

# 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

*It is difficult to get a man to understand something when his salary depends upon his not understanding it.<sup>1</sup>*

## INTRODUCTION

Under the Food, Drug, and Cosmetic Act (“Act”), a generic drug must use the warning label of the name-brand drug it copies.<sup>2</sup> The name-brand manufacturer (“Pioneer”) writes the name-brand drug’s warning based upon safety and effectiveness tests it conducts to receive premarket approval under the Act.<sup>3</sup> The Act permits generic manufacturers to rely upon the Pioneer’s safety tests so cheaper generic drug copies can reach consumers after the Pioneer’s new drug patent expires.<sup>4</sup>

But what if a Pioneer buries an unfavorable research study or neglects to update its warning—should generic manufacturers be strictly liable for their reprints of the Pioneer’s inadequate label? Can strict liability apply separately to the label, or is the warning inseparable from the product? Fifty years ago, a tort scholar observed that applying strict liability to food but not its container imposes a distinction that does not exist in reality.<sup>5</sup>

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1. UPTON SINCLAIR, I, *CANDIDATE FOR GOVERNOR* 109 (Univ. of Cal. Press, 1994) (1935).

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

3. *Id.* § 355(b), (d).

4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of the U.S.C.) [hereinafter Hatch-Waxman Amendments].

5. William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 *YALE L.J.* 1099, 1138 (1960) (calling it a “metaphysical distinction”

Imagine you are a generic drug manufacturer.<sup>6</sup> Unlike the research-based Pioneer giants, your company is a simple manufacturing plant.<sup>7</sup> Three years ago, you submitted samples of your generic pills to the Food and Drug Administration (“Agency”) for bioequivalency testing: The pills have to contain the same active ingredient and absorb into human tissue at the same rate as the name-brand drug before the Agency will approve them.<sup>8</sup>

Four months after generic sales begin, a woman sues your company and the drug’s Pioneer.<sup>9</sup> The woman consumed the name-brand drug for years but recently had her prescription filled by your generic at the pharmacy. She alleges the drug’s warning failed to caution that taking the drug for many years creates a risk of serious neurological damage.<sup>10</sup> Only through the lawsuit do you learn the following facts: The Pioneer successfully kept the medical community in the dark regarding the drug’s serious side effects.<sup>11</sup> After over a decade of investigation, at great cost to taxpayers, a publicly funded group finally uncovered a hidden study about the drug’s serious side effects.<sup>12</sup> The hidden study confirms that the drug causes the same side effects the plaintiff alleges. Trade secret law had prevented you viewing, in detail, the contents of the Agency’s

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that “can only be regarded as amazing”). Tort law for prescription drugs has historically mirrored tort law for food since food and drugs are products “for intimate bodily use.” *Id.* at 1139.

6. This hypothetical case is fictional. It was created, however, by compiling actual court decisions and reports about Pioneers and their name-brand drugs.

7. *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 98th Cong.* 10 (1983) [hereinafter *Hearings*] (statement of Mark Novitch, Acting Comm’r, Food and Drug Administration) (indicating generic companies “are production oriented,” unlike “research-based” Pioneers).

8. 21 U.S.C. § 355(j)(8) (2006) (defining bioequivalency).

9. *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1167–68, 1174 (W.D. Wash. 2006) (finding manufacturer who had sold generic Prozac for only four months could be liable for failing to warn of risk of suicide).

10. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 305 (Cal. Ct. App. 2008) (alleging plaintiff developed permanent neurological problems after consuming generic Reglan for four years).

11. United States’ Complaint in Intervention at 1–2, U.S. *ex rel.* *Gobble v. Forest Lab.*, No. 03-10395-NMG (D. Mass. Feb. 13, 2009) (claiming Pioneer failed to disclose negative studies about Celexa and Lexapro, and gave doctors false information about the drugs’ safety and effectiveness).

12. Shankar Vedantam, *A Silenced Drug Study Creates an Uproar*, WASH. POST, Mar. 18, 2009, at A01 (reporting Seroquel’s Pioneer buried a negative research study for twelve years, after which a publicly funded group uncovered the hidden study at great expense).

