

# ADDING INSULT TO INJURY: PAYING FOR HARMS CAUSED BY A COMPETITOR'S COPYCAT PRODUCT

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## I. INTRODUCTION

After Elizabeth Conte complained of recurring gastrointestinal discomfort, her physician diagnosed gastroesophageal reflux disease, for which he prescribed the antiemetic metoclopramide.<sup>1</sup> Wyeth sold the brand-name version of this prescription drug (Reglan®), which at the time competed against generic versions manufactured by other companies. The labeling for these drugs indicated a maximum twelve-week duration of use, but it allegedly failed to include adequate information about the adverse consequences associated with longer-term usage. After almost four years of taking only generic versions of the drug, Ms. Conte developed tardive dyskinesia, a serious neurological condition associated with the long-term use of metoclopramide but not then adequately highlighted as a risk on the package insert.<sup>2</sup>

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1. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 304–05 (Ct. App. 2008).

2. See *id.*; see also Christopher Kenney et al., *Metoclopramide, an Increasingly Recognized Cause of Tardive Dyskinesia*, 48 J. CLINICAL PHARMACOLOGY 379, 381–82 (2008); Jill U. Adams, *Metoclopramide: Another “Black Box” Warning*, L.A. TIMES, Mar. 9, 2009, at E3.

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As happens with growing regularity whenever pharmaceutical products cause injury, litigation ensued. Ms. Conte asserted failure-to-warn and similar claims against the three generic manufacturers that had supplied the drugs used to fill her prescriptions during that time period, even though she conceded on appeal that her physician had never read any labeling that they had distributed;<sup>3</sup> Ms. Conte also pursued a negligent misrepresentation claim against Wyeth, even while conceding that she had never ingested Reglan.<sup>4</sup> The trial judge granted summary judgment to all of the drug companies, and, in 2008, the California Court of Appeal affirmed as to the generic manufacturers but reversed on the claim against Wyeth.<sup>5</sup>

At first glance, this outcome seems absurd.<sup>6</sup> On closer examination, however, the court offered a plausible rationale for possibly imposing liability on the one company that definitely had not supplied the drug that caused Ms. Conte's injuries; after all, to hold otherwise would deprive her of any opportunity for recourse insofar as each of the involved drug manufacturers could establish that their alleged failure to disclose a knowable risk did not in fact lead to her injury.<sup>7</sup> The California court encountered an odd set of facts: company A's product caused the plaintiff's injury, but company A's allegedly tortious behavior in connection with the marketing of

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3. See *Conte*, 85 Cal. Rptr. 3d at 318–19.

4. See *id.* at 309.

5. See *id.* at 305–06, 318–21; see also Bob Egelko, *Way Clear for Suit Against Wyeth*, S.F. CHRON., Jan. 22, 2009, at B8 (reporting that the California Supreme Court declined to review the case). The appellate court did not address separate claims of malpractice asserted against her physician.

6. See *Moretti v. Wyeth, Inc.*, No. 2:08-cv-00396-JCM-(GWF), 2009 WL 749532, at \*4 (D. Nev. Mar. 20, 2009) (characterizing *Conte* as an outlier in the course of granting defendants summary judgment on essentially identical facts); Lawrence J. McQuillan & K. Lloyd Billingsley, Op-Ed., *Don't Hold Drugmakers Liable for Competitors' Generics*, SAN JOSE MERCURY NEWS, Feb. 15, 2009 (“This unfair decision has stunned observers and drawn warnings of negative consequences. . . . *Conte* is bad law, bad public policy and a national embarrassment that will cost California and the nation jobs and new medicines.”); see also Bridget M. Ahmann & Erin M. Verneris, *Name Brand Exposure for Generic Drug Use: Prescription for Liability*, 32 HAMLIN L. REV. 767, 788 (2009) (“*Conte* has turned products-liability law on its head.”); *id.* at 790 (“Any expansion of *Conte* . . . could well have a negative and unintended impact on an innovator's incentive to develop new drugs, as well as a generic manufacturer's incentive to ensure the safety of its own drugs.”).

7. See *infra* pt. III.B (elaborating); see also Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. (forthcoming 2010); cf. Jean A. Brodie, Case Note, *Foster v. American Home Products Corp.: Tort Liability for Injuries Caused by Someone Else's Product?*, 12 T.M. COOLEY L. REV. 431, 451–52 (1995) (explaining that, in an earlier decision rejecting a similar effort to impose liability for negligent misrepresentation on the brand-name drug manufacturer, the federal appellate court had not squarely confronted this argument, which plaintiffs then unsuccessfully highlighted in their petition for an en banc rehearing); *id.* at 452, 466–67 (concluding that the court correctly declined to impose liability against the brand-name manufacturer, and arguing that it should instead have found some way of disregarding the fact that physicians rarely see the labeling distributed with generic versions of a drug).

that product could not have caused her injury, while company B's product could not have caused plaintiff's injury, but company B's allegedly tortious behavior in connection with the marketing of that product arguably caused her injury.

One cannot, however, simply dismiss *Conte* as involving a peculiar set of circumstances: given the rapidly increasing use of generics to fill prescriptions,<sup>8</sup> it and a handful of other recent decisions involving the tort obligations of brand-name and generic drug manufacturers may represent the front edge of a wave of such litigation.<sup>9</sup> After briefly summarizing the different routes to market for pharmaceutical products, this article evaluates the potential difficulties that may arise when patients suffer injuries from the use of generic drugs and seek to hold someone responsible.

## II. MARKETING GENERIC PHARMACEUTICAL PRODUCTS

Generic drugs have become big business in this country. As previously skeptical patients and physicians grow accustomed to the idea of using generics, companies have rushed to fill the growing demand for inexpensive versions of brand-name pharmaceutical products.<sup>10</sup> A number of large manufacturers have overseas headquarters in countries such as India.<sup>11</sup> Even brand-name companies have reacted by offering cheaper generic versions of their own products after patents expire,<sup>12</sup> while generic

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8. See Melissa Healy, *Just as Good?: Generic Drugs Save Money, but There's a Growing Clamor from Patients and Doctors That Some Aren't as Effective as Their Brand-Name Brethren*, L.A. TIMES, Mar. 17, 2008, at F1 ("Currently, 64% of all prescriptions filled in the United States are for generics. That percentage is expected to rise steeply over the next few years."); Natasha Singer, *Generics Face Longer Wait for Approval*, N.Y. TIMES, Feb. 20, 2010, at B3 (reporting that generics now account for over 70 percent of dispensed prescriptions).

9. See Ahmann & Verneris, *supra* note 6, at 769 (warning of "a new—as yet uncharted—frontier of liability for name-brand drug manufacturers").

10. See Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1994 (2007) ("[T]oday's generics industry has annual sales of about \$35 billion."); Marc Kaufman, *Generic Drugs Hit Backlog at FDA: No Plans to Expand Review Capabilities*, WASH. POST, Feb. 4, 2006, at A1 (reporting that the agency had 800 pending applications for approval of generic drugs under review, a record high that it thought would increase substantially in the next few years); *id.* ("Consumer acceptance of generics has increased markedly in recent years."); Julie Schmit, *Drugmakers Gamble Big on Generics*, USA TODAY, Aug. 24, 2004, at 1B.

11. See Marc Kaufman, *FDA Scrutiny Scant in India, China as Drugs Pour into U.S.: Broad Overseas Checks Called Too Costly*, WASH. POST, June 17, 2007, at A1; Saritha Rai, *Indian Drug Maker Says It Will Keep Attacking Patents Despite Pfizer Loss*, N.Y. TIMES, Dec. 20, 2005, at C7; see also Lyndsey Layton, *FDA Says Firm Faked Generic-Drug Tests*, WASH. POST, Feb. 26, 2009, at A2 ("As pharmaceutical manufacturing has burgeoned in countries such as India and China, public health advocates and lawmakers have grown increasingly concerned about the safety of imported drugs and the FDA's ability to police them.").

12. Innovator companies sometimes introduce "authorized generics" (i.e., a drug product manufactured under the terms of their U.S. Food and Drug Administration (FDA) license

companies sometimes invest in limited marketing efforts to brand their knock-off products.<sup>13</sup>

In the Drug Amendments of 1962, Congress for the first time addressed generic drugs: in order to provide information about potential substitutability, it required that the established name appear alongside the brand name of prescription drugs.<sup>14</sup> Congress did not at that time, however, provide a clear mechanism for the routine approval of generic drugs. It took another two decades, and efforts by the U.S. Food and Drug Administration (FDA) to create a streamlined route for generic approval,<sup>15</sup> before Congress codified such a mechanism.<sup>16</sup> After a period of market exclusivity (typically five years) and the expiration of any remaining patents on the innovator drug, manufacturers wishing to sell generic versions may apply for abbreviated new drug approval (ANDA).

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but sold—by either the pioneer manufacturer or one of its licensees—using a different brand name and at a reduced price). See *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 273–76 (4th Cir. 2006) (rejecting a challenge to the government’s failure to prevent this practice); Leila Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004, at B1; Milt Freudenheim, *Generic Pharmaceuticals: Now the Big Drug Makers Are Imitating Their Imitators*, N.Y. TIMES, Sept. 20, 1992, § 3, at 5; Joe Nocera, *Generic Drugs: The Window Has Loopholes*, N.Y. TIMES, July 1, 2006, at C1; cf. Ellen Byron, *101 Brand Names, One Manufacturer*, WALL ST. J., May 9, 2007, at B1 (reporting that this practice exists in numerous other industries).

13. See David J. Morrow, *Old Drugs, New Labels: Brand Name Generics and Other Linguistic Anomalies*, N.Y. TIMES, June 13, 1998, at D1; see also Duane M. Kirking et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 J. AM. PHARMACEUTICAL ASS’N 578, 579, 582 (2001).

