was safe to enter a spot at which David knew or had reason to know that bullets would be flying, David could be liable.[219] David similarly might be liable if his negligent operation of a shooting range led the plaintiff to be hit by a bullet fired by John,[220] if he negligently published a book that advised John on how to shoot the plaintiff,[221] or if he negligently supplied a faulty bulletproof vest to the plaintiff.[222] In these and an endless variety of other imaginable scenarios, David might be held liable for his negligence, despite the fact that he did not

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that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.").

217. *See, e.g.*, Kitchen v. K-Mart Corp., 697 So. 2d 1200, 1208 (Fla. 1997) (holding that a negligent entrustment action is proper when a person provides a firearm to an intoxicated person); Estate of Heck *ex rel.* Heck v. Stoffer, 786 N.E.2d 265, 271 (Ind. 2003) (articulating a duty to exercise reasonable care in the storage of a firearm to prevent access and use by a third party).

218. *See* RESTATEMENT (SECOND) OF TORTS § 311(1) (1965) ("One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information . . . .").

219. *See id.*

220. *See* Dionne v. City of Trenton, 261 N.W.2d 273, 277 (Mich. Ct. App. 1977).

221. *See* Rice v. Paladin Enters., Inc., 128 F.3d 233, 241 (4th Cir. 1997) (recognizing that the publisher of an instructional book used by a hit man to plan a contract killing could be "civilly liable for aiding and abetting" the murder).

222. *See* House v. Armour of Am., Inc., 929 P.2d 340, 348 (Utah 1996) (finding a genuine issue of material fact as to whether the manufacturer and the distributor of body armor owed the plaintiff, a SWAT team officer, a duty to warn him of the limitations of their product).

fire the bullet that struck the plaintiff. David's liability in these scenarios does not depend on any of the special theories, like alternative liability, that apply in situations in which the plaintiff is unable to determine who shot her. Those theories are irrelevant when it is clear that David is not the one who shot the plaintiff, but the plaintiff nevertheless sues David for some other tortious conduct that contributed to her injury.

The same logic applies when the plaintiff suffered harm from use of a drug or other product. In some instances, the plaintiff may not be able to determine which of several manufacturers produced the particular dose she received. In those situations, the plaintiff will need to invoke one of the special tort theories—concert of action, alternative liability, enterprise liability, or market share liability—that might overcome her inability to identify the product's manufacturer.[223] The availability of those theories should be irrelevant, however, when the plaintiff can identify the product's manufacturer but nevertheless has claims against some other manufacturer who engaged in some other tortious conduct that was also a cause of the plaintiff's injury. In other words, a manufacturer could be sued not because it made or might have made the product in question but because it was simply an additional tortfeasor liable for some form of wrongdoing other than making and selling the product the plaintiff received.

The distinction between an indeterminate manufacturer and an additional tortfeasor seems simple. Yet defendants and judges have often blurred and confused the two in cases about the liability of brand-name and generic drug makers. The trouble dates all the way back to the *Foster* case, in which the brand-name manufacturer's arguments focused heavily on the unavailability of nonidentification theories, such as alternative liability and market share liability, that

223. *See* OWEN, *supra* note 60, § 11.3, at 782–90 (defining market share liability, alternative liability, enterprise liability, and concert-of-action liability). Each of these four theories has been applied to product manufacturers. *See* Dawson v. Bristol Labs., 658 F. Supp. 1036, 1038–40 (W.D. Ky. 1987) (discussing concert of action and finding that the plaintiff had stated a valid claim under a concert-of-action theory); Hall v. E.I. Du Pont de Nemours & Co., 345 F. Supp. 353, 376–78 (E.D.N.Y. 1972) (explaining the rationale underlying enterprise liability and allowing the plaintiff's action to proceed under that theory); Sindell v. Abbott Labs., 607 P.2d 924, 937 (Cal. 1980) (explaining that under market share liability, "[e]ach defendant will be held liable for the proportion of the judgment represented by its share of that market unless it demonstrates that it could not have made the product which caused plaintiff's injuries"); Minnich v. Ashland Oil Co., 473 N.E.2d 1199, 1200 (Ohio 1984) (endorsing the doctrine of alternative liability found in RESTATEMENT (SECOND) OF TORTS § 433(B)).

were irrelevant to the case.[224] Biting into the red herring offered by the drug manufacturer, the Fourth Circuit similarly emphasized the unavailability of those theories and failed to confront squarely the idea that the brand-name manufacturer could be liable as an additional tortfeasor even though it did not make the drug that killed Brandy Foster.[225] Throughout the long line of precedent that flowed out of *Foster*, courts have repeatedly made the same mistake, dwelling on the irrelevant concept of liability being imposed on multiple manufacturers because of uncertainty about who made a product and conflating that concept with the separate and distinct issue of whether a manufacturer can be liable for wrongdoing other than making and selling the product the plaintiff received.[226]

The indeterminate manufacturer and additional tortfeasor scenarios implicate fundamentally different concerns. The former raises important questions about the appropriate judicial response to the inevitability of factual uncertainty in the world,[227] whereas the latter often presents equally profound—but very different—questions about the complex web of causal factors underlying events, the nature and degree of connection courts should demand between a defendant's actions and a plaintiff's injury, and the proper scope or limits of one's obligations toward others. The issue of brand-name and generic drug makers' liability is complicated and difficult enough without being obscured in a tangle of irrelevant issues.

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224. *See* Brief of Appellee/Cross-Appellant, *supra* note 92, at 13–15 (arguing that under Maryland law, the plaintiff in a products liability action must be able to identify the defendant's product as the source of the plaintiff's injury).

225. Foster v. Am. Home Prods. Corp., 29 F.3d 165, 168 (4th Cir. 1994) (citing case law establishing that "Maryland law refused to adopt non-identification theories of product liability").

226. *See, e.g.*, Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1266–67 (W.D. Okla. 2009) (citing Oklahoma's rejection of market share liability, alternative liability, concert-of-action liability, and enterprise liability theories in granting summary judgment to the defendants); Sharp v. Leichus, No. 2004-CA-0643, 2006 WL 515532, at *2–3 (Fla. Cir. Ct. Feb. 17, 2006) (concluding that the principles of market share liability foreclosed the imposition of liability on defendants who could positively show that they did not manufacture the drug ingested by the plaintiff), *aff'd per curiam*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007).

227. *See* Allen Rostron, *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. REV. 151, 158 (2004) (explaining that market share liability responds to situations in which the plaintiff has been injured by one of several defendants but cannot easily identify which particular defendant actually caused the injury).

C. The Elements of Negligence Claims

With those preliminary clarifications in mind, I turn to the central issue of whether a brand-name drug manufacturer can ever be liable for negligence that causes a person to be injured by use of the brand-name drug's generic equivalent. The plaintiffs' arguments in these cases essentially boil down to the straightforward proposition that brand-name manufacturers should be held liable when plaintiffs can satisfy all the elements required for establishing negligence claims. In other words, the plaintiffs do not argue for the creation of any sort of special rule for their cases. They do not ask courts to bend or waive the normal requirements for negligence claims. Instead, plaintiffs simply point to the basic elements required for negligence liability and contend that those elements can be met.

Everyone has a general duty to exercise the care of a reasonable person under the circumstances, in order to avoid causing harm to others.[228] Liability for negligence arises when a defendant's failure to exercise reasonable care was an actual and proximate cause of harm to the plaintiff.[229] At first blush, at least, it does appear that these basic elements of a negligence claim can be satisfied in situations, like in the *Foster* and *Conte* cases, in which a plaintiff took a generic drug but believes the brand-name manufacturer was negligent. For example, suppose the plaintiff accuses the brand-name manufacturer of negligently designing the product. The plaintiff would need to prove that the manufacturer really did fail to exercise reasonable care in developing the product, and that the type of illness or other injury caused by the drug was reasonably foreseeable. But if the plaintiff could do that, the elements of a negligence claim would fall neatly into place. The brand-name manufacturer could easily foresee that generic manufacturers would copy its design, at least with respect to the crucial, active ingredients of the product. It therefore knew that a flaw in the drug's design would cause harm not only to those who take the brand-name version of the drug, but also to those taking the generic versions. As a result, harm to a plaintiff caused by the faulty

228. *E.g.*, DOBBS, *supra* note 214, § 117, at 277 (explaining how courts developed "a general duty or standard of care describing the duty of all persons to exercise ordinary care, meaning the care of a reasonable person, for the benefit of other persons"); *id.* § 227, at 578 ("Among strangers—those who are in no special relationship that may affect duties owed—the default rule is that everyone owes a duty of reasonable care to others to avoid physical harms.").