2009]

THE EXTINCT DISTINCTION OF PRIVACY

“master file” on the drug.<sup>13</sup> Even if you filed a Freedom of Information Act (“FOIA”) request regarding the master file, you probably would not receive very much from the Agency.<sup>14</sup>

During discovery, you learn the Pioneer spent hundreds of millions of dollars each year to advertise its drug as safe and beneficial.<sup>15</sup> You wonder how much money the Pioneer spent to ensure its warning label was adequate during the twenty years the Pioneer had exclusive rights over its name-brand drug.<sup>16</sup>

Discovery also reveals the Pioneer paid doctors to sign their names to scientific articles about the drug that the Pioneer itself wrote.<sup>17</sup> Medical journals published those ghostwritten pieces, believing they were independent reviews of the drug instead of what they really were: nothing more than advertisements.<sup>18</sup> As for the few independent articles actually written by a doctor, praising the drug’s benefits, the doctor confesses he never conducted any of the studies referred to in those articles.<sup>19</sup> The doctor received grant money from the Pioneer but the Pioneer remained unimplicated in the falsified articles.<sup>20</sup>

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13. 21 C.F.R. § 314.430 (2008) (stating the Agency maintains a master file for every drug but that the Pioneer may block public access to parts of the file by claiming the information constitutes trade secrets).

14. *Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141, 145 (D.C. Cir. 2006) (noting that in response to a FOIA request, the Agency only disclosed about 9,000 pages out of roughly 250,000 pages in the drug master file on RU-486, the abortion pill).

15. IMS HEALTH, TOTAL U.S. PROMOTIONAL SPEND [SIC] BY TYPE, 2008 (2008), [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/U.S.\\_Promo\\_Spend\\_Data\\_2008.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/U.S._Promo_Spend_Data_2008.pdf) [hereinafter IMS HEALTH, PROMOTION].

16. A new drug patent lasts 20 years but can effectively be extended three to ten years because the Agency will not approve competing generic drugs during those years. 21 U.S.C. § 355(c)(3)(E) (2006).

17. Associated Press, *FDA Eases Promotion of Off-Label Uses for Drugs*, Jan. 12, 2009 (reporting Pioneer Merck ghostwrote articles about Vioxx, a pain drug voluntarily recalled after lawsuits alleged it caused dangerous cardiac side effects).

18. United States’ Complaint in Intervention at 15, U.S. *ex rel. Gobble v. Forest Lab.*, No. 03-10395-NMG (D. Mass. Feb. 13, 2009) (alleging drug Pioneer “coordinated the ‘placement’” of false and misleading news articles about its drug “in numerous national and local media outlets”).

19. Brendan Borrell, *A Medical Madoff: Anesthesiologist Fabricated Data in 21 Studies*, SCI. AM., Mar. 10, 2009, <http://www.scientificamerican.com> (search “Medical Madoff” then follow “A Medical Madoff” hyperlink) (regarding falsified publications recommending Celebrex, Bextra, Lexapro, and other pain drugs instead of cheaper generics).

20. *Id.*

As to your generic, pretrial testing determined there were no manufacturing defects. Your generic was not adulterated; it was bioequivalent. It carried the same warning label as the name-brand, as required by federal law.<sup>21</sup>

Before trial, the Pioneer's attorneys depart the courthouse, the case against their client dismissed. The court did not hold the Pioneer liable because the plaintiff took a generic version of the drug—your version.<sup>22</sup> The only significant difference between your drug and the Pioneer's drug is the price.<sup>23</sup>

Industry reports reveal the Pioneer earned billions from its drug each year the drug's true risks remained hidden.<sup>24</sup> Your company, on the other hand, sold the generic for 80% less than the Pioneer, as contemplated by the federal law that permitted you to rely on the Pioneer's expensive safety tests.<sup>25</sup>

After dismissing the Pioneer, the court rules that you assumed the risk the Pioneer's safety tests were flawed.<sup>26</sup> The court does not realize a generic manufacturer cannot sell its bioequivalent drug for 80% less than the name brand if it must repeat years of safety tests.<sup>27</sup> You understand these savings are the very purpose of the Act's provision that permits you to rely on the Pioneer's tests, but the court refuses to accept such justification.<sup>28</sup> The court issues a verdict against your company for the full amount of plaintiff's damages. If

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21. 21 U.S.C. § 355(j)(2)(A)(v) (2006); 21 C.F.R. § 314.93(e)(1)(i) (2008).

22. *E.g.*, *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at \*6 (N.D.N.Y. July 19, 2006) (holding Prozac's Pioneer was not liable for inadequate suicide risk warning on generic Prozac because Pioneer did not make the drug ingested).

23. *Hearings, supra* note 7, at 1 (statement of Rep. Waxman, Chairman, H. Subcomm. on Health and the Environment).