14. Pub. L. No. 87–781, §§ 112(a), 131(a), 76 Stat. 780, 790–91 (codified at 21 U.S.C. § 352(e)(2), (n)(1) (2006)); see also 21 C.F.R. § 201.10(g) (2009); *Abbott Labs. v. Gardner*, 387 U.S. 136, 138 (1967) (“The underlying purpose of the 1962 amendment was to bring to the attention of doctors and patients the fact that many of the drugs sold under familiar trade names are actually identical to drugs sold under their ‘established’ or less familiar trade names at significantly lower prices.”); John G. Giunarra, Jr., Note, *Drug Amendments of 1962—Generic-Name Prescribing: Drug Price Panacea?*, 16 STAN. L. REV. 649, 652–57 (1964). The pharmaceutical industry forcefully objected to FDA’s efforts to implement this requirement. See Harry A. Sweeney, Jr., *The “Generic Every Time” Case: Prescription Drug Industry in Extremis*, 21 FOOD DRUG COSM. L.J. 226, 230, 244 (1966).

15. See FDA, *Theapeutically Equivalent Drugs: Availability of List*, 45 Fed. Reg. 72,582 (Oct. 31, 1980); FDA, *Procedures for Establishing a Bioequivalence Requirement*, 42 Fed. Reg. 1624 (Jan. 7, 1977); FDA, *New Drugs: Abbreviated Applications*, 35 Fed. Reg. 6574 (Apr. 24, 1970); *Burroughs Wellcome Co. v. Schweiker*, 649 F.2d 221 (4th Cir. 1981) (rejecting objections to FDA’s “paper NDA” policy); Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 274–77 (1985).

16. See *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98–417, tit. I, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2006)) (commonly referred to as the “Hatch-Waxman Act”); see also *Biotech. Indus. Org. v. Dist. of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) (noting that the Hatch-Waxman Act sought to “increase[] price competition in the drug marketplace by simplifying the approval process for generic drugs” (quoting 130 CONG. REC. 23,058–59)). See generally Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585 (2003).

To secure an ANDA, FDA only requires that the sponsor of a generic drug demonstrate that its product is “bioequivalent” to—meaning that it has essentially the same rate and extent of absorption as—the innovator drug, a showing that substitutes for the much costlier clinical trials demanded as part of an application for new drug approval (NDA) to demonstrate safety and effectiveness of the innovator drug.<sup>17</sup> Although FDA requires that sponsors of ANDAs mimic the innovator drug in most significant respects, it has allowed certain variations in composition,<sup>18</sup> dosage form,<sup>19</sup> and labeling.<sup>20</sup> Whether or not a generic drug has minor differences

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17. See 21 U.S.C. § 355(j)(2)(A)(iv) (2006); 21 C.F.R. pt. 320 (2009); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318–21 (D.C. Cir. 1998); *Schering Corp. v. FDA*, 51 F.3d 390, 398–99 (3d Cir. 1995); *Somerset Pharm., Inc. v. Shalala*, 973 F. Supp. 443, 453–54 (D. Del. 1997) (deferring to FDA’s scientific judgment that metabolite testing could serve as an indicator of bioequivalence for generic versions of the drug selegiline hydrochloride indicated for the treatment of Parkinson’s disease). For details on bioequivalence testing (authored by FDA officials), see Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & L. 275, 278–79 (1995–1996); Stuart L. Nightingale & James C. Morrison, *Generic Drugs and the Prescribing Physician*, 258 JAMA 1200, 1201–03 (1987). A similar mechanism exists for medical devices subject to premarket approval (PMA) requirements: six years after approval of a PMA for the same type of Class III device, subsequent manufacturers could file what amounts to an abbreviated PMA by cross-referencing the innovator’s safety and effectiveness data. See 21 U.S.C. § 360(h)(4).

18. See *United States v. Generix Drug Corp.*, 460 U.S. 453, 454–55 (1983) (“The term ‘generic drug’ is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called ‘pioneer drug’ that is marketed under a brand name.”).

19. See *Warner-Lambert Co. v. Shalala*, 202 F.3d 326 (D.C. Cir. 2000) (rejecting a challenge brought by the manufacturer of a pioneer drug approved in a capsule dosage form against FDA’s decision to approve as “therapeutically equivalent” an ANDA for a capsule-shaped tablet version enclosed by a gelatin shell); see also *Pfizer v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999) (dismissing as unripe a challenge brought by the manufacturer of a brand-name antihypertensive to FDA’s decision to accept for filing an application for a generic version that used a different extended-release mechanism). Sponsors of such ANDAs normally first must file a “suitability petition” with the agency. See 21 C.F.R. § 314.93(b) (2009) (“[A]n abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength . . . must first obtain permission from FDA to submit such an abbreviated application.”); *Novartis Pharm. Corp. v. Leavitt*, 435 F.3d 344, 345–47 (D.C. Cir. 2006).

20. See *Zeneca, Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000) (explaining that a generic drug may include additional risk labeling if necessitated by the inclusion of a different inactive ingredient with allergenic potential); *SmithKline Beecham v. Watson Pharms., Inc.*, 211 F.3d 21 (2d Cir. 2000) (holding that the federal requirement for use of the same labeling with generic drugs trumped copyright laws that otherwise might have protected the lengthy user’s guide and audiotape prepared by the brand-name manufacturer of a smoking-cessation product); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (sustaining FDA’s authority to approve a generic drug for only a subset of the innovator drug’s labeled indications); Julie Dohm, Comment, *Expanding the Scope of the Hatch-Waxman Act’s Patent Carve-out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 157–59, 176–89 (2007). Generic drug manufacturers would have to abide by any risk-labeling changes that FDA mandates for the brand-name version. See GUIDANCE FOR INDUSTRY: REVISING ANDA LABELING FOLLOWING REVISION OF THE RLD

in formulation, critics argue that FDA's bioequivalence testing does not always ensure therapeutic equivalence.<sup>21</sup>

Alternatively, manufacturers can try to file a "paper NDA," which allows a company to bring a slightly modified version of a pioneer drug to market by cross-referencing the contents of the original NDA or published literature and filing supplemental research as deemed necessary.<sup>22</sup> This approach has triggered controversy because it essentially appropriates confidential safety and effectiveness data submitted by the sponsor of the innovator drug and may lead to FDA marketing approval even before the expiration of the patent term and exclusivity periods.<sup>23</sup>

Because manufacturers of generic drugs do not need to make the substantial investment in drug discovery or premarket testing,<sup>24</sup> they can sell

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LABELING (May 2000), available at [www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm); see also Julie Schmit, *Updating Generic-Drug Labels Can Take Months*, USA TODAY, Apr. 21, 2005, at 3B (focusing on over-the-counter drugs).

21. See Melinda Beck, *Inexact Copies: How Generics Differ from Brand Names*, WALL ST. J., Apr. 22, 2008, at D1; Thomas M. Burton, *Doctors Raise Warnings About a Form of Clozapine: FDA-Approved Generic Version of Schizophrenia Drug Has Disturbing Effects in Studies*, WALL ST. J., Oct. 24, 2000, at B1; Melissa Healy, *FDA Standards Are Questioned*, L.A. TIMES, Mar. 17, 2008, at F7; Robyn Shelton, *Rx for Trouble? Generics Don't Always Work as Well as Brand Names, Critics Say*, ORLANDO SENT., Aug. 10, 2008, at A1. But see Aaron S. Kesselheim et al., *Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-analysis*, 300 JAMA 2514, 2524 (2008) ("Even though there is little evidence of important clinical differences between generic and brand-name drugs in cardiovascular disease, many editorials expressed a negative view of generic drug interchangeability . . ."); *id.* ("One explanation for this discordance between the data and editorial opinion is that commentaries may be more likely to highlight physicians' concerns based on anecdotal experience . . .").

22. See 21 U.S.C. § 355(b)(2) (2006); FDA, Draft Guidance for Industry on Applications Covered by Section 505(b)(2), 64 Fed. Reg. 68,697 (Dec. 8, 1999); Burroughs Wellcome Co. v. Bowen, 630 F. Supp. 787, 789 (E.D.N.C. 1986) ("A 'paper' NDA is one in which the required safety and effectiveness data are not the result of original testing by the NDA applicant, but rather are obtained from literature reports of testing done by others."); Jill D. Deal, *Some FDA Applications Can Escape Full Testing*, NAT'L L.J., May 22, 2000, at B18; *FDA Defends Its Use of Drug-Version Law: At Issue Is Whether the Agency Has Infringed the Patents by Approving Similar Versions of Medicines*, PHILA. INQUIRER, Oct. 16, 2003, at C3 (reporting that the agency's approval of a modified form of Paxil® sold by Synthon undercut the exclusive rights held by Apotex to sell the first generic copy of this antidepressant).

23. See Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 103–04 (2004); Peter O. Safir, *Current Issues in the Pioneer Versus Generic Drug Wars*, 50 FOOD & DRUG L.J. 335, 338 (1995); Leila Abboud & Anna Wilde Mathews, *FDA to Allow Back Door for Some Generics*, WALL ST. J., Oct. 14, 2003, at B1.