229. *See id.* §§ 114–115, at 269–73 (discussing the harm and causation requirements in negligence actions).

design of a generic drug is a readily foreseeable result of the brand-name manufacturer's negligence.

The same is true when the claim focuses on the adequacy of the warnings or instructions accompanying the product. At least as a general matter, the brand-name manufacturer had a duty to exercise reasonable care in formulating its product labeling. It could readily foresee that generic manufacturers would copy the labeling and put it on their generic versions of the drug. As a result, a plaintiff might be able to show that if the brand-name manufacturer had acted with reasonable care in preparing its product's labeling, the plaintiff never would have been harmed by use of the generic drug. Proving such a claim may not necessarily be easy. The plaintiff would need to show that the brand-name manufacturer really did fail to exercise reasonable care in crafting the warnings and instructions, that the type of illness or other injury caused by use of the drug was reasonably foreseeable, and that adequate warnings or instructions would have altered the doctor's decisionmaking about the use of the drug so as to prevent the plaintiff from being harmed by it.[230] A plaintiff might, however, be able to prove all of these elements. The plaintiff might be able to show, for example, that her doctor never would have prescribed the drug for the plaintiff if a stronger warning about a particular risk had been provided. Alternatively, the plaintiff might be able to show that her doctor still would have prescribed the drug but would have changed the manner of its use in some way that would have prevented or reduced the resulting harm, such as prescribing the drug in a lower dosage, for a shorter period of use, or with closer monitoring for a particular adverse reaction about which a warning had been given.

When the plaintiff has taken a generic drug and subsequently sues the brand-name manufacturer for negligently failing to give adequate warnings, it should not matter whether the plaintiff's doctor looked at the labeling on the brand-name version of the drug (or some other source of information attributable to the brand-name manufacturer, such as the drug's entry in the *Physicians' Desk Reference*) or saw the labeling on the generic version of the drug. The

230. Under the learned intermediary rule, a prescription drug manufacturer generally has a duty to give adequate warnings and instructions only to doctors, rather than directly to patients. The rationale for this rule is that when a drug is available only by prescription, the doctor is the one who really needs the warnings and instructions to make sound decisions about using the drug in a patient's treatment. *See* OWEN, *supra* note 60, § 9.6, at 630–33.

required causal link between the inadequate warnings and the plaintiff's injury exists either way. If the doctor looked at the brand-name labeling, a stronger warning provided there by the brand-name manufacturer would have reached the doctor. And if the brand-name manufacturer had provided a stronger warning in its labeling, the same information would have automatically appeared on the generic labeling,[231] and thus would have reached a doctor who looked only at that generic labeling. In either event, the plaintiff may plausibly contend that a stronger warning would have prevented her injuries by changing her doctor's decision about the use of the drug.

Many of the cases about brand-name manufacturers' liability for generic drug injuries have focused on negligent misrepresentation claims.[232] Like an inadequate warning claim, a negligent misrepresentation claim would center on the labeling, advertising, or other information provided about the product. But it would require proof that the defendant went further than just failing to provide important information and instead affirmatively made some false or misleading statement about the product.[233] Like any other negligence claim, a negligent misrepresentation claim is based on the assertion that the defendant's failure to exercise reasonable care was an actual and proximate cause of the plaintiff's injury.[234] More specifically, the plaintiff must show that someone reasonably or justifiably relied on the defendant's misrepresentation, and that reliance led to the plaintiff's injury.[235] This reliance element is a slightly more precise way of articulating the general requirement, applicable to all negligence claims, that a plaintiff must show a causal connection between the defendant's negligence and the plaintiff's injury.[236]

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231. *See supra* note 58 and accompanying text.

232. *See, e.g.*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 168–71 (4th Cir. 1994); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 310–11 (Ct. App. 2008).

233. *See* OWEN, *supra* note 60, § 3.2, at 117–18 (explaining that a defendant's mere failure to communicate potential dangers, as opposed to making an affirmative statement, is normally insufficient to constitute a misrepresentation).

234. *See* RESTATEMENT (SECOND) OF TORTS § 311 (1965).

235. OWEN, *supra* note 60, § 3.2, at 125–26; *id.* § 3.3, at 133–34.

236. *See id.* § 3.2, at 126 ("Typically, causation is embedded in reliance, and proof of the former often establishes the latter."). That the brand-name manufacturer's misrepresentation may not be the most direct or immediate cause of the injury should not bar the plaintiff's claim. A plaintiff merely needs to show that a defendant's negligence was a proximate cause of the injury, not that it was the most direct or immediate cause. For example, if one person negligently spills gasoline, and another later negligently creates a spark that ignites the gasoline, both can be held responsible for the resulting fire. *See* DOBBS, *supra* note 214, § 186, at 460 ("If the first actor negligently creates a risk of harm and the second actor negligently triggers the

A plaintiff suing a brand-name drug manufacturer may be able to prove these required elements even though she received the generic version of the drug. The plaintiff might show, for example, that the brand-name manufacturer falsely overstated the drug's safety or understated its risks, that these misstatements occurred because the manufacturer failed to exercise reasonable care, and that the plaintiff's doctor relied on the misstatements in prescribing the drug. If the manufacturer had not made false statements about the drug, the plaintiff's doctor would have made a different decision about whether or how to use the drug, and the plaintiff's injury would have been avoided or at least reduced. Again, it should not matter whether the plaintiff's doctor saw the misrepresentation in materials generated by the brand-name manufacturer or the generic drug manufacturer.[237]

Plaintiffs in these cases thus can establish the prima facie elements of a negligence claim against the brand-name manufacturer, whether the focus is on product design, inadequate warnings, or negligent misrepresentations. That a pharmacy happened to give the plaintiff the generic version of the drug, rather than the brand-name product, simply does not preclude establishment of the elements necessary to hold the brand-name manufacturer liable for negligence.

D. The Presence of Additional Tortfeasors in Products Liability Scenarios

Because plaintiffs can present plausible claims based on the standard elements of negligence, drug manufacturers must argue for the creation of a special rule that would trump the normal application of those elements. Their basic argument is that a drug manufacturer should be liable only for harm suffered by those who actually used its products.[238] They contend that a manufacturer should not be

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risk, both actors are tortfeasors, both are causes in fact of the harm, and both are commonly held liable . . . .").

237. If the doctor saw the misrepresentation in information produced by the brand-name manufacturer, the doctor's reliance on the brand-name manufacturer's misrepresentation may be direct. But even in the far more rare instances when the doctor saw the misrepresentation only in the generic labeling, the required reliance is still present, although the chain of events has one small extra step. The brand-name manufacturer initially made the misrepresentation, the generic manufacturer relied on that misrepresentation in copying it onto the labeling of the generic version of the drug, and the plaintiff's doctor in turn relied on the misrepresentation as reprinted in the generic drug labeling. Either way, the plaintiff's injury flows out of reliance on the brand-name manufacturer's misstatement about the drug.

238. *See, e.g.*, Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 309 (Ct. App. 2008) ("Wyeth argues . . . that it cannot be held liable to Conte for her injuries caused by generic

responsible for injuries that did not directly result from the use of its products, even if those injuries were actual and foreseeable results of the manufacturer's negligence. In short, they believe manufacturers can only be liable qua manufacturers.

The drug makers contend that this limitation on their liability is a long and well-established principle. "It is hornbook law," argued the brand-name manufacturer in the *Conte* case, "that a product manufacturer owes no duty to a plaintiff who does not use its product."[239] Likewise, observers denouncing the *Conte* decision claimed that it has been clear "since the dawn of product liability" that "[y]ou can only sue the manufacturer of the product that injured you."[240]

Is that true? Again, it may be for strict liability claims, but such claims represent an unusual deviation from normal tort law principles.[241] In the realm of negligence, it is far less clear that any such principle exists.