24. *See* IMS HEALTH, TOP 15 U.S. PHARMACEUTICAL PRODUCTS BY SALES (2008), [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/2008\\_Top\\_15\\_Products\\_by\\_U.S.\\_Sales.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/2008_Top_15_Products_by_U.S._Sales.pdf) [hereinafter IMS HEALTH, TOP 15].

25. *Hearings, supra* note 7, at 1 (statement of Rep. Waxman).

26. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994) (ruling generic Phenergan manufacturer assumed the risk the Pioneer's safety tests were faulty); *Goldych*, 2006 WL 2038436, at \*3–4 (citing *Foster*, 29 F.3d at 169) (stating generic Prozac manufacturer “blindly” accepted the risk that the Pioneer's warning label was faulty).

27. *Hearings, supra* note 7, at 38 (statement of Milton Bass, general counsel to the National Association [Generic] Pharmaceutical Manufacturers) (indicating Agency-required safety tests are approximately 95% of drug approval costs).

28. *Id.*

2009]

THE EXTINCT DISTINCTION OF PRIVACY

forced to pay the judgment, you have no choice but to close your manufacturing plant.

This hypothetical case is a compilation of actual court decisions and reports about Pioneers, name-brand drugs, and how those drugs are promoted. While Pioneers aggressively market drug benefits and downplay the risks, each year millions of people experience severe side effects from prescription drugs.<sup>29</sup> Lawsuits across the nation allege permanent neurological damage from taking Reglan for nausea.<sup>30</sup> Psychiatric drugs like Paxil, Prozac, and Zoloft allegedly cause heightened risk of suicide.<sup>31</sup> In an Alabama case, a woman claimed her skin, organs, body tissues, and teeth began to disintegrate after she took generic Keflex for an infection.<sup>32</sup> The financial impact of misleading Pioneer drug promotion is severe, and the largest victims are government health care programs.<sup>33</sup>

In an Agency workshop, a leading scientist for Wyeth Research, a Pioneer, reported that every year around two million hospitalized patients experience severe side effects from prescription drugs.<sup>34</sup> The Pioneer researcher stated those negative drug reactions are one of the leading causes of death in the United States, imposing a \$100 billion

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29. IMS HEALTH, PROMOTION, *supra* note 15 (reflecting drug marketing budgets); Andrew Dorner, *Pharmacogenomics in Phase I/II Clinical Trials*, in 2002 WORKSHOP ON PHARMACOGENETICS/PHARMACOGENOMICS IN DRUG DEVELOPMENT & REGULATORY DECISION-MAKING 15 (2002), <http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm088724.pdf>.

30. *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1354 (N.D. Ga. 2008); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 305 (Cal. Ct. App. 2008); *Kelly v. Wyeth*, No. 20033314F, 2007 WL 1302589, at \*1 (Mass. Dist. Ct. Apr. 12, 2007).

31. *E.g.*, *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 256–57 (E.D. Pa. 2006) (regarding Paxil and Zoloft), *vacated*, No. 08-437, 2009 U.S. LEXIS 1818, at \*1 (U.S. Mar. 9, 2009); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at \*1 (N.D.N.Y. July 19, 2006) (concerning Prozac).

32. *Barnhill v. Teva Pharm. USA*, No. 06-0282-CB-M, 2007 WL 5787186, at \*1 (S.D. Ala. Apr. 24, 2007).

33. *See* Press Release, U.S. Dep't of Justice, Eli Lilly & Co. Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), <http://www.usdoj.gov/opa/pr/2009/January/09-civ-038.html> (regarding largest criminal fine in U.S. history to date, for a Pioneer's allegedly false drug promotion). Only eight months later, Pioneer Pfizer paid an even larger criminal fine for alleged illegal marketing of Viagra, Lipitor, Zoloft, and other drugs. Associated Press, *Pfizer to Pay Record \$2.3 Billion Penalty*, Sept. 2, 2009, [http://www.msnbc.msn.com/id/32657347/ns/business-us\\_business/page/2/](http://www.msnbc.msn.com/id/32657347/ns/business-us_business/page/2/).

34. Dorner, *supra* note 29, at 15. Dr. Dorner was Director of Molecular Medicine and Experimental Medicine for Wyeth Research when he disclosed these statistics of prescription drug harm to the Agency. *Id.*

annual burden on society.<sup>35</sup> It is puzzling that Pioneers avoid liability for inadequate generic drug labels when a Pioneer researcher admits—to the Agency no less—that prescription drug side effects pose deadly risks to human beings and cause billions in societal financial loss.