24. It may take up to five years and an initial investment of \$1 million to secure FDA approval of an ANDA for a generic drug product. See FDA, Proposed Rule, Requirements for Submission of In Vivo Bioequivalence Data, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003); Richard J. Findlay, *Originator Drug Development*, 54 FOOD & DRUG L.J. 227, 229 (1999); see also *In re Barr Lab., Inc.*, 930 F.2d 72 (D.C. Cir. 1991) (reviewing a dispute over FDA delays). Although seemingly substantial, these pale in comparison to the effort required to bring a novel drug to market. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180–81 (2003) (\$802 million); Peter Landers, *Cost of Developing a New Drug Increases to About \$1.7 Billion*, WALL ST. J., Dec. 8, 2003, at B4.



their products at far less than the prices charged by the innovator company. Many states provide that pharmacists may substitute generic drugs when filling prescriptions for the brand-name version.<sup>25</sup> Even without generic substitution requirements, insurers have created incentives designed to encourage patients to opt for generic versions of prescribed brand-name drugs whenever possible.<sup>26</sup>

Given this prospect of losing significant market share (and with it the ability to recoup their far greater investment in product research and development),<sup>27</sup> innovator companies use various strategies to fend off generic competition.<sup>28</sup> The most controversial tactic involves the settlement of patent infringement litigation with “reverse payments” made by the patent holder if the allegedly infringing generic manufacturer agrees to delay

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25. See *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 847 n.4 (1982) (“Since the early 1970’s, most States have enacted laws allowing pharmacists to substitute generic drugs for brand name drugs under certain conditions.”); *Pharm. Soc’y N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 957–59 (2d Cir. 1978) (declining to preliminarily enjoin the implementation of a state statute that required pharmacists to substitute generic drugs under limited circumstances); Henry G. Grabowski & John M. Vernon, *Substitution Laws and Innovation in the Pharmaceutical Industry*, LAW & CONTEMP. PROBS., Winter/Spring 1979, at 43, 49–52 (cataloging these laws). In addition to allowing physicians to override by specifying nonsubstitution, some states have exempted certain classes of drugs from these substitution laws. See, e.g., *Abbott Labs. v. Mylan Pharms., Inc.*, 15 So. 3d 642, 645–46, 656–57 (Fla. Dist. Ct. App. 2009); Jonathan D. Rock-off, *Cost of Medicine Could Increase: Brand-Name Drugmakers Target Generic Prescriptions*, BALT. SUN, June 17, 2008, at 1A (discussing widespread efforts to exclude epilepsy drugs); Sarah Rubenstein, *Pill Push: Industry Fights Switch to Generics for Epilepsy—Big Drug Makers Help Patient Groups Lobby*, WALL ST. J., July 13, 2007, at A1.

26. See *Del Greco v. CVS Corp.*, 337 F. Supp. 2d 475, 479 (S.D.N.Y. 2004); Haiden A. Huskamp et al., *The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending*, 349 NEW ENG. J. MED. 2224, 2225 (2003); Geoffrey F. Joyce et al., *Employer Drug Benefit Plans and Spending on Prescription Drugs*, 288 JAMA 1733, 1734 (2002) (explaining that “generic drugs typically have the lowest co-payment”); Daniel Yi, *Generic Spending on Rise at Drug Firm: Largest U.S. Pharmacy Benefits Manager Says It Fills 54% of Prescriptions with Substitutes*, L.A. TIMES, May 20, 2006, at C1.

27. See Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 347 (1992) (“The typical product in our sample lost about half the market to generics two years after initial entry. . . . [This] significantly curtailed the expected revenues to innovative firms from the latter phases of their drug’s life cycle.”); John Hudson, *Generic Take-up in the Pharmaceutical Market Following Patent Expiry: A Multi-Country Study*, 20 INT’L REV. L. & ECON. 205, 216, 217 fig.1, 219–20 (2000); Diedra Henderson, *Dose of Relief: Are Generic Drugs Just What the Cost-Cutters Ordered?*, BOSTON GLOBE, Apr. 30, 2006, at D1 (“By the time nine generics vie against the branded innovator drug, prices plummet to 20 percent of the branded drug price tag, according to the FDA.”); Barbara Martinez & Jacob Goldstein, *Big Pharma Faces Grim Prognosis—Industry Fails to Find New Drugs to Replace Wonders Like Lipitor*, WALL ST. J., Dec. 6, 2007, at A1; Daniel Yi, *Savings Ahead in Generic Medicines: Patents Are Expiring on Four Big Brand Names*, L.A. TIMES, July 15, 2006, at A1.

28. See Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 5–11, 69–70 (1995) (describing the many ways that brand-name drug manufacturers use submissions to regulatory agencies in an effort to exclude potential competitors).

market entry.<sup>29</sup> NDA holders also may raise bioequivalence objections in an effort to stall generic competition: in some instances, these are broad-based assaults on the standards used by FDA,<sup>30</sup> in other cases, brand-name companies object to the agency's approval of a particular ANDA.<sup>31</sup> The filing of these so-called "blocking" petitions has become increasingly common in recent years.<sup>32</sup> Although widely criticized as designed to serve anticompetitive ends, such behavior also may represent entirely reasonable (perhaps even obligatory) steps insofar as courts have begun to allow for the imposition of tort liability on brand-name companies for injuries caused by generic drugs sold by their rivals.

In the case of biotechnology drugs, the ANDA mechanism does not offer generic sellers the same ease of market entry. First, FDA has used its biologics premarket review process for most biotech pharmaceutical products, which does not at present include the same statutory provisions governing approval of generic copies.<sup>33</sup> Second, sponsors of "biogenerics"

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29. See James Kanter, *Europe Is Studying Delays in Access to Generic Drugs*, N.Y. TIMES, July 9, 2009, at B4; Marc Kaufman, *Drug Firms' Deals Allowing Exclusivity: Makers of Generics Being Paid to Drop Patent Challenges, FTC Review Finds*, WASH. POST, Apr. 25, 2006, at A12; Lyndsey Layton, *FTC Sues in "Pay-for-Delay" Pact: Drugmaker Paid Rivals to Withhold Generic, Agency Says*, WASH. POST, Feb. 3, 2009, at A4; Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A1. Questions about the legality of this practice, which are beyond the scope of this article, have prompted an active debate in the academic literature. See, e.g., Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); Anne-Marie C. Yvon, Note, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1897-912 (2006); Symposium, *Soaring Prices for Prescription Drugs: Just Rewards for Innovations or Antitrust Violations?*, 39 U.S.F. L. REV. 1 (2004).

30. See *Schering Corp. v. Shalala*, 995 F.2d 1103, 1104 (D.C. Cir. 1993) (per curiam) (describing one company's efforts to challenge FDA's bioequivalence criteria for nonsystemic drugs); *Fisons Corp. v. Shalala*, 860 F. Supp. 859, 861 (D.D.C. 1994) (same).

31. See, e.g., *Astellas Pharma US, Inc. v. FDA*, 642 F. Supp. 2d 10, 18-21 (D.D.C. 2009) (declining request for preliminary injunction against ANDA for an immunosuppressant drug used to prevent rejection of organ transplants); *Biovail Corp. v. FDA*, 519 F. Supp. 2d 39 (D.D.C. 2007); Linda A. Johnson, *Wyeth Sues FDA to Block Generic Rival of Antibiotic Zosyn*, BOSTON GLOBE, Sept. 24, 2009, at 10 (summarizing objections to the agency's approval of a generic version of an older formulation that the brand-name manufacturer had discontinued four years earlier after it added a pair of ingredients to guard against the possibility of a dangerous chemical reaction).

32. See Marc Kaufman, *Petitions to FDA Sometimes Delay Generic Drugs: Critics Say Companies Misusing Process*, WASH. POST, July 3, 2006, at A1 (reporting an official estimate that, of the 170 citizen petitions pending before the agency, approximately 30 percent are "blocking petitions").

33. See David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 196-97 (2005); see also *id.* at 198-220 (discussing the use of paper NDAs as an alternative route); Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics Under Existing Law and Proposed Reforms to the Law*, 62



may find it impossible to satisfy the standard of proof normally required for ANDAs because large-molecule drugs are derived through a complex and somewhat mysterious production process.<sup>34</sup> For this reason, innovator biotech firms have argued strenuously that generic competitors cannot establish bioequivalence.<sup>35</sup>

In fact, after finding no deficiencies in an ANDA submission for a generic version of recombinant human growth hormone (r-hGH), FDA announced that it would have to delay further action on the application until it had an opportunity to resolve these sorts of fundamental regulatory and policy issues.<sup>36</sup> After a federal court ordered the agency to stop “egregious[ly]” delaying action on the application for generic r-hGH,<sup>37</sup> FDA finally approved this drug.<sup>38</sup>

Technical questions about bioequivalence may not pose an insurmountable obstacle for products that replace natural proteins in the body (e.g., erythropoietin (EPO) for treating anemia), though they may present an insuperable barrier for more complex products used to treat autoimmune diseases and cancer.<sup>39</sup> Although biotech generics probably would not offer

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FOOD & DRUG L.J. 77, 87–90, 98–104 (2007) (same); Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, 37 (2006).

34. See Erika Jonietz, *Generic Biotech*, TECH. REV., Dec. 2004, at 54, 56 (“The reliance on living cells gives the process a black-box quality; small changes in, say, temperature or purification conditions can have unintended results, affecting how well a drug works or even causing severe side effects.”); Marc Kaufman, *Biotech Drugs' Generic Future Debated*, WASH. POST, Feb. 10, 2005, at A1 (explaining that Centocor's Remicade® undergoes 310 discrete manufacturing steps); Andrew Pollack, *In Biotech Brews, Questions of Consistency*, N.Y. TIMES, June 11, 2007, at H7.

35. See Anna Wilde Mathews & David P. Hamilton, *FDA Takes Step Toward Allowing Generic Versions of Biotech Drugs*, WALL ST. J., Feb. 18, 2004, at A1 (“Biotech companies argue that their medicines are too complex and prone to unexpected variations for others to duplicate them without performing the extensive tests conducted on the original products.”); see also Leila Abboud, *Raging Hormones: How Drug Giant Keeps a Monopoly on 60-Year-Old Pill*, WALL ST. J., Sept. 9, 2004, at A1 (reporting that the long-running battle to introduce a generic version of Premarin, which is derived from the urine of pregnant horses, “offers a preview of the looming debate” over biotech generics).