Consider this example. A plaintiff purchased a new Ford automobile. Soon after, while driving through an intersection, she was hit by a truck whose driver negligently failed to stop for a red traffic light. Although the plaintiff's car should have been able to withstand the impact without causing any injury to the plaintiff, a flaw in the design of the car's gas tank caused the car to explode, leading the plaintiff to suffer terrible burn injuries. If the plaintiff asserts tort claims against both the truck driver and Ford, the truck driver cannot avoid liability by saying he did not manufacture or sell the plaintiff's car. That the truck driver did not manufacture or sell the car would be irrelevant because he would not be sued on the ground that he manufactured or sold it; he would be sued because of his negligent driving.

Now assume that the truck driver happens to work for Toyota and was delivering a load of new Toyota automobiles when he struck the plaintiff. The analysis and result do not change. If the plaintiff sues Toyota, contending that it is liable for the truck driver's negligence through respondeat superior, Toyota cannot avoid liability by saying it is not the company that manufactured the plaintiff's car.

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metoclopramide because Wyeth has no duty to users of the generic version of its products, which are produced by other manufacturers.").

239. Respondent Wyeth's Brief, *supra* note 145, at 2.

240. Beck & Herrmann, *supra* note 192.

241. *See supra* Part III.A.

The plaintiff would not be suing Toyota on the ground that it manufactured the car. The plaintiff would be suing Toyota because, through its employee, Toyota was negligent in some other respect that led to the plaintiff's injuries. To repeat a term used earlier, Toyota would be an additional tortfeasor even though it was not the manufacturer of the product that the plaintiff purchased.[242]

This hypothetical example is not parallel in all respects to the issue of brand-name drug manufacturers' liability for generic drug injuries. It merely demonstrates the simple proposition that a manufacturer can be liable, at least in some circumstances, when its negligence causes a plaintiff to be injured by a product that the manufacturer did not produce. The manufacturer is not blamed for manufacturing something it did not manufacture; instead, the manufacturer is held liable because it was negligent in some other respect.

To make the hypothetical example somewhat more similar to the cases involving brand-name and generic drugs, imagine that Toyota was negligent in some way related to its activities as an automaker, rather than just through the careless driving of its employee. For example, suppose that Toyota negligently designed a gas tank and then licensed the dangerous design to the manufacturer of the plaintiff's car; that Toyota went to other automakers, including the manufacturer of the plaintiff's car, and convinced them to stop giving certain types of warnings; or that Toyota carelessly made false representations about the safety of a very specific component or feature of the plaintiff's car. In those situations, Toyota should not be able to escape liability merely by saying that it did not manufacture or sell the plaintiff's car. Courts should instead look carefully at what Toyota did and decide whether Toyota's role in influencing the design of the product or the information disseminated about it was substantial enough to justify holding Toyota liable for its negligence.

Courts have taken this approach in a wide variety of circumstances. They have held that liability can be imposed, at least in some situations, when a defendant did not actually manufacture or sell the product in question but nevertheless was negligent in a way that contributed to the danger posed by the product. For example, courts have held that a nonmanufacturing designer of a product can be held liable for injuries attributable to the product's flawed design

242. *See supra* Part III.B.

or inadequate warnings.[243] A franchisor or trademark licensor can be held liable if it participated substantially in developing the design of a product even though it did not manufacture the product itself.[244] Likewise, a defendant that endorsed or certified a product as being safe can be held liable for negligence even though it did not manufacture or sell the product.[245] A trade association or other organization that sets insufficient safety standards for a product can be held liable for negligence even though it did not manufacture or sell the product.[246] A manufacturer that acquires assets from another company may be obligated in some circumstances to give warnings to those who purchased products made by the other company in the past.[247] A manufacturer of machines can be held liable when another company fails to put adequate warnings on replacement parts for the machines, even though the manufacturer did not make or sell the

243. *See* Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 590–91 (Tex. 1986) (finding that the defendant could be held liable for failing to warn about the hazards associated with a soft drink bottle cap and closure system it designed, even though it did not manufacture or sell the soft drink bottle that injured the plaintiff); Melissa Evans Buss, *Products Liability and Intellectual Property Licensors*, 27 WM. MITCHELL L. REV. 299, 311–14 (2000) (reviewing cases and concluding that a manufacturer can be held liable when it "negligently develops a design, which is later embodied in a final product by a separate manufacturer, and a third party's injuries are caused by their negligent design").

244. *See* Harris v. Aluminum Co. of Am., 550 F. Supp. 1024, 1027 (W.D. Va. 1982) ("[T]here is authority holding that implied warranty principles do extend to franchisors who promote the sale of soft drink products but do not actually manufacture or sell the product."); OWEN, *supra* note 60, § 15.4, at 1030–32 ("Courts widely agree that trademark owners and franchisers that substantially control product safety may be subject to liability for injuries from defective products made and sold by their licensees.").

245. *See* Hanberry v. Hearst Corp., 81 Cal. Rptr. 519, 682, 684–87 (Ct. App. 1969) (holding that a magazine publisher would be liable for negligent misrepresentation if one of its magazines endorsed dangerous shoes as safe after failing to properly test them); OWEN, *supra* note 60, § 15.7, at 1050–52 (reviewing cases and finding that courts hold that certifiers and endorsers can be liable for negligence even though they are not subject to strict liability).

246. *See* Meneely v. S.R. Smith, Inc., 5 P.3d 49, 57 (Wash. Ct. App. 2000) (concluding that the defendant trade association owed the plaintiff a duty of care in setting safety standards for the manufacturers and retailers of the plaintiff's swimming pool and diving board); OWEN, *supra* note 60, § 15.7, at 1053–56 (explaining that trade associations are not subject to strict liability but have been held liable in some cases for negligently developing and promulgating safety standards for products manufactured by their members); *id.* § 15.7, at 1058 (noting that other types of standard-setting organizations may be held liable for negligence even though they do not manufacture or sell the products for which they set standards).

247. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 13 (1998) (explaining that a successor manufacturer can be held liable for failing to warn about risks of products made by the predecessor manufacturer if the successor provides or agrees to provide repair, replacement parts, or similar services to predecessor's customers); OWEN, *supra* note 60, § 15.5, at 1040–41 (describing these "commonsense principles of responsibility" as "reasonable and fair").

replacement parts in question and put adequate warnings on the parts that it did manufacture and sell.[248] Again, these are just a few examples of the broad array of imaginable scenarios in which someone who did not manufacture or sell a product that causes injury nevertheless can be held liable for negligence that contributes to the product's danger and resulting harm. Examples also abound beyond the realm of tort law. In the intellectual property field, those who contribute to infringement of a patent, copyright, or trademark can be held liable along with those who actually infringe.[249] And in securities law, those who assist or support the violation of a securities statute or rule can be held liable along with those who directly violate the provision.[250]

None of these examples are perfect parallels to the issue of brand-name and generic drugs. Brand-name drug manufacturers do not grant licenses to generic drug makers. They do not endorse or certify the generic manufacturers' products. Nor do they urge the generic manufacturers to copy their products or labeling. Instead, the mimicry of brand-name drug designs and labeling occurs through the operation of the FDA's regulatory scheme for approval of generic drugs.[251] The FDA demands that generic drug makers follow in the brand-name manufacturer's footsteps if they want to take advantage of the abbreviated new drug approval mechanism. The brand-name manufacturer thus does not solicit or encourage duplication of its products or labeling, but the generic manufacturer does not unilaterally or unexpectedly choose to imitate the brand-name manufacturer's actions. The imitation of the brand-name products is

248. *See* Clarke Indus., Inc. v. Home Indem. Co., 591 So. 2d 458, 462 (Ala. 1991) (finding that the manufacturer of a sander failed to give adequate warning that replacement parts made by another manufacturer might combust); *see also* Sage v. Fairchild-Swearingen Corp., 517 N.E.2d 1304, 1308 (N.Y. 1987) (holding that the manufacturer of an original part could be held liable for a design defect even though the plaintiff was actually injured by a replacement part that was copied from the manufacturer's design but was not actually produced by the manufacturer).

249. *See* 35 U.S.C. § 271(b) (2006) ("Whoever actively induces infringement of a patent shall be liable as an infringer."); Mark Bartholomew & John Tehranian, *The Secret Life of Legal Doctrine: The Divergent Evolution of Secondary Liability in Trademark and Copyright Law*, 21 BERKELEY TECH. L.J. 1363, 1366–68 (2006) (discussing the availability of both vicarious liability and contributory liability theories to plaintiffs in copyright and trademark infringement actions).