36. See *FDA Defers Approval of Novartis Growth Drug*, WALL ST. J., Sept. 3, 2004, at A8; see also Stephen Heuser, *Regulators Struggle with Generic Biodrugs*, BOSTON GLOBE, Apr. 24, 2006, at E1 (reporting that the European Union approved a generic version of this drug while FDA efforts to issue guidelines had stalled).

37. See *Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d 29, 40 (D.D.C. 2006).

38. See Diedtra Henderson, *FDA Clears a Generic Biotech Drug: Case Fails to Clarify the Approval Process*, BOSTON GLOBE, June 1, 2006, at D1; see also Stephanie Saul, *States, Bridling at Insulin's Cost, Push for Generics*, N.Y. TIMES, Jan. 11, 2007, at A1 (reporting that FDA has failed to issue guidelines that would allow it to review generic versions of biologic insulin and r-hGH).

39. See FDA, *Scientific Considerations Related to Developing Follow-on Protein Products*, 69 Fed. Reg. 50,386 (Aug. 16, 2004); *Hearing Before the Senate Judiciary Comm.: The Law of Biologic Medicine*, 108th Cong. (2004); see also David M. Dudzinski & Aaron S. Kesselheim, *Scientific and Legal Viability of Follow-on Protein Drugs*, 358 NEW ENG. J. MED. 843 (2008).

the same dramatic reductions in price seen with conventional drugs because of the need to invest in complex manufacturing facilities, they still promise substantial cost savings to patients and providers.<sup>40</sup> Congress recently addressed the issue.<sup>41</sup>

### III. LITIGATING GENERIC PHARMACEUTICAL TORT CASES

Even though generic drugs now account for more than two-thirds of dispensed prescriptions, until recently they have played almost no discernible role in products liability litigation. In the last few years, courts have begun to confront challenging questions presented when plaintiffs assert tort claims for injuries caused by the use of generic drugs. First, special difficulties may arise when resolving lawsuits filed against the manufacturers of such products; second, plaintiffs in these cases sometimes seek to press claims against the manufacturers of the brand-name products as well.

#### A. *Claims Against Manufacturers of Generic Drugs*

Generic drug manufacturers might find themselves in a weaker litigating position than their brand-name brethren. For instance, in trying to mount a defense against design defect or failure-to-warn claims, they may face an evidentiary disadvantage because of their lack of access to the clinical trials underlying the NDA for the innovator product<sup>42</sup> or the postmarketing (“Phase IV”) studies increasingly mandated by FDA.<sup>43</sup> Indeed, even information discovered during litigation against brand-name manufacturers may not come to the attention of generic competitors (or anyone

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40. See Henry Grabowski et al., *The Market for Follow-on Biologics: How Will it Evolve?*, 25 HEALTH AFF. 1291, 1293–95 (2006); Bruce Japsen, *Europe Jumps Ahead on Cheaper Biotech Medications*, CHI. TRIB., Apr. 30, 2009, at 22; Andrew Pollack, *Costly Drugs Known as Biologics Prompt Exclusivity Debate*, N.Y. TIMES, July 22, 2009, at B1.

41. In connection with passage of health reform legislation, Congress created a pathway for the introduction of generic biologics, though subject to an exclusivity period of twelve years for the innovator. See Biologics Price Competition and Innovation Act, Pub. L. No. 111–148, tit. VII(A), 124 Stat. 804 (2010); Victoria Colliver, *New Rule on Biotech Seen as Mixed Blessing*, S.F. CHRON., Mar. 28, 2010, at D4.

42. See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y L. & ETHICS 717, 736–38 (2005) (discussing the applicable trade secrecy protections). Subject to trade secret protections, FDA may release safety and effectiveness data in an NDA after it approves an ANDA. See 21 U.S.C. § 355(l)(5) (2006); 21 C.F.R. § 314.430(f)(5) (2009). If the alleged design defect related to the use of a different dosage form or an inactive ingredient not found in the brand-name product, then the supplier of the slightly altered generic version would have generated the necessary bioequivalence data. See *supra* notes 17–19 and accompanying text.

43. See Lars Noah, *Platitudes About “Product Stewardship” in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOMM. & TECH. L. REV. 359, 360–61 n.6, 367 (2009); Gardiner Harris, *Drug Makers Remain Years Behind on Testing Approved Medicines, Report Finds*, N.Y. TIMES, Oct. 27, 2009, at A18.

else),<sup>44</sup> which provides another reason why plaintiffs may want to include the former as defendants. So far, however, courts have not applied a more forgiving standard of knowability to manufacturers of generic drugs.<sup>45</sup>

In addition, generic drug manufacturers might find themselves more vulnerable to design defect claims. The special standard announced in the *Products Liability Restatement* narrowly defines utility in terms of the “therapeutic benefits” of various available pharmaceutical choices,<sup>46</sup> which would seem to exclude cost as a factor.<sup>47</sup> If, as often happens, an innovator company introduces a new and slightly improved (and more expensive) version of the original drug,<sup>48</sup> then manufacturers of generic versions of the original drug seemingly could not point to cost savings in response to allegations of product obsolescence.

Sellers of generic drugs may encounter peculiar problems when it comes to off-label uses: if an innovator company secures FDA approval for a new indication, then it may receive three years of additional market exclusivity for that use—this would not prevent the prescribing of the generic version for that new use,<sup>49</sup> but the labeling for the generic drug will not include any information (including, in all likelihood, risk information) associated with

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44. See, e.g., *In re Zyprexa Injunction*, 474 F. Supp. 2d 385, 391–93 (E.D.N.Y. 2007); Mary Williams Walsh, *Judge to Unseal Documents on the Eli Lilly Drug Zyprexa*, N.Y. TIMES, Sept. 6, 2008, at C4. See generally Laurie Kratyk Doré, *Secrecy by Consent: The Use and Limits of Confidentiality in the Pursuit of Settlement*, 74 NOTRE DAME L. REV. 283 (1999); Daniel J. Givelber & Anthony Robbins, *Public Health Versus Court-Sponsored Secrecy*, LAW & CONTEMP. PROBS., Summer 2006, at 131.

45. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169–70 (4th Cir. 1994) (dictum); *id.* at 169 (“When a generic manufacturer adopts a name brand manufacturer’s warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed.”); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 543–44 (E.D. Pa. 2006) (dictum), *aff’d*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded on other grounds*, 129 S. Ct. 1578 (2009); *id.* at 544 (“While it is true that the ANDA process requires generic manufacturers to use the same labeling as the previously approved innovator drug, we cannot agree that this absolves them of liability for the representations made on their own drugs.”); *Bell v. Lollar*, 791 N.E.2d 849, 855 (Ind. Ct. App. 2003) (“We see no reason to provide greater protection against state law failure to warn claims to generic drugs than to pioneer drugs. . . . Purepac was free to strengthen its label [for a generic version of the Rx drug Tylenol 3] by adding an alcohol warning.”); see also *infra* note 80 and accompanying text (discussing federal preemption defense).

46. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

47. See Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 859–61 (2009).

48. See *infra* note 82.

49. See *Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141, 145–48 (4th Cir. 2002) (holding that the approval of a second indication (protected by a separate exclusivity period) did not prevent FDA from approving generic versions for only the original (and no longer protected) indication notwithstanding the likelihood of off-label prescribing of the generic drugs for the new indication); Eisenberg, *supra* note 42, at 724, 729–30; see also 21 C.F.R. § 314.150(b)(10)(ii) (2009); *Nat’l Ass’n Pharm. Mfrs., Inc. v. Ayerst Lab.*, 850 F.2d 904, 913 (2d Cir. 1988).

that new use.<sup>50</sup> In the event that a patient suffers an injury while using the generic version (which completely failed to mention risks associated with the new indication approved only for the brand-name version), would a court have any way of finessing this problem? If a physician prescribed the generic version for the new indication after consulting the fuller labeling of the innovator drug, would that insulate the generic manufacturer from a failure-to-warn claim (and might it open the brand-name manufacturer to an inadequate warning claim in the event of any alleged shortcomings in the risk information)?

### B. *Claims Against Manufacturers of Brand-Name Drugs*

Even without differences in labeling, patients who suffer injuries while taking a generic drug sometimes pursue claims against the manufacturer of the innovator product, no doubt in the hopes of finding deeper pockets.<sup>51</sup> For the most part, courts have rejected such efforts.<sup>52</sup> Even so, to the extent that physicians and patients may rely on representations made by brand-name manufacturers (after all, generic manufacturers generally do little to promote their versions of well-known prescription drugs<sup>53</sup>), use of the

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50. See Lars Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PRODS. & TOXICS LIAB. 139, 156 (1994).

51. Cf. Milt Freudenheim, *Cleaning out the Medicine Cabinet: Prescription Drug Makers Reconsider Generics*, N.Y. TIMES, Sept. 11, 1997, at D1 (“[T]he generics business as a whole has taken a pounding in recent years, as more than 200 companies furiously cut prices.”). In declining to apply strict products liability against pharmacies and hospitals, courts have explained that these entities otherwise might shy away from generic drugs because brand-name manufacturers would provide a better assurance of indemnification. See *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247, 253 (Cal. 1985); *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1109 (N.M. Ct. App. 1996).

52. See, e.g., *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612–14 (8th Cir. 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1266–67 (W.D. Okla. 2009); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1355–58 (N.D. Ga. 2008); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 519–20 & n.2, 538–43 (E.D. Pa. 2006) (dictum), *aff’d*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded on other grounds*, 129 S. Ct. 1578 (2009); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); see also *Doe 2 v. Ortho-Clinical Diagnostics, Inc.*, 335 F. Supp. 2d 614, 626–28 (M.D.N.C. 2004) (holding that the company that originally discovered and patented the mercury-based preservative thimerosal, which later was copied by other manufacturers and used in their vaccines and other drug products, owed no duty to warn users). Occasionally, the innovator company supplies bulk quantities of drug product to a generic company for labeling, see *supra* note 12, which would simplify the tort issues.

53. See Michael A. Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Can Better Care Cost Less?*, 291 JAMA 1850, 1854 (2004) (noting “the vigorous marketing of newer, more costly agents compared with virtually no marketing for older, off-patent drugs”); Thomas M. Burton, *Bested Interests: Why Generic Drugs Often Can't Compete Against Brand Names*, WALL ST. J., Nov. 18, 1998, at A1 (“It is rare for generic-drug companies to dispatch salespeople to visit doctors . . .”). Instead, insurers and retailers may try to promote the use of generic drugs. See Scott Hensley, *Negative Advertising: As Drug Bill Soars, Some Doctors Get an "Unsales" Pitch*, WALL ST. J., Mar. 13, 2006, at A1; Marc Kaufman, *Doctors Hear Alternatives to Drug-Firm Sales Pitches*, WASH. POST, Aug. 5, 2002, at A1; Stephanie

generic version would not alter the fact that inadequate warnings accompanying the brand-name drug caused the injury. Indeed, the physician may have prescribed the brand-name product (based on information supplied by the manufacturer of that product), only to have the pharmacist dispense a generic version manufactured by an entirely different company.<sup>54</sup> As explained previously, generic substitution may happen because state law or the patient's health insurance policy requires or encourages it.<sup>55</sup>

In rare cases, some courts have allowed victims to sue both brand-name and generic manufacturers when unable to identify the particular source of a drug. Under this "market share" theory, which until recently courts largely reserved for the diethylstilbestrol (DES) litigation, the imposition of liability sometimes sought to approximate the aggregate risk created by the different suppliers,<sup>56</sup> with one jurisdiction going so far as to prevent

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Saul, *Generics: An Inflation Therapy*, N.Y. TIMES, Sept. 21, 2007, at C1 ("[P]ublicity about Wal-Mart's plan had raised awareness of generics.").

54. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 309–18 (Ct. App. 2008) (allowing misrepresentation claims against the brand-name manufacturer even though products liability claims would not have been available in such a case); *id.* at 311 ("We are not marking out new territory by recognizing that a defendant who authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury . . ."); *id.* at 315 ("Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them."); *id.* at 320–21 ("We hold that Wyeth's common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing metoclopramide, whether the prescription is written for and/or filled with Reglan or its generic equivalent."); *id.* at 318–19 (rejecting failure-to-warn claims against the manufacturers of the generic products that injured plaintiff because her physician had not read or relied upon their labeling); see also *Clark v. Pfizer Inc.*, No. 1819, 2008 Phila. Ct. Com. Pl. LEXIS 74, at \*20–29 (Mar. 14, 2008) (allowing misrepresentation claim where the manufacturer of Neurontin® (gabapentin) had promoted it for off-label uses and plaintiff was injured by generic versions); cf. *Miles Labs., Inc. v. Superior Court*, 184 Cal. Rptr. 98, 103 (Ct. App. 1982) (allowing a claim for failure to warn of risks of use during pregnancy against the manufacturer of a DES product labeled solely for use in male (prostate cancer) patients because it might have been dispensed in place of other DES products labeled for the prevention of miscarriages). But see *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 167–68, 170–72 (4th Cir. 1994) (rejecting negligent misrepresentation claims against the manufacturer of the brand-name version of promethazine when a pharmacist had substituted a generic version); see also Ahmann & Vernieris, *supra* note 6, at 779 & n.77 (counting eighteen jurisdictions as following *Foster*).

55. See *supra* notes 25–26 and accompanying text. Pharmacists who engage in generic substitution consistent with a state's drug product selection laws generally would not have to fear any tort liability. See, e.g., *Ullman v. Grant*, 450 N.Y.S.2d 955, 956 (Sup. Ct. 1982).

56. See, e.g., *Sindell v. Abbott Labs.*, 607 P.2d 924, 936–38 (Cal. 1980); *Martin v. Abbott Labs.*, 689 P.2d 368, 382–83 (Wash. 1984); see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 15 cmt. c (1998) (summarizing case law on market share liability, but declining to take a position on its appropriateness); RESTATEMENT (THIRD) OF TORTS: APPOINTMENT OF LIABILITY § 26 cmt. n (2000). But see *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 338–45 (Ill. 1990) (rejecting market share liability in a DES case); *Sutowski v. Eli Lilly & Co.*, 696

exculpation by suppliers that clearly could not have caused a particular plaintiff's harm.<sup>57</sup> An extension of such risk-contribution notions even in cases where patients can identify the source of the drug as a generic manufacturer might justify imposing some tort liability on the manufacturer of the brand-name version for causing the injury through a design defect or failure to warn, even if it did not supply the particular dosage unit that ultimately harmed the plaintiff.

In *Conte*, however, the California Court of Appeal did not draw on market share liability to justify its holding,<sup>58</sup> not surprising insofar as California's version of this doctrine allowed exculpation.<sup>59</sup> Moreover, plaintiff in *Conte* did not confront the serious identification problems encountered in the DES cases; she knew exactly which companies had supplied the product that caused her injury, but the court decided to visit full responsibility on a different company that clearly had not produced the drug purchased by plaintiff. This takes an already controversial theory of liability and seemingly turns it on its head.<sup>60</sup> The court in *Conte* made much of the fact that Wyeth indirectly had promoted the use of competitors' versions of

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N.E.2d 187, 190–93 (Ohio 1998) (same). See generally Christopher J. McGuire, Note, *Market-Share Liability After Hymowitz and Conley: Exploring the Limits of Judicial Power*, 24 U. MICH. J.L. REFORM 759 (1991); Andrew Nace, Note, *Market Share Liability: A Current Assessment of a Decade-Old Doctrine*, 44 VAND. L. REV. 395 (1991).

57. See *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1078 & n.2 (N.Y. 1989) (allowing only those DES manufacturers who did not market for use during pregnancy to escape liability); *In re N.Y. County DES Litig.*, 615 N.Y.S.2d 882, 885 (App. Div. 1994); see also *Smith v. Cutter Biological, Inc.*, 823 P.2d 717, 728–29 (Haw. 1991) (taking a similar approach to litigation involving HIV-contaminated blood factor concentrates). Other jurisdictions that have adopted market share liability allow exculpation. See, e.g., *Conley v. Boyle Drug Co.*, 570 So. 2d 275, 284, 286–87 (Fla. 1990); *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 52 (Wis. 1984). Nonetheless, they may allocate relatively greater shares of responsibility to those companies more actively involved in preclinical testing, securing original FDA approval, and marketing the product. See *id.* at 53–54; see also *id.* at 50 n.11 (rejecting the argument that market share liability would discourage the introduction of cheaper generic drugs); Andrew G. Celli, Jr., Note, *Toward a Risk Contribution Approach to Tortfeasor Identification and Multiple Causation Cases*, 65 N.Y.U. L. REV. 635, 666 n.207 (1990) (elaborating on the possible relevance of the industry “leader” factor mentioned in *Collins*).

58. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 310 n.8, 311 (Ct. App. 2008).

59. See *Sindell*, 607 P.2d at 937. Indeed, earlier in its opinion, the *Sindell* court rejected the concert-of-action theory because it “would render virtually any manufacturer liable for the defective products of an entire industry, even if it could be demonstrated that the product which caused the injury was not made by the defendant.” *Id.* at 933; see also *id.* (adding that “parallel or imitative conduct . . . describes a common practice in industry: a producer avails himself of the experience and methods of others making the same or similar products”); *Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004, 1017 (D.S.C. 1981) (“[Enterprise liability theory, which] would render every manufacturer an insurer . . . of all generically similar products made by others, is repugnant to the most basic tenets of tort law.”).

60. Even courts that recognize market share liability without exculpation apparently would forgo the risk-contribution approach when a plaintiff manages to identify the supplier of the DES that caused injury in a particular case. See *Hymowitz*, 539 N.E.2d at 1073 (“In DES cases in which such identification is possible, actions may proceed under established principles of



its brand-name drug by specifying their shared generic name.<sup>61</sup> Of course, though they surely would prefer to make no such cross-references, brand-name companies must do so under federal law.<sup>62</sup>

Perhaps the court in *Conte* viewed Wyeth's labeling as a product in its own right, entirely distinct from the drug itself.<sup>63</sup> Indeed, it cited an earlier decision that had allowed a negligent misrepresentation claim to proceed against the publisher of *Good Housekeeping* magazine for endorsing allegedly defective shoes.<sup>64</sup> Even so, authors and publishers of information generally need not fear tort liability of any sort,<sup>65</sup> while manufacturers

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products liability.”); cf. *Lyons v. Premo Pharm. Labs, Inc.*, 406 A.2d 185, 190–91 (N.J. Super. Ct. App. Div. 1979) (rejecting precursors to market share theory against DES manufacturers in a case where the plaintiffs had identified but settled with the supplier of the drug that caused their injuries). Instead, the court in *Conte* allowed exculpation by the very companies that had produced the generic versions used by plaintiff.

61. See *Conte*, 85 Cal. Rptr. 3d at 309–10, 314–15, 318; *id.* at 313 (“[I]t is . . . eminently foreseeable that a physician might prescribe generic metoclopramide in reliance on Wyeth’s representations about Reglan.”).

62. As mentioned previously, the drug industry vehemently objected to the requirement that the “established name” appear adjacent to the brand name in labeling and advertising. See *supra* note 14. Moreover, apart from this requirement (and putting aside the fact that brand-name companies never would choose to make favorable remarks about their competitors’ products), federal law generally prohibits manufacturers from making any references to other drugs. See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 589 (2001).