250. *See* William H. Kuehnle, *Secondary Liability Under the Federal Securities Laws—Aiding and Abetting, Conspiracy, Controlling Person, and Agency: Common-Law Principles and the Statutory Scheme*, 14 J. CORP. L. 313, 315 (1989) (noting that secondary liability "has become so well established in the securities law that courts rarely question its basis").

251. *See supra* Part I.A–B.

systematic and overseen by the FDA, making it not only highly foreseeable to the brand-name manufacturer but also effectively subject to the brand-name manufacturer's control. If the generic drug is an insufficiently close copy of the brand-name product, for example, the brand-name manufacturer can have the FDA remove the generic drug from the market.[252] Likewise, if the brand-name manufacturer determines that the product's warnings or instructions should be enhanced in some way, the FDA will force generic producers of the drug to fall perfectly in line behind the brand-name manufacturer's lead.[253] The unique regulatory scheme surrounding prescription drugs thus provides a mechanism by which the copying of brand-name drugs' designs and labeling is not initiated or encouraged by the brand-name manufacturer, but it is nevertheless systematic, predictable, and subject to significant control by the brand-name manufacturer through the FDA.

The prescription drug scenario is therefore unlike situations in which one manufacturer unilaterally decides to imitate another manufacturer's design and no other link connects the two companies. For example, in *Piscitello v. Hobart Corp.*,[254] a federal district court in Massachusetts faced a situation in which the plaintiff injured her hand in a meat grinder and sued both the manufacturer of the machine and another company whose design the manufacturer had copied.[255] The judge rejected the claims against the company that developed the design but otherwise had no connection to the product or its manufacture, saying that "[i]t would be unfair to impose such an expansive view of tort liability on those whose original design is mimicked without the designer's permission."[256] Meat grinders, like most products, are not subject to anything like the FDA's regulatory scheme, which systematizes the copying of brand-name drugs and their labeling and gives brand-name manufacturers the ability to foresee and control the actions of their generic imitators.

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252. *See supra* note 58 and accompanying text.

253. *See supra* notes 25–27 and accompanying text.

254. Piscitello v. Hobart Corp., 799 F. Supp. 224 (D. Mass. 1992).

255. *Id.* at 224–25.

256. *Id.* at 226. The court also noted that there was nothing particularly distinctive about the design in question, given that it had been utilized for most grinders over the years. *Id.* at 225. Indeed, the design could not be validly patented because it "did not require invention to devise it but only the use of ordinary judgment and mechanical skill." *Id.* at 225 n.5 (quoting Hobart Mfg. Co. v. Landers, Frary & Clark, 26 F. Supp. 198, 202 (D. Conn. 1939), *aff'd per curiam*, 107 F.2d 1016 (2d Cir. 1939)).

In arguing on these points, the brand-name manufacturers often seem to be denying the obvious. They maintain that they have no control over generic drugs or their producers,[257] and they insist that they cannot reasonably foresee that dangerous flaws in a brand-name product or its labeling will lead to injuries suffered by those taking the product's generic equivalents.[258] Many courts, from *Foster* onward, have accepted those assertions.[259] The brand-name manufacturers' characterizations of the situation, however, are hard to square with reality. If a brand-name drug manufacturer is negligent in designing its product or in preparing labeling or other information disseminated to doctors, it is highly foreseeable that the risk created will extend to those taking the generic substitutes as well as those taking the brand-name version of the drug. And given that brand-name manufacturers effectively dictate crucial aspects of the generic products' designs and the contents of their labeling, the brand-name manufacturers' insistence that they have no control over generic drugs is like a person saying that he has no control over his shadow.

The issue ultimately boils down to how the copying of brand-name drugs and labeling that occurs under the auspices of the FDA and its regulatory scheme should affect the question of liability. Is the FDA's regulatory system a reason to absolve the brand-name manufacturers of liability for generic drug injuries, or a reason to say that they can be held liable for the foreseeable consequences of their negligence regardless of whether a particular patient took the brand-name or generic version of the drug? That the brand-name manufacturer does not voluntarily consent to the generic manufacturer's imitation of the product points toward a conclusion that the brand-name manufacturer should not be liable to those injured by the generic drug. Several other factors point strongly in the

257. *See* Respondent Wyeth's Brief, *supra* note 145, at 1, 23 (repeatedly disclaiming any control on Wyeth's part over the manufacture or sale of the generic drug).

258. *See id.* at 22 (arguing that a brand-name drug manufacturer cannot reasonably foresee that its warnings will be relied upon by plaintiffs who ingest the generic version of its products).

259. *See, e.g.*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 171 (4th Cir. 1994) (concluding that to hold a brand-name manufacturer liable for products of generic manufacturers over whom it had no control "would be to stretch the concept of foreseeability too far"); Sharp v. Leichus, No. 2004-CA-0643, 2006 WL 515532, at *7 (Fla. Cir. Ct. Feb. 17, 2006) ("It would be manifestly unfair to hold a name brand manufacturer responsible for injuries that arise from a product that is beyond its control."), *aff'd per curiam*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007); Stanley v. Wyeth, Inc., 991 So. 2d 31, 34 (La. Ct. App. 2008) ("[A] manufacturer cannot reasonably expect that consumers will rely on the information it provides when actually ingesting another company's drug.").

other direction: the brand-name manufacturers can readily foresee generic imitation of their products, can easily identify exactly who is producing the generic versions, and, through the FDA, can force every generic manufacturer to go along with any change to the product or its labeling that safety demands.

Plausible arguments can be made in either direction. Resolution of the issue should not be based on erroneous and overbroad generalizations—accepted too often by courts in the past—about manufacturers being liable only for the manufacture and sale of their own products. Instead, the issue warrants a more cautious examination of the real consequences and policy concerns at stake.

E. The Impact of Brand-Name Manufacturers' Liability for Generic Drug Injuries

Given that the general principles and rules of tort law do not provide a decisive answer, the issue turns on equity and policy considerations. Although drug makers have labored mightily to portray themselves as having the high ground in these respects, their contentions wilt under closer scrutiny.

Critics of the *Conte* decision insist that the unfairness of holding anyone liable for someone else's product is particularly acute in the context of brand-name and generic prescription drugs. Brand-name manufacturers, they argue, lay out the enormous investment in research and testing necessary to develop a new drug and to steer it through the long and unpredictable FDA approval process.[260] They then bear the heavy costs of promotional efforts to popularize a drug, such as running advertisements and sending out sales representatives to inform doctors about the drug.[261] The generic manufacturers then sweep into the market after the brand-name drug's patent protection has expired and reap profits from selling the drug without having incurred any of the costs of its development and promotion.[262] The brand-name manufacturers believe that these circumstances make it "totally unfair and draconian" for them to be held responsible for

260. *See, e.g.*, Reply to Answer to Petition for Review at 17–20, Conte v. Wyeth, Inc., No. S169116 (Cal. Jan. 21, 2009) (describing the "considerable resources" invested in new drugs and the low odds of obtaining FDA approval).

261. For a description of brand-name manufacturers' promotional efforts, see *supra* notes 30–34 and accompanying text.

262. *See* Reply to Answer to Petition for Review, *supra* note 260, at 15–16 (noting how "generic manufacturers benefit from the innovators' investment of resources").

injuries suffered through use of the generic drugs.[263] Indeed, the lawyers who represent drug companies have tried to come up with a catchy name for the theory of liability asserted against brand-name manufacturers by patients who took generic drugs, dubbing it "pioneer liability" or "innovator liability" to underscore the notion that it would punish those who do the valuable and difficult work of introducing new drugs.[264]

These arguments rely on a subtle tactic that distracts courts' attention from the real issue presented. Whenever the brand-name manufacturers cite fairness concerns, they compare themselves only to the generic drug makers.[265] They emphasize reasons why a brand-name manufacturer may deserve liability less than the generic drug producers who ride on its coattails. By presenting the fairness question as a choice between blaming the generic drug maker or the brand-name manufacturer, they omit the plaintiff from the calculus. They convince courts that the equities of the situation favor the brand-name manufacturer over the generic producer, never addressing the possibility that the innocent plaintiff's needs should trump those of both manufacturers in any truly comprehensive assessment of what is fair and just in these circumstances.

Holding a defendant liable for negligence that was a significant cause of a plaintiff's injury is not unfair. If the plaintiff took a generic drug, the brand-name manufacturer will not be subject to strict

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263. Respondent Wyeth's Brief, *supra* note 145, at 23.

264. *See, e.g.*, Beck & Herrmann, *supra* note 192 (asserting that the *Conte* decision "created a huge 'free rider' problem in that pioneer manufacturers are stuck with liability for generic products that . . . they do not get any profit from"); *California Becomes First State to Recognize Innovator Liability*, MAYER BROWN (Jan. 26, 2009), http://www.mayerbrown.com/publications/article.asp?id=6060&nid=6 ("[I]nnovator liability is currently being considered by courts in a number of additional jurisdictions. In light of the appellate court decision in *Conte*, courts may now revisit the reasoning of prior, well-established holdings.").

265. *See, e.g.*, Reply to Answer to Petition for Review, *supra* note 260, at 16 ("[T]he Court of Appeal's holding is fundamentally unfair and contrary to the public interest. It saddles an innovator with a duty to all those who use its competitors' generic products and concomitantly immunizes the generic manufacturers from liability to users of their own products. In so doing, it unfairly inflates the costs of the name-brand manufacturer and unfairly minimizes the costs of its generic manufacturer competitors by shifting costs from the latter to the former."); Brief of Appellee/Cross-Appellant, *supra* note 92, at 25–26 ("When a prescription is written so as to allow generic substitution; the pharmacist dispenses a generic product as permitted; the generic manufacturer profits from the sale of its product; and the product ultimately causes harm, there is no reason or justification for the brand name manufacturer, whose product was not prescribed exclusively, was not sold, was not used, and did not cause harm, and who did not profit from a sale—indeed, lost a sale to a generic competitor—to incur liability for harm caused by its competitor's product.").

liability; it will be liable only if it failed to use reasonable care in some vital aspect of developing and testing the drug or in crafting the drug's warnings, instructions, or promotional statements.[266] Simply requiring the manufacturer to act with the care of a reasonable person should not be too much to demand. As the plaintiff in *Conte* rightly asked, "[W]hat is unfair about requiring a defendant to shoulder its share of responsibility for injuries shown to have been caused, at least in part, by its dissemination of false information, which it reasonably should expect to be relied on by its intended recipients?"[267] Between the brand-name manufacturer and the generic drug manufacturer, fairness might favor the former. But between a brand-name manufacturer that acted negligently and the innocent plaintiff who suffered serious harm as a result, the fairness inquiry easily tilts in favor of the latter. In the *Foster* case, for example, the brand-name manufacturer allegedly knew that the product and its generic imitations posed a potentially fatal danger to children, but failed to give adequate warnings that would have saved lives but hurt sales.[268] The FDA eventually confirmed that the drug needed a much stronger warning, but that was too late for Brandy Foster and the other children already dead as a result of the manufacturer's actions.[269] Likewise, in the *Conte* case, the brand-name manufacturer allegedly knew about but downplayed the drug's risks, causing Elizabeth Conte and many others to develop a severe and potentially life-threatening neurological disorder.[270] Again, the FDA eventually confirmed that the product's warnings were dangerously flawed.[271] The plaintiffs in this category of cases deserve the opportunity to prove that their allegations are true. And if they succeed, holding the brand-name drug makers responsible for the harm resulting from their negligence is far from unfair.

The injustice of giving brand-name manufacturers immunity from liability for generic drug injuries is particularly severe to the extent that it would mean no drug maker would have any legal responsibility for a plaintiff's injuries. Courts rejecting claims brought against brand-name manufacturers by patients who took generic

266. *See supra* Part III.A.
267. Brief of Appellant, *supra* note 33, at 18.
268. *See supra* notes 80–97 and accompanying text.
269. *See supra* notes 121–24 and accompanying text.
270. *See supra* notes 145–57, 168–77 and accompanying text.
271. *See supra* notes 189–90 and accompanying text.

drugs often seem to assume plaintiffs will still have adequate remedies because the generic drug manufacturers will be liable.[272] This assumption, however, glosses over the arguments made by generic drug manufacturers in these cases and the real possibility that a plaintiff who took a generic drug could be left with no viable claim against any manufacturer, even for harm caused by an egregiously flawed product or a grossly inadequate warning.

Indeed, the generic drug makers believe they should never face any liability because federal law should preempt all state-law tort claims against them.[273] The Supreme Court will soon make an important ruling on the preemption issue,[274] but even if the Court rules against preemption, the generic drug manufacturers have a number of other cards to play in many instances. In particular, they contend that they should never be liable for providing inadequate or misleading statements in drug labeling if the plaintiff's doctor never actually looked at the generic drug's labeling and instead saw only the information disseminated by the brand-name manufacturer.[275] In other words, when a doctor gets information about a drug from the brand-name manufacturer, but the patient receives the generic drug, both the brand-name and generic manufacturers will insist that they can have no liability. The brand-name manufacturer will say the plaintiff did not take its product, and the generic drug maker will say the plaintiff's doctor did not rely on its warnings or representations about the product. According to the drug companies, both manufacturers should escape liability in those circumstances, even if both were negligent and their wrongdoing combined to cause catastrophic harm to the plaintiff.

Likewise, in the opposite situation, when a plaintiff's doctor saw the flawed warnings and misleading representations about the drug only in the generic product's labeling, but the plaintiff took the brand-name drug, both manufacturers again would insist that neither can be held liable. This situation would occur very rarely, if ever, because doctors typically do not learn about a drug from the generic product's

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272. *See* Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169–70 (4th Cir. 1994) ("We do not accept the assertion that a generic manufacturer is not responsible for negligent misrepresentations on its product labels if it did not initially formulate the warnings and representations itself."); *supra* notes 119–20 and accompanying text.

273. *See supra* note 43 and accompanying text.

274. *See supra* notes 47–48 and accompanying text.

275. Conte v. Wyeth, 85 Cal. Rptr. 3d 299, 318–19 (Ct. App. 2008); *see supra* notes 185–87 and accompanying text.

labeling.[276] Instead, doctors are much more likely to receive information generated by the brand-name manufacturer, whether through the brand-name product's labeling, the *Physicians' Desk Reference*, or sales representatives or advertisements touting the brand-name drug. But to the extent that it ever happened, the manufacturers' responses to the dilemma would be just as unfair as in the more common scenario in which the doctor relied on information about the brand-name drug but the patient received the generic equivalent. Either way, the doctor saw one company's labeling, but the plaintiff received another company's product. According to the manufacturers, the injured patient thus has no claim against either.

Table 1 illustrates the possibilities. The drug companies' arguments would preclude liability for inadequate warnings or misrepresentations in every instance in which the doctor's source of information did not match the pharmacist's source of the drug itself. No manufacturer would be liable in situations like *Foster* and *Conte*, represented by the upper-right quadrant of the diagram, or in the much less common but equally problematic scenario represented by the lower-left quadrant.

Table 1. Implications of the Drug Companies' Arguments about Inadequate Warning and Misrepresentation Claims

		The patient takes the drug made by . . .	
		Brand-name manufacturer	**Generic manufacturer**
The doctor relies on information from . . .	**Brand-name manufacturer**	Brand-name manufacturer can be liable	No manufacturer can be liable
	Generic manufacturer	No manufacturer can be liable	Generic manufacturer can be liable

When the brand-name manufacturer negligently made dangerous missteps in preparing its warnings and other representations about its product, and when the generic manufacturer carelessly repeated those statements verbatim on its labeling, what

276. I suspect that there may never be a situation in which a doctor prescribes a drug based solely on information generated by the generic drug manufacturer. *See* Plaintiff's Memorandum Concerning Pertinent Aspects of the Rostron Article, *supra* note 202, at 8 ("The likelihood of any doctor's even possessing a generic prescription drug's label, much less reading or relying on it, in the ordinary course of his or her practice, is so remote as to border on the nonexistent."). But I nevertheless address that scenario, because it is impossible to be certain or to prove that it never happens, and because I think it is helpful to consider every possible permutation in developing theories about the handling of these situations.

legitimate basis could exist in principle, policy, or fairness for absolving both manufacturers of liability because of a fortuitous mismatch between which version of the drug's labeling the doctor happened to remember seeing and which version of the drug the pharmacist happened to dispense? The drug manufacturers never squarely answer that question. Instead, one manufacturer will simply argue that "it wasn't my drug," and the other will separately contend that "it wasn't my label." And they will hope that the court lets each avoid liability. Indeed, when pressed at an oral argument by a judge who wanted to know why a plaintiff injured because of inadequate warnings should be left with no recourse because her pharmacist dispensed the generic version of a drug, the defendants suggested that "consumers who opt for generic drugs over name-brand equivalents may have effectively lost their right to recompense for injuries suffered from inadequate warnings in the bargain."[277] In other words, if the plaintiff saved a little money by taking the generic version of a drug, the plaintiff should not be heard to complain no matter how harmful the drug turns out to be or how careless its manufacturers turn out to have been.