63. See Brodie, *supra* note 7, at 465 (explaining that plaintiffs in an earlier similar case unsuccessfully had made such an argument: “Viewing the information as a product separate from the drug could, arguably, justify imposition of liability for the contents of the labeling if it caused harm, even if the drug itself was not involved.”); see also Noah, *supra* note 47, at 884 & n.190 (arguing that drug companies produce and distribute information as much as they sell products); Beatrice Sky Resendes, Note, *The Extinct Distinction of Privy: 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); cf. Schaffer v. A.O. Harvestore Prods., Inc., 74 F.3d 722, 728–30 (6th Cir. 1996) (holding that an owner’s manual accompanying a custom-built manure-handling system was not a product itself but that a company could be held strictly liable for failing to warn if it provided instructions in the course of marketing such a system).

64. See *Conte*, 85 Cal. Rptr. 3d at 311 (citing *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519 (Ct. App. 1969)); cf. *Walters v. Seventeen Magazine*, 241 Cal. Rptr. 101, 102–03 (Ct. App. 1987) (rejecting tort claims against magazine that ran advertisements for tampons suspected of causing toxic shock syndrome). The parallel seems inapt insofar as the publisher derived some benefit from endorsing a product, see *id.* at 102, while a brand-name drug company only stands to lose business from the fact that it must reference the generic name, see *Ahmann & Verneris, supra* note 6, at 783 n.104.

65. See, e.g., *Jones v. J.B. Lippincott Co.*, 694 F. Supp. 1216 (D. Md. 1988) (rejecting negligence and strict products liability claims against the publisher of a nursing textbook brought by a student who was injured after trying a listed remedy for constipation); *Liberelli v. Hoffman-La Roche, Inc.*, No. 80 Civ. 5626, 1981 U.S. Dist. LEXIS 11049 (S.D.N.Y. Feb. 23, 1981) (dismissing tort claim against the publisher of the *Physician’s Desk Reference* for failing to warn of Valium’s addictive nature); *Demuth Dev. Corp. v. Merck & Co.*, 432 F. Supp. 990, 993 (E.D.N.Y. 1977) (rejecting a negligence claim against the publisher of an encyclopedia of chemicals and drugs brought by a company alleging lost business because the book exaggerated the toxicity of a chemical used in one of its products); *Bailey v. Huggins Diagnostic & Rehab. Ctr., Inc.*, 952 P.2d 768, 770–73 (Colo. Ct. App. 1997) (rejecting tort

of products routinely face liability for faulty information that appears on product labels or in owner's manuals.<sup>66</sup>

Misrepresentation theories pose numerous puzzles. For instance, courts have not allowed plaintiffs to circumvent limitations on prescription drug failure-to-warn claims by recasting these as instances of misrepresentation.<sup>67</sup> The *Products Liability Restatement* recognizes misrepresentation claims, including both negligent and innocent ones, as entirely separate from the three traditional categories of defectiveness.<sup>68</sup> The *Conte* court had before it a claim of negligent misrepresentation.<sup>69</sup> The possibility of imposing liability for nonnegligent misrepresentations suggests, however, a focus on affirmative representations that suffer from later-discovered

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claims against the author of a book that had exaggerated the risks associated with mercury in dental amalgam); see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 19 cmt. d (1998) (emphasizing the intangible nature of information-laden products such as books). The *Products Liability Restatement* suggested, instead, the use of negligent misrepresentation claims in such cases. See *id.*; see also Deborah A. Ballam, *The Expanding Scope of the Tort of Negligent Misrepresentation: Are Publishers Next?*, 22 LOY. L.A. L. REV. 761 (1989) (discussing the expansion of misrepresentation claims against public accountants and other professionals for economic losses incurred by foreseeable third parties, and suggesting the extension of such claims to publishers of incorrect financial information); Lars Noah, *Medical Education and Malpractice: What's the Connection?*, 15 HEALTH MATRIX 149, 159–60 (2005) (noting a growing judicial willingness to allow third parties to assert negligent misrepresentation claims).

66. See Lars Noah, *Authors, Publishers, and Products Liability: Remedies for Defective Information in Books*, 77 OR. L. REV. 1195, 1212 (1998) (“The conceptual separation between the product itself and information contained within the product, so evident in cases declining to hold authors and publishers strictly liable, is absent in the prescription drug liability context.”); see also *Smith v. Linn*, 563 A.2d 123, 124–27 (Pa. Super. Ct. 1989) (rejecting negligent misrepresentation and strict products liability claims brought on behalf of the reader of a diet book who died of complications associated with the diet), *aff'd*, 587 A.2d 309 (Pa. 1991); *id.* at 126 (rejecting the suggested parallel to inadequate warning claims against pharmaceutical manufacturers); cf. Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 464–65 (2002) (discussing potential liability of entities that supply inaccurate information about therapeutic products even though they played no role in their production or distribution).

67. See, e.g., *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1119–23 (D. Kan. 2002) (learned intermediary doctrine). Thus, in prescription drug cases, generally the physician must receive and rely upon the alleged misrepresentation. Conversely, plaintiff-friendly doctrines of strict products liability, such as lower knowability thresholds and postsale duties to warn reasonably traceable customers, would seemingly have no application in misrepresentation cases.

68. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 9 (1998); see also Gary Massey, Jr., Comment, *Interpreting the Restatement of Torts Section 402B After the Changes to Section 402A*, 28 CUMB. L. REV. 177, 213 (1998) (“402B will remain relatively unchanged in the new Restatement and will retain its strict liability principles. With the contraction of 402A . . . , plaintiffs are likely to find 402B far more attractive than they have in the past.”).

69. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 305, 307, 309–10 (Ct. App. 2008); see also *id.* at 311–14 (citing *Randi W. v. Muroc Jt. Unified Sch. Dist.*, 929 P.2d 582 (Cal. 1997)). Although the court in *Randi W.* followed the negligent misrepresentation formula set forth in § 311 of the *Restatement (Second) of Torts*, it also evaluated several policy factors that inform duty analysis. Whether or not these supported the California Supreme Court's decision to impose an obligation of full disclosure on former employers in connection with job references, the application of these factors does not support the imposition of a duty in *Conte*. See

inaccuracies rather than omissions of risk information.<sup>70</sup> Finally, misrepresentation claims evidently would obviate any requirement of identity between the advertised product and the substitute product that caused an injury. Although the generic drugs at issue in *Conte* apparently matched the brand-name version in all relevant respects, a person might reasonably rely on the information supplied with one product in the course of using a substitute product posing somewhat different risks.<sup>71</sup>

Thus, *Conte* might apply in cases of therapeutic interchange as well. Often, a drug class may include several similar, though not bioequiva-

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Alissa J. Strong, "But He Told Me It Was Safe!": The Expanding Tort of Negligent Misrepresentation, 40 U. MEM. L. REV. 105, 124–26, 140–42 (2009) (criticizing both opinions). Although it is entirely foreseeable, given state generic substitution laws, that a patient might get another version of a drug even though a physician prescribed the brand-name product in reliance on the labeling and any advertising for that drug (or that, even if the physician consulted the labeling for the generic version, this labeling would mimic that supplied with the brand-name drug), the connection hardly seems to be terribly close. Nor does it seem morally blameworthy for brand-name manufacturers to adhere to federal law in cross-referencing generic drug names in their labeling. Unlike the defendants in *Randi W.*, brand-name manufacturers would not have the option of simply remaining silent (they must provide full prescribing information to satisfy their regulatory and tort obligations); and, given the near impossibility of formulating bulletproof labeling, insurability represents a concern: cost spreading would further burden the shrinking share of customers for the brand-name drug (or else later patients taking unrelated drugs produced by that defendant) for the benefit of customers of the competitor's drug (who are already free riding on the original research and development efforts of the brand-name manufacturer). This threatens to chill therapeutic product innovation, and it relieves generic manufacturers of any incentives to engage in serious safety monitoring or to seek revisions in their product labeling when justified. Unlike the glowing reference letters in *Randi W.* for an ex-employee suspected of child molestation, Wyeth did not propagate blatant half-truths about Reglan that the medical community reasonably relied on when prescribing metoclopramide from whatever source; on the contrary, the labeling clearly indicated a maximum twelve-week duration of use, which Conte's physician blithely disregarded.

70. See, e.g., *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 819–23 (N.D. Ohio 2004) (rejecting negligent misrepresentation claims against manufacturers of prescription weight-loss drug); *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978) (package insert incorrectly implied to physician that antibiotic solution was safe to use continuously as an irrigant during surgery); *Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 433 (Tex. 1974) (allowing a claim to proceed against the seller of a prescription analgesic drug for misrepresenting it as nonaddictive).

71. *Cf.* *Ladd v. Honda Motor Co.*, 939 S.W.2d 83, 95–101 (Tenn. Ct. App. 1996) (allowing claim based on a manufacturer's earlier advertising of older models that had created the impression that children safely could operate ATVs); *id.* at 99 (explaining that "manufacturers should not be permitted to insulate themselves from liability under Section 402B simply by using general advertisements of an entire product line"). In one peculiar failure-to-warn case, a court held that labeling might be inadequate even if the risk of the very injury suffered by plaintiff was clearly disclosed, on the grounds that plaintiff might have been deterred from taking the drug had the risk of some other more serious injury been fully disclosed. See *Sanderson v. Upjohn Co.*, 578 F. Supp. 338, 339–40 (D. Mass. 1984); see also *McMahon v. Eli Lilly & Co.*, 774 F.2d 830, 834–35 (7th Cir. 1985). *But cf.* *Canesi v. Wilson*, 685 A.2d 49, 54 (N.J. App. Div. 1996), *aff'd in part*, 730 A.2d 805 (N.J. 1999). If courts would find proximate cause satisfied in such cases, then they equally might allow misrepresentation claims against brand-name companies for failing to disclose information that would have dissuaded use even

lent, brand-name products (sometimes referred to as “me-too” drugs), such as cholesterol-lowering statins, selective serotonin reuptake inhibitors (SSRIs) used as antidepressants, and angiotensin-converting enzyme (ACE) inhibitors used as antihypertensives.<sup>72</sup> Although few state laws authorize pharmacists to make therapeutic substitutions when dispensing prescriptions,<sup>73</sup> private insurers often create incentives for physicians to allow such switches.<sup>74</sup> Thus, patients may receive a slightly different (cheaper) brand-name or generic drug than the one initially selected by the physician based on information supplied by another brand-name company.<sup>75</sup> In the event of undisclosed risks associated with all drugs in a therapeutic class,<sup>76</sup> could a patient assert negligent misrepresentation claims against a brand-name company that had supplied incomplete risk information even if it did not supply the slightly different drug that injured the patient? Obviously, the company would not have promoted use of the competitor’s me-too product,<sup>77</sup> except in the sense that it had generally encouraged the use of medications from this therapeutic class.