This argument overlooks the fact that many consumers have little choice about whether to receive generic drugs because health insurance plans or government programs like Medicaid may refuse to cover brand-name drugs once generic substitutes become available.[278] Even when consumers do willingly pick generic drugs to save money, they do not thereby waive their right to hold negligent parties liable. Imagine, for example, facing the parents of an infant child who died as a result of taking cough syrup, and telling them that the brand-name manufacturer that wrote the product's inadequate warnings will not be held responsible for negligently putting profits ahead of safety, but that, on the other hand, they should look on the bright side because they probably saved a few dollars when the pharmacist gave

277. Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279, 308 n.40 (D.N.H. 2009). The judge in *Bartlett* posed this question in the context of deciding whether federal law preempts inadequate warning claims against generic drug manufacturers. The judge concluded that Congress could not have intended to leave consumers of generic drugs without a remedy against a manufacturer for harm suffered because a drug's labeling provided inadequate warnings. *Id.* at 308–09.

278. *See* Abbott Labs. v. Andrx Pharm., Inc., No. 05 C 1490, 2005 WL 1323435, at *15 (N.D. Ill. June 3, 2005) (explaining that once a generic version of a brand-name drug becomes available, the managed-care provider will pay more toward the generic version than toward the branded product), *vacated on other grounds*, 452 F.3d 1331 (Fed. Cir. 2006).

them a generic version of the cough syrup.[279] That notion "is not only distasteful but also contrary to fundamental principles of tort law."[280]

Brand-name manufacturers stand on firmer ground, however, when they insist that generic drug makers should not be given unfair advantages over them.[281] For example, the California Court of Appeal concluded in *Conte* that although the plaintiff could proceed to trial on her negligent misrepresentation claim against the brand-name drug manufacturer, the generic manufacturers could not be held liable because Conte's doctor did not look at the generic product labeling or otherwise rely on any generic manufacturer's representations about the product.[282] By letting the generic manufacturers avoid responsibility for Conte's injuries, the court created an unfair imbalance between the treatment of the brand-name and generic drug producers. Under the *Conte* approach, if a drug lacks adequate warnings, its brand-name manufacturer may wind up being liable for harm to those who took either the brand-name or the generic version of the drug, whereas the generic manufacturers likely will wind up not being liable to anyone. That asymmetry is particularly unfair given that the brand-name manufacturers make substantial investments in developing new drugs from which generic producers profit by copying. In the pithy words of one blog reader reacting to discussion of the *Conte* decision, "I should get in on this generic med business—tons of money and no risk."[283] Although fairness considerations should tip the balance on these issues toward innocent plaintiffs and against manufacturers, they do not justify such an odd misallocation of the responsibility between the brand-name manufacturer and its generic imitators.

The unfairness of this imbalance is exacerbated by the inherent difficulty of determining why a doctor prescribed a certain drug for a particular patient. Researchers have found, for example, that doctors often do not recognize or do not accurately report the factors that

279. *See supra* note 85 and accompanying text.

280. *Bartlett*, 659 F. Supp. 2d at 308 n.40.

281. *See, e.g.*, Reply to Answer to Petition for Review, *supra* note 260, at 16 (complaining that the *Conte* decision "saddles an innovator with a duty to all those who use its competitors' generic products and concomitantly immunizes the generic manufacturers from liability to users of their own products," thereby "unfairly inflat[ing] the costs of the name-brand manufacturer and unfairly minimiz[ing] the costs of its generic manufacturer competitors").

282. *See supra* notes 185–87 and accompanying text.

283. Ed Silverman, *Brand-Name Makers Liable for Generic Injuries*, PHARMALOT (Nov. 8, 2008, 8:34 AM), http://www.pharmalot.com/2008/11/brand-name-makers-liable-for-generic-injuries (comment posted by "G" on Nov. 8, 2008, 4:56 PM).

actually drove their therapeutic decisionmaking about use of prescription drugs.[284] When asked why they chose a drug, doctors exaggerate the extent to which they rely on scientific sources, such as reports in medical journals, while understating the influence of commercial channels of information such as a drug company's advertisements and sales representatives.[285] Doctors' self-assessments therefore seem to be unreliable indicators of what really drives prescribing behavior.[286]

Cases like *Foster* and *Conte* illustrate the perils of putting too much weight on what doctors say about their reasons for prescribing a drug. In each case, the doctor's deposition testimony about his prescription decisionmaking was equivocal and ambiguous.[287] Compounding that difficulty, the drug manufacturers in each case procured declarations from the doctors that muddied the matter even further.[288] The reality is that doctors typically learn about drugs from an array of sources,[289] and it is generally unrealistic to expect them to be able to pinpoint exactly which sources or pieces of information they relied upon in prescribing a drug for a particular patient. This problem is not a reason to give drug manufacturers immunity from liability, but rather it demonstrates why courts should strive to handle these sorts of cases in ways that treat plaintiffs and defendants fairly without putting undue weight on doctors' unreliable self-reporting.

Although important concerns about fairness and sound public policy exist on all sides of the issue, manufacturers ultimately should be held responsible when their negligence causes severe harm to others. In cases like *Foster*, courts have gone too far in categorically exempting brand-name drug manufacturers from liability to those injured by use of generic drugs. In drawing the boundaries of liability, however, courts should take into account the potential for unfairly creating an imbalance in the liability exposure of brand-name and generic drug producers, as well as the difficulties of determining the particular sources of information on which a doctor relied in

284. *See* Jerry Avorn, Milton Chen & Robert Hartley, *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 AM. J. MED. 4, 4 (1982) ("This limits the value of self-report as a means of determining how physicians make prescribing decisions.").

285. *Id.*

286. *Id.* at 7.

287. *See supra* notes 98–103, 160–65 and accompanying text.

288. *See supra* notes 104–08, 166–67 and accompanying text.

289. Brief of Appellants/Cross-Appellees, *supra* note 91, at 24.

prescribing a drug for a patient. Part IV proposes a scheme of liability that takes account of these myriad concerns.

IV. A PROPOSED APPROACH TO LIABILITY OF BRAND-NAME AND GENERIC DRUG MANUFACTURERS

Weighing the significant considerations at stake when a plaintiff asserts tort claims based on a harmful flaw in the design or labeling of the brand-name and generic versions of a drug,[290] the liability framework described here seeks to achieve a fair balance of the interests of injured plaintiffs, brand-name manufacturers, and their generic counterparts.

A. Design-Defect Claims

In cases in which a patient took a brand-name drug and claims to have suffered harm because of a defect in the product's design, the analysis will be relatively simple. The brand-name manufacturer may be liable because it designed, manufactured, and sold the item that caused the plaintiff's alleged injuries. The precise contours of that liability vary from state to state and continue to be the subject of intense controversy.[291] In particular, courts disagree about the extent to which strict liability should be available for a design-defect claim when the product is a prescription drug.[292] But under whatever approach the relevant state uses, a brand-name manufacturer might

290. Manufacturing defect claims do not raise the sorts of problems discussed in this Article. Unlike a flaw in a drug's design or labeling, a manufacturing defect typically will be a problem unique to one manufacturer. For example, if a mistake on a generic drug manufacturer's production line causes some units of the product to be tainted with impurities or to contain the wrong amount of a crucial ingredient, there would be no sound reason to hold the brand-name manufacturer responsible, barring some sort of unusual scenario in which the brand-name manufacturer was somehow involved in setting up or running the generic manufacturer's operations. Likewise, no reason would exist for holding generic drug makers responsible for errors occurring in production of the brand-name drug.