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if the patient’s injury arose from a risk peculiar to the generic substitute (for instance, a manufacturing defect or allergenicity linked to an inactive ingredient not found in the brand-name drug).

72. See Thomas H. Lee, “Me-Too” Products—Friend or Foe?, 350 *NEW ENG. J. MED.* 211 (2004); Frank R. Lichtenberg & Tomas J. Philipson, *The Dual Effects of Intellectual Property Regulations: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry*, 45 *J.L. & ECON.* 643, 651–52, 655–56 (2002) (treating these as drug “subclasses”); Melody Petersen, *New Medicines Seldom Contain Anything New, Study Finds*, *N.Y. TIMES*, May 29, 2002, at C1.

73. See Glenn Ruffenach, *When Druggists Second-Guess Doctors: Changing Drugs in Prescriptions Is Controversial*, *WALL ST. J.*, May 9, 1988, at A25 (describing a law in the state of Washington that permits it); see also *Am. Coll. of Physicians, Therapeutic Substitution and Formulary Systems*, 113 *ANNALS INTERNAL MED.* 160, 162 (1990); John C. Ballin, Editorial, *Therapeutic Substitution—Usurpation of the Physician’s Prerogative*, 257 *JAMA* 528 (1987) (criticizing this practice).

74. See Frank J. Ascione et al., *Historical Overview of Generic Medication Policy*, 41 *J. AM. PHARMACEUTICAL ASS’N* 567, 573–74 (2001); Milt Freudenheim, *Not Quite What Doctor Ordered: Drug Substitutions Add to Discord over Managed Care*, *N.Y. TIMES*, Oct. 8, 1996, at D1. Thus, when generic versions of one drug in a therapeutic class become available, other similar drugs may lose significant market share even though still patent protected. See Scott Hensley, *Side Effects: As Generics Pummel Its Drugs, Pfizer Faces Uncertain Future*, *WALL ST. J.*, Jan. 5, 2006, at A1.

75. See Ernst R. Berndt et al., *Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market*, 85(2) *AM. ECON. REV.* 100, 102 (1995) (predicting that promotional efforts by one manufacturer might spill over to increase demand for other drugs in the same therapeutic category).

76. See, e.g., David Brown, *Blood-Pressure Drugs Linked to Birth Defects*, *WASH. POST*, June 8, 2006, at A12 (reporting that a new study found a significant increase in the risk of birth defects when pregnant women used ACE inhibitors during their first trimester); Thomas M. Burton, *FDA to Require Diabetes Warning on Class of Schizophrenia Drugs*, *WALL ST. J.*, Sept. 18, 2003, at D3; Bernadette Tansey, *Doctors Warned of Drugs’ Danger: Anti-Epilepsy Medications Tied to Risk of Suicide*, *S.F. CHRON.*, Feb. 1, 2008, at C1.

77. On the contrary, companies may go to great lengths to try and differentiate their products on the basis of fairly small differences. See *Rhone-Poulenc Rorer Pharms., Inc. v. Marion*

Separately, one can imagine a situation where a physician reads the labeling for (and intends to prescribe) a generic version of a drug—putting aside for the moment the unlikelihood that a physician would bother specifying the particular supplier of such a drug—and the patient suffers a serious injury from a side effect known to both the brand-name and generic manufacturers but not disclosed in the labeling for their drugs. As a regulatory matter, brand-name companies have the opportunity and obligation to make revisions in labeling when necessitated by new risk information,<sup>78</sup> but manufacturers of generic versions have far less latitude: generally, they must follow the lead of the innovator company.<sup>79</sup> If the injured patient pursued a failure-to-warn claim against the generic manufacturer, then the defendant may have a valid implied preemption defense,<sup>80</sup> which again might call for pinning the blame for nondisclosure on the reluctant brand-name company.

Finally, in any of these situations where courts might allow someone injured by a generic drug to pursue tort claims against the brand-name manufacturer, does anything change if the latter decides to exit the marketplace? (In at least one sense, brand-name companies routinely exit upon the arrival of generic competitors: they generally cease advertising the product.<sup>81</sup>) As a regulatory matter, so long as FDA does not withdraw

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Merrell Dow, Inc., 93 F.3d 511, 513–14 (8th Cir. 1996) (Lanham Act litigation involving promotional campaigns for competing antihypertensives); David A. Kessler et al., *Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace*, 331 NEW ENG. J. MED. 1350, 1350 (1994) (suggesting that many me-too products “are virtually indistinguishable” from one another); Anna Wilde Mathews, *Detective Work: Reading Fine Print, Insurers Question Studies of Drugs*, WALL ST. J., Aug. 24, 2005, at A1; Suzanne Vranica, *Advertising: Pharmaceuticals Try Bolder Tactics—Pfizer Campaign Includes Rare Swing at Rival Drug in a Competitive Market*, WALL ST. J., Apr. 5, 2004, at B3.

78. See FDA, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,609 (Aug. 22, 2008) (amending 21 C.F.R. § 314.70(c)(6)). In most instances, new risk information emerges within the first few years of marketing, long before FDA would begin to approve generic versions. Nonetheless, as illustrated by several recent cases (e.g., Vioxx, Prempro, Seldane), evidence of postapproval risks may not surface until several years after initial FDA approval.

79. See *supra* note 20. That said, ANDA holders could initiate an effort at relabeling both branded and generic versions by petitioning the agency. See FDA, Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,955, 17,961 (Apr. 28, 1992) (codified as amended at 21 C.F.R. pt. 314(C)). In practice, this differs little from the manner in which NDA holders would revise their labeling to reflect newly discovered risk information. See Noah, *supra* note 43, at 369–71 (discussing limitations on drug manufacturers’ power to unilaterally revise labeling); Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 359 (1994).

80. See *Gaeta v. Perrigo Pharms. Co.*, 672 F. Supp. 2d 1017 (N.D. Cal. 2009); *Smith v. Wyeth, Inc.*, No. 5–07-CV-18-R, 2009 WL 425032 (W.D. Ky. Feb. 20, 2009). Most courts, however, have rejected a preemption defense in such cases. See, e.g., *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 607–12 (8th Cir. 2009); see also Lesley A. Stout, Note, *Making Changes: Generic Drug Labeling and the Case Against Federal Preemption*, 98 KY. L.J. 623 (2010).

81. See Jayanta Bhattacharya & William B. Vogt, *A Simple Model of Pharmaceutical Price Dynamics*, 46 J.L. & ECON. 599, 609 (2003); *id.* at 619 (“[T]he number of ads declines more



the innovator's NDA on safety or effectiveness grounds, existing (and the possibility for future) ANDAs would remain unaffected.<sup>82</sup> For example, Hoffmann-La Roche recently decided to withdraw its much-litigated drug Accutane<sup>®</sup> (isotretinoin),<sup>83</sup> but this move would not prevent the continued marketing of generic versions of the product.<sup>84</sup> Would courts still hold Roche responsible for launching this product in the first place?

Claims against the innovator company for manufacturing defects in the generic version—or design defects related to intentional deviations from

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quickly after patent expiry than before.”); Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J.L. & ECON. 299, 315 (1988) (finding “that leaders cut back sharply on their advertising over time as generic entrants become entrenched”); see also *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 149, 152–53 (D.D.C. 2008) (dismissing antitrust claims against the manufacturer of Prilosec<sup>®</sup> (omeprazole) for introducing a slightly modified formulation (Nexium<sup>®</sup>) and ceasing to advertise its original prescription formulation). This would not, however, invariably defeat negligent misrepresentation claims, both because of the lingering effects of prior advertising on physician prescribing behavior and because labeling for the brand-name drug would continue to appear in the *Physicians Desk Reference*. If, however, the brand-name manufacturer withdrew the drug altogether, then it would no longer make available any product labeling.

82. See 21 U.S.C. § 355(j)(5), (6) (2006); see also FDA, Removal of Nomifensine Maleate from List of Approved Drug Products, 51 Fed. Reg. 21,981 (June 17, 1986); *Parkinson's Drug Pulled off the Market*, WASH. POST, Mar. 30, 2007, at A8. Brand-name companies may, however, introduce new and slightly improved products (and discontinue all sales of earlier versions) in an effort to switch prescribers to the new (and not yet substitutable) product. See, e.g., *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 416–18 (D. Del. 2006) (summarizing the allegations in *TriCor*<sup>®</sup> (fenofibrate) antitrust litigation); see also Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 361–63 & n.14 (2006); Gardiner Harris, *Fast Relief: As a Patent Expires, Drug Firm Lines up Pricy Alternative*, WALL ST. J., June 6, 2002, at A1. (In that case, it would become a question of liability in cases of therapeutic substitution. See *supra* notes 73–77 and accompanying text.) This type of behavior occurs in other industries as well. See, e.g., Andrew Pollack, *As Patent Ends, a Seed's Use Will Survive*, N.Y. TIMES, Dec. 18, 2009, at B3 (reporting that, as the patent on its original technology nears expiration, Monsanto will introduce a new and improved version of its genetically modified herbicide-resistant soybean, adding that, “after 2014, Roundup Ready soybeans would become agricultural biotechnology's equivalent of a generic drug”).