291. *See* OWEN, *supra* note 60, § 8.10, at 566–79 ("Many have been bewitched, bedazzled, and bewildered in attempting to figure just how principles of design defectiveness should be applied to prescription drugs . . . ."); Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 707 (1990) ("Unfortunately, the courts seem unable to agree on a consistent set of liability rules to apply in drug injury cases."); Henderson & Twerski, *supra* note 15, at 162–81 (responding to criticisms of the *Third Restatement*'s approach to design-defect claims against prescription drug manufacturers); Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 842–48 (2009) (explaining the different approaches courts use in resolving design-defect claims for prescription drugs).

292. OWEN, *supra* note 60, § 8.10, at 566–79.

be liable when the plaintiff took the brand-name drug. Generic manufacturers, on the other hand, should not be liable for a design flaw in a brand-name product. They neither manufactured that product nor played a role in determining its design.

The situation is more complicated when the plaintiff instead took a generic version of the drug. In that scenario, the brand-name manufacturer and generic manufacturer share responsibility for the design of the product that the plaintiff received, because the brand-name manufacturer initially developed the drug, and the generic manufacturer copied key aspects of that original design to produce a product close enough in its material characteristics to earn FDA approval as a generic equivalent. Both the brand-name manufacturer and the generic manufacturer thus have a sufficient connection to the product's design to justify imposing liability on both for harm resulting from a dangerous flaw in the design.

The brand-name manufacturers will vigorously contest this conclusion on the ground that they should not be liable for a design defect in someone else's product. Moreover, the approach that I suggest creates some asymmetry, with brand-name manufacturers bearing some risk of liability for design flaws in generic products, but generic manufacturers facing no risk of liability for design defects in brand-name drugs.

Two considerations, however, could soften the effect on brand-name manufacturers. One is that a plaintiff who took a generic drug will be able to prevail on a design-defect claim against the brand-name manufacturer only by proving negligence. In other words, strict liability cannot be imposed, and the brand-name manufacturer will be able to avoid liability simply by exercising reasonable care in developing the product. This would be consistent with the general view in products liability that nonmanufacturing designers can be held liable for negligence but are not subject to strict liability.[293]

In addition, it would be appropriate for courts in these circumstances, in which a plaintiff who took the generic drug prevails on a design-defect claim, to assign primary liability to the generic manufacturer and to hold the brand-name manufacturer liable only in a secondary capacity. If the generic manufacturer is capable of paying the judgment (or whatever share of the judgment is assigned to that manufacturer under comparative fault or similar principles), it should

293. *See supra* notes 74–75, 243 and accompanying text.

be required to do so. The brand-name manufacturer would become obligated to pay only in the event that the generic manufacturer was defunct, bankrupt, or otherwise unable to compensate the plaintiff.

Tort law utilizes this sort of primary-secondary liability structure in other contexts. The most prominent example is the doctrine of respondeat superior, under which an employer can be held liable for a tort committed by its employee within the scope of the employment.[294] The employee has primary liability, while the employer's liability is only secondary in nature, and therefore the employer is entitled to demand full indemnification from the employee for any amount it pays the plaintiff.[295] Products liability law provides another example. Although courts can impose strict tort liability on wholesale and retail sellers of a defective product, the liability of these nonmanufacturing sellers is secondary to that of the manufacturer.[296] If unaware of the defect, the wholesale or retail seller may be liable to a plaintiff, but then will be entitled to full indemnification by the manufacturer.[297] In each of these situations, the defendant with secondary liability essentially bears the burden of compensating the plaintiff only if the primarily liable defendant cannot do so.

This sort of primary-secondary liability approach would be appropriate for design-defect claims brought by plaintiffs who took generic drugs, but not because brand-name manufacturers should be forced to serve as insurers or guarantors for the liabilities of the generic drug producers. Likewise, the idea is not that brand-name manufacturers should be subjected to unwarranted liability merely because they may have deeper pockets than many generic drug producers. Liability instead should be structured in this manner because sufficient grounds exist for imposing liability on both the

294. *See* DOBBS, *supra* note 214, § 333, at 905 (explaining the vicarious liability theory of respondeat superior).

295. *Id.* § 333, at 906.

296. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 886B(2) (1979) ("[I]ndemnity is granted [when t]he indemnitor supplied a defective chattel . . . as a result of which both [tortfeasors] were liable to the third person, and the indemnitee innocently or negligently failed to discover the defect . . . .").

297. *Id.* For a thorough discussion of the issue, see Dragan M. Ćetković, *Loss Shifting: Upstream Common Law Indemnity in Products Liability*, 61 DEF. COUNS. J. 75, 79 (1994). Some states have gone further and enacted "innocent seller" statutes giving retailers and other nonmanufacturing sellers even greater protection from liability than that afforded by the common law doctrine of indemnification. *Id.*; *see also* OWEN, *supra* note 60, § 15.2, at 1010–11 & nn.81–90 (explaining that some states, in response to fairness concerns, have enacted statutes to shield retailers from liability and "in at least a couple instances statutory provisions exempt non-manufacturers unconditionally from strict products liability in tort").

brand-name manufacturer and the generic manufacturer, but the former's link to the product is not as direct as that of the latter. Put another way, between the brand-name manufacturer who acted negligently and the innocent plaintiff who suffered serious harm as a result, the law should come down on the side of the plaintiff. But between the brand-name manufacturer and the generic manufacturer, the balance tips in favor of imposing liability primarily on the latter because it manufactured and profited from the sale of the particular item that directly inflicted the plaintiff's injuries.

B. Inadequate Warning and Misrepresentation Claims

Inadequate warnings and misrepresentations pose difficult issues as well, and they have been the focus of *Foster*, *Conte*, and most of the other relevant cases in this area. Although the line between an inadequate warning claim and a misrepresentation claim is sometimes indistinct, the former essentially involves omission of important information about the product's risks, whereas the latter typically involves a false statement about the product.[298] These types of claims thus relate not only to the product itself but also to the information provided about the product. That duality underlies the dilemma posed by these claims in cases about brand-name and generic drugs. If one manufacturer supplied the product itself, but another supplied information about the product, who should be responsible for harm that results if the product causes injury because the information was inadequate, misleading, or erroneous?

The drug manufacturers' arguments ultimately would lead to the conclusion that a defendant can be held liable only if it supplied both the drug that the plaintiff received and the faulty information on which the plaintiff's doctor relied.[299] When there was a mismatch between the source of the drug and the source of information, neither manufacturer could be held accountable. In some instances, the plaintiff might have viable claims against other parties, such as a medical malpractice claim against a doctor, but many plaintiffs would simply be unable to recover any compensation. The brand-name and generic manufacturers would avoid liability even if they each acted in appallingly negligent ways and unmistakably caused the plaintiff to

298. *See* OWEN, *supra* note 60, § 3.2, at 117–23 (discussing whether a defendant's failure to disclose information about a product can support a misrepresentation claim or only a failure-to-warn claim).

299. *See supra* Table 1, notes 272–80, and accompanying text.

suffer very severe harm. Rather than permit this unjust result, courts should recognize that a drug manufacturer can be held liable even if it did not supply both the product and the faulty information that caused the plaintiff's injuries.

Reaching that conclusion, however, leaves unanswered some difficult questions about exactly what the scope of manufacturers' liability should be in various situations. Table 2 lays out, once again, each of the four basic scenarios that may arise.

Table 2. A Proposed Approach to Inadequate Warning and Misrepresentation Claims

		The patient takes the drug made by . . .	
		Brand-name manufacturer	**Generic manufacturer**
The doctor relies on information from . . .	**Brand-name manufacturer**	Brand-name manufacturer can be liable	Generic manufacturer can be liable (with brand-name manufacturer only secondarily liable)
	Generic manufacturer	Brand-name manufacturer can be liable (with generic manufacturer only secondarily liable)	Generic manufacturer can be liable

In each situation, one could argue that all manufacturers of the drug should be liable because, in some sense, the conduct of every manufacturer was an actual cause of the plaintiff's harm. For example, if a patient took the brand-name drug and her doctor looked only at the brand-name product's labeling, one could argue that the generic manufacturers nevertheless caused the plaintiff's injuries by failing to speak up about the product's risks. If a generic manufacturer had told the FDA that the information in the product's labeling was inadequate or misleading, the FDA could have required every producer of the drug, including the brand-name manufacturer, to change the labeling. Such a change could have saved the plaintiff from suffering harm. Likewise, if a patient took a generic version of the drug and her doctor relied upon information solely from the generic product's labeling, the plaintiff could still blame the brand-name manufacturer for drafting the flawed content of the original labeling that the generic manufacturer copied. If the brand-name manufacturer had written adequate labeling in the first place, or later asked the FDA for necessary changes to ensure safe use of the drug, the plaintiff would not have been injured.