83. See Steven Bushong, *Controversial Acne Drug: Accutane off Shelves, but Lawsuits Live*, COLUMBUS DISPATCH, July 3, 2009, at 1A. For additional background on Accutane, see Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 233–37, 256 (2007).

84. See Margaret A. Honein et al., *Can We Ensure the Safe Use of Known Human Teratogens?: Introduction of Generic Isotretinoin in the US as an Example*, 27 DRUG SAFETY 1069, 1075 (2004). In contrast, when it ceased marketing Tegison<sup>®</sup> (etretinate) for severe psoriasis, the company persuaded the agency to withdraw the NDA. See FDA, Notice, Hoffmann-La Roche, Inc.: Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 53,384, 53,385 (Sept. 10, 2003). After the manufacturer of Bendectin withdrew the drug because of excessive tort liability, however, FDA clarified that it had not changed its views about the continued safety and effectiveness of the drug, see FDA, Determination That Bendectin Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness, 64 Fed. Reg. 43,190 (Aug. 9, 1999), which would have allowed generic versions to enter the market, see Gina Kolata, *Controversial Drug Makes a Comeback*, N.Y. TIMES, Sept. 26, 2000, at F1.



the brand-name product—would seem to be further attenuated,<sup>85</sup> even if marketing efforts undertaken by the innovator company had generated the demand for a product supplied by another entity.<sup>86</sup> Thus, if patients suffer injuries from flaws peculiar to the competitor's prescription drug product, then they should not look to the brand-name manufacturer for recourse—whether the copycat version represented an FDA-approved generic,<sup>87</sup> a drug specially compounded by a pharmacist,<sup>88</sup> or an outright counterfeit.<sup>89</sup> Insofar as the negligent misrepresentation theory recognized in *Conte* might have allowed such claims to proceed as well, it illustrates still another flaw in the court's analysis.

#### IV. CONCLUSION: BEYOND PRESCRIPTION DRUGS?

More than two-thirds of all prescriptions get filled with generic drugs, but almost none of the voluminous tort litigation involving pharmaceuti-

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85. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 317 n.16 (Ct. App. 2008); see also *Sheffield v. Eli Lilly & Co.*, 192 Cal. Rptr. 870, 876–79 (Ct. App. 1983) (declining to apply market share theory to a claim that a single batch of polio vaccine suffered from a manufacturing defect). If similar (though not entirely bioequivalent) versions of biotech products ever come to market, would courts view the labeling and advertising for the innovator product as sufficiently connected to justify imposing liability for negligent misrepresentation? Because of the inevitable differences among biologics produced by various manufacturers, commentators doubt that market share liability should extend to this context. See Frederick H. Fern & Leslie Steineker McHugh, *Market Share Liability for Pharmaceuticals: The Distinction Between DES and DPT*, 11 J. LEGAL MED. 391, 411–12, 418 (1990); Andrew R. Klein, *Beyond DES: Rejecting the Application of Market Share Liability in Blood Products Litigation*, 68 TUL. L. REV. 883, 907, 922–23 (1994).

86. See *supra* note 71 and accompanying text.

87. See, e.g., *In re Copley Pharm., Inc., "Albuterol" Prods. Liab. Litig.*, 158 F.R.D. 485, 487–88 (D. Wyo. 1994) (certifying a class action on behalf of patients who were injured by bacterial contamination of four batches of a generic bronchodilator drug later recalled by the manufacturer); see also Susan Okie, *Multinational Medicines—Ensuring Drug Quality in an Era of Global Manufacturing*, 361 NEW ENG. J. MED. 737 (2009) (discussing reports of quality control problems with generic drugs); Natasha Singer, *F.D.A. Again Warns the Generic Maker Apotex About the Conditions at Its Plants*, N.Y. TIMES, Apr. 16, 2010, at B16 (“Concerns about the quality and effectiveness of generics have become prevalent enough among doctors and patients that the F.D.A. held a public advisory meeting this week to discuss the issue . . .”).

88. See *Fontanez v. Parenteral Therapy Assoc.*, 974 So. 2d 1101, 1105–06 (Fla. Dist. Ct. App. 2007); *Dove v. Ruff*, 558 N.E.2d 836, 837–40 (Ind. Ct. App. 1990); *Brown v. S. Baptist Hosp.*, 715 So. 2d 423, 426 n.2, 431 (La. Ct. App. 1998); *Schroeder v. Lester E. Cox Med. Ctr., Inc.*, 833 S.W.2d 411, 416–19, 422 (Mo. Ct. App. 1992); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 925, 932–33 (Utah 2003); cf. *Fisher v. Prof'l Compounding Ctrs. of Am.*, 311 F. Supp. 2d 1008, 1019–21 (D. Nev. 2004) (holding that suppliers of bulk fenfluramine used to compound diet drugs had failed to ensure that pharmacists knew of the risks associated with this drug substance).

89. See *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 204–07, 215 (E.D.N.Y. 2004) (dismissing claims against the manufacturer of Epogen® where counterfeiters had diverted, substantially diluted, and then sold the drug on the gray market); *id.* at 207–11 (allowing negligence claims against the distributor to proceed); cf. Stephanie Feldman Along, *Green Medicine: Using Lessons from Tort Law and Environmental Law to Hold Pharmaceutical*

cal products names manufacturers of generic drugs. To some extent, this discrepancy makes perfect sense: FDA cannot approve generic versions of drugs for the first five or more years after it approves the pioneer firm's new drug, during which time significant additional risk information tends to accumulate. To the extent, however, that it represents plaintiffs' understandable search for deeper pockets (or simply an effort to dodge the often insurmountable decision-causation problems with failure-to-warn claims against generic drug manufacturers), courts must guard against reinforcing this imbalance. Brand-name drug manufacturers should not face liability for injuries caused by their generic competitors' products. If tort law would permit such claims under the rubric of negligent (or innocent) misrepresentation, then this suggests that some fundamental flaws may exist in the doctrine as presently configured. In *Conte*, the California court's analysis seemed straightforward enough but led to an ultimately dubious result.

This article has focused on prescription drugs simply because of the higher likelihood of litigation involving generic versions of such products and the distinctiveness of the applicable regulatory controls. Nonetheless, the same sorts of questions may arise with other types of consumer goods, ranging from nonprescription drugs and foods to household chemicals and appliances; in other words, crossover tort litigation could occur in any market served by brand-name companies that actively promote their wares but face competition from largely identical but lower-priced store brands.<sup>90</sup>

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*Manufacturers and Authorized Distributors Liable for Injuries Caused by Counterfeit Drugs*, 69 U. PITT. L. REV. 245, 265–72 (2007) (suggesting an entirely inapt nondelegable duty theory to hold manufacturers liable for hazardous counterfeiting).

90. See Patricia B. Cunningham & Erin C. Witkow, *Private-Label Versions: Free Enterprise or Free-loading?*, NAT'L L.J., Aug. 27, 2007, at S1; Jayne O'Donnell & Sandra Block, *Consumers Get Frugal, So Retailers Get Creative*, USA TODAY, Jan. 28, 2009, at 1B (“[C]onsumers are shifting to less-costly store brands.”). On retailers' strategies to encourage such substitution, see Eric Goldman, *Brand Spillovers*, 22 HARV. J.L. & TECH. 381, 390–91 & n.40, 395–96 (2009). So far, courts have rejected the few such cases that have arisen. See *Piscitello v. Hobart Corp.*, 799 F. Supp. 224, 226 (D. Mass. 1992) (“It would be unfair to impose such an expansive view of tort liability on those whose original [meat grinder] design is mimicked without the designer's permission.”); *Powell v. Standard Brands Paint Co.*, 212 Cal. Rptr. 395, 398 (Ct. App. 1985) (“[T]he law does not require a [paint] manufacturer to study and analyze the products of others and to warn users of risks of those products.”); *Vill. of Cross Keys, Inc. v. U.S. Gypsum Co.*, 556 A.2d 1126, 1135 (Md. 1989); *Spaulding v. Lesco Int'l Corp.*, 451 N.W.2d 603, 605–06 (Mich. Ct. App. 1990) (concluding that the publisher of a “do-it-yourself” installation guide for above-ground swimming pools “had no duty to warn of the alleged dangers of another's product”). Similarly, market share liability has until recently confined itself to prescription drug (primarily DES) cases. See Allen Rostron, *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. REV. 151, 153, 170–72 (2004) (explaining that courts have limited extensions of the theory to “fungible” products produced by multiple manufacturers); Laura L. Worley, Comment, *The Iceberg Emerged: Wisconsin's Extension of Risk Contribution Theory Beyond DES*, 90 MARQ. L. REV. 383, 384–86, 396 (2006) (discussing recent decision applying market share liability to lead paint manufacturers).

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Conversely, in some sectors (e.g., dietary supplements<sup>91</sup>), small companies may engage in patterns of aggressive marketing while larger, more risk-averse firms may content themselves with offering branded (and somewhat more expensive) versions that some customers purchase, essentially free riding on the earlier efforts of more entrepreneurial companies to popularize particular types of new products. Putting aside the fact that the smaller competitors might offer a less attractive target for litigation, might they face liability insofar as customers took seriously the exaggerated claims for their products, even though the injury resulted from the use of the branded version for which that manufacturer had carefully made no exaggerated claims? *Conte* would seem to allow it, which again may cast serious doubt on the wisdom of its capacious approach to negligent misrepresentation.

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91. See Nanci Hellmich, *The Botanical Business: For the Big Drug Firms, Market Is Ripe for Expansion into Herbals*, USA TODAY, Oct. 14, 1998, at 1D.