Though perhaps liability could theoretically be imposed on every manufacturer of the drug even in situations in which one manufacturer actually provided both the drug and the information on which the patient's doctor relied, as a practical matter this solution would stretch the net of liability too far. Although all of the drug's manufacturers may have acted negligently, and although each one's conduct technically would have been an actual cause of the plaintiff's harm, the link between a manufacturer and the injury becomes weaker and more indirect if the manufacturer neither produced the drug that the plaintiff received nor generated the information that the plaintiff's doctor saw. At some point, the interests weighing in the plaintiff's favor can no longer justify the sheer logistical difficulties presented by the proliferation of potential liability. For example, imagine a situation in which a patient took a drug manufactured by Company X, based entirely on information supplied by Company X, but dozens or even hundreds of other companies made the same drug, and thus could have acted to strengthen the warnings and prevent the harm.[300] Would it really be worth the additional complexity of making all of those companies, in addition to Company X, potentially liable for the injury? Moreover, allowing all manufacturers of the drug to be held liable would open the door to very difficult questions about allocating liability among them. That thorny nest of issues can be avoided by drawing a simple and common-sense line that limits liability to the one manufacturer that produced both the drug that the plaintiff received and the information that the plaintiff's doctor saw. Lines must be drawn somewhere.[301]

This still leaves the more difficult dilemma of what to do in situations in which one manufacturer made the drug but another generated the labeling or other information on which the doctor relied in prescribing the drug. In these situations, with only two manufacturers involved, each having a distinct and significant connection to the plaintiff's injury, no extreme practical difficulties or complexities weigh against imposing liability on both manufacturers. The most common scenario, addressed in cases like *Foster* and *Conte* and illustrated in the upper right quadrant of Table 2, occurs when

300. That a drug could be produced by hundreds of different manufacturers is not merely a hypothetical possibility. *See* Rostron, *supra* note 227, at 159 (describing how hundreds of pharmaceutical companies produced the drug diethylstilbestrol (DES)).

301. In the immortal words of Judge William Andrews, "We draw an uncertain and wavering line, but draw it we must as best we can." Palsgraf v. Long Island R.R. Co., 162 N.E. 99, 104 (N.Y. 1928) (Andrews, J., dissenting).

the patient took the generic drug but the doctor relied exclusively on information from the drug's brand-name producer. The opposite situation, represented by the lower left quadrant of Table 2, could also happen, with the patient taking the brand-name drug but the patient's doctor relying on information from a generic manufacturer, although that is likely to be a very rare occurrence.[302]

In these situations, in which one manufacturer supplied the drug and the other provided the faulty information about the drug, both manufacturers should be potentially liable. Each has a direct and substantial link to the plaintiff's use of the drug and resulting harm. Regardless of whether the plaintiff received the brand-name or generic version of the drug, the brand-name manufacturer could have prevented the plaintiff's injuries by acting carefully and by providing adequate and accurate information about its product. Likewise, regardless of whether the plaintiff took the brand-name or generic drug, the generic manufacturer could have prevented the harm by pointing out the flaws in the information being disseminated about the product and by asking the FDA to take corrective action. When each manufacturer has such a strong causal connection to the plaintiff's injuries, both should potentially be liable.

The liability of the two manufacturers in these situations could have the same primary-secondary structure suggested for design-defect claims.[303] Whichever manufacturer actually made the drug that a plaintiff received should be primarily liable; the other manufacturer, which generated the information on which the plaintiff's doctor relied, should be obligated to pay damages only if the primarily liable manufacturer turns out to be insolvent or otherwise unable to pay. This would alleviate at least some of the unfairness that brand-name manufacturers see in being held liable when generic manufacturers profited by copying the brand-name product and riding the coattails of the brand-name manufacturers' research efforts and discoveries. If generic manufacturers capture most of the market for the drug, they will wind up bearing the bulk of the liability to those successfully asserting inadequate-warning or misrepresentation claims.

This approach to liability of brand-name and generic drug manufacturers also would have the salutary effect of diminishing the significance of evidentiary disputes about what information a particular doctor had in mind when prescribing a drug for a certain

302. *See supra* notes 36–37, 276 and accompanying text.

303. *See supra* Part IV.A.

patient. As past cases like *Foster* and *Conte* illustrate, that is often an extremely muddled factual question to which no clear answer will exist.[304] The approach proposed here reduces the chances that a plaintiff's entire case will hinge on difficult determinations about a doctor's hazy and conflicting recollections. For example, when the plaintiff took the generic drug, the generic drug maker will be the manufacturer with primary liability for inadequate warnings or misrepresentations. If the generic manufacturer can pay the damages awarded, trying to prove that the brand-name manufacturer is secondarily liable because the plaintiff's doctor relied on its information will be a moot point. When the generic manufacturer cannot pay, the brand-name manufacturer's potential secondary liability will become relevant and therefore the question of what information the doctor considered may become crucial. The approach proposed here, however, will reduce to some extent the odds that a plaintiff's entire recovery turns on nebulous factual determinations about what influenced a doctor's decision to write a prescription.

CONCLUSION

The California Court of Appeal defied an imposing body of precedent when it ruled in *Conte* that a brand-name drug manufacturer could be liable for harm suffered by a person who took a generic product made by another company. Although widely scorned as a misguided and aberrational departure from sound policy and tort principles, *Conte* in fact represents the most careful and sophisticated consideration that any court has given to these difficult issues. Rather than brush aside the plaintiff's arguments with conclusory assumptions and crude overgeneralizations, the California court followed basic tort principles and methodically reviewed the elements of the claims asserted and the crucial competing interests underlying the case. Whether one agrees with its conclusions, the California court deserves credit for giving these issues the fresh look that they deserved.

Though I ultimately come out on the plaintiffs' side of the key questions analyzed here, no one should doubt that imposing liability on drug manufacturers is a serious matter that deserves courts' most cautious and thorough analysis. Drug companies engage in a business of critical importance, developing products of enormous potential

304. *See supra* notes 98–108, 160–67 and accompanying text.

benefit to humanity. Tort law could go too far in discouraging the development of innovative new drugs. The application of legal rules could be skewed too much against defendants in drug cases, with judges and juries demanding perfection that cannot be attained and seeing negligence that does not really exist. Overwarning about every imaginable risk may drive doctors and patients to overlook truly significant precautionary information, deter doctors from prescribing worthwhile drugs, or scare patients out of taking drugs that would benefit them. These risks are real.

At the same time, drug companies also have been responsible for some of the world's most notorious product catastrophes, such as DES, the Dalkon Shield, and thalidomide.[305] The FDA's regulatory oversight repeatedly has proven insufficient to prevent unreasonably dangerous drugs from reaching consumers.[306] Tort law provides vital incentives for drug makers to act with appropriate care. Courts should apply tort law in a manner that encourages drug companies to continue producing innovative products but also to act reasonably to ensure that their products are safe and accompanied by adequate warnings and accurate information. Striking the right balance is a challenge, but it is one that courts must continue striving to meet. These issues can quite literally be matters of life and death.

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305. *See generally* CTR. FOR JUSTICE & DEMOCRACY, THE BITTEREST PILL: HOW DRUG COMPANIES FAIL TO PROTECT WOMEN AND HOW LAWSUITS SAVE THEIR LIVES (2008) (discussing the serious injuries and deaths caused by DES, the Dalkon Shield, thalidomide, and other products).

306. *See* COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYS., INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 17 (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., 2007) ("FDA's performance in approving drugs or monitoring their safety after approval has been questioned and criticized."). For a discussion of how political influence has damaged the FDA's scientific integrity, see generally James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939 (2008).