Yet an overwhelming majority of courts do not hold Pioneers responsible when defective warning labels copied onto generic packaging cause human injury.<sup>36</sup> Nearly every jurisdiction that has considered the issue applies strict liability to the generic but not the Pioneer, finding the Pioneer did not manufacture the drug consumed.<sup>37</sup> But, the alleged defect in a failure-to-warn case is not a manufacturing error: the alleged defect is an inadequate warning about health risks when using the drug as prescribed.<sup>38</sup>

In addition, an injured consumer does not need a direct sale from a manufacturer for a strict liability claim.<sup>39</sup> This historic requirement for a sale, called the doctrine of privity, comes from contract law.<sup>40</sup> Since tort law imposes duties irrespective of contract, privity has not been necessary in tort claims for nearly one hundred years.<sup>41</sup> Indeed, strict liability applies to all entities supplying products to the stream of commerce, including component part manufacturers that have control over other manufacturers in a product's chain of distribution.<sup>42</sup>

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35. *Id.*

36. *E.g.*, *Barnhill*, 2007 WL 5787186, at \*1–2 (stating Keflex's Pioneer was not liable for defective warning label on generic Keflex).

37. *E.g.*, *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1169–74 (W.D. Wash. 2006) (finding generic Prozac manufacturer of *four months* was strictly liable for not warning of suicide risk even though generic label was identical to Pioneer's; Agency rejected need for suicide warning; and drugs in that jurisdiction were considered "unavoidably unsafe" products under REST. 2D – TORTS, 402A cmt. k (1965)). The decedent in *Laisure* had taken name-brand Prozac for eight months before beginning to take the generic, but Prozac's Pioneer was dismissed. *Id.* at 1167–68.

38. *E.g.*, cases cited *supra* notes 26, 30, 36, 37.

39. *E.g.*, *Nelson v. Superior Court*, 50 Cal. Rptr. 3d 684, 688 (Cal. Ct. App. 2006) (ruling strict liability protects bystanders injured by defective products since retail sale is unnecessary); *Francioni v. Gibsonia Truck Corp.*, 372 A.2d 736, 740 (Pa. 1977) (deciding lessors can be subject to strict products liability since a sale is not required).

40. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916).

41. *Id.* (holding privity is irrelevant to tort claims by people injured by inherently dangerous items; in this case, wooden car wheels).

42. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963) (noting retailer and manufacturer could both be jointly liable); *Taylor v. Elliott*

2009]

THE EXTINCT DISTINCTION OF PRIVILEGE

This Note argues that Pioneers are component part manufacturers of generic drugs because they supply the warning labels generics must, by law, carry.<sup>43</sup> Pioneers owe a duty of care to generic drug consumers because they are intimately connected to the generic industry, and can control generic manufacturers.<sup>44</sup> Part I of this Note provides background on prescription drugs and their regulation by the Food, Drug, and Cosmetic Act. Part II recommends applying strict liability to prescription drugs because the doctrine exists specifically for highly technical goods that are shrouded by trade secret protection. Part III argues that Pioneers are component part manufacturers that supply the stream of commerce with generic drug warning labels.

### I. REGULATION AND SALE OF PRESCRIPTION DRUGS IN THE UNITED STATES

The Federal Food, Drug, and Cosmetic Act regulates the sale and labeling of all prescription drugs in the United States.<sup>45</sup> The agency charged with implementing the Act is the Food and Drug Administration.<sup>46</sup> In 1984, Congress passed the Hatch-Waxman Amendments to the Act to encourage the manufacture of cheaper generic drugs.<sup>47</sup>

#### A. *The Food, Drug, and Cosmetic Act, as Amended in 1984 by the Hatch-Waxman Amendments*

A new prescription drug cannot be sold in the United States without Agency approval.<sup>48</sup> A new drug is one not recognized as safe and effective to treat a particular medical condition.<sup>49</sup> The new drug applicant must prove the drug is safe, effective, and has an adequate warning label.<sup>50</sup>

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Turbomachinery Co., 90 Cal. Rptr. 3d 414, 424 (Cal. Ct. App. 2009) (concerning potential component part liability for asbestos gasket manufacturer).

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

44. See generally *Taylor*, 90 Cal. Rptr. 3d at 422 (outlining California's test for determining when a component part manufacturer is strictly liable).

45. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2006).

46. *Id.* § 355(a), (b), (j).

47. Hatch-Waxman Amendments, *supra* note 4.

48. 21 U.S.C. § 355(a) (2006).

49. *Id.* § 321(p). Drugs are not just generally approved—their safety and effectiveness for each medical condition must be established. *Id.*

50. *Id.* § 355(b), (d) (stating new drug applicant must provide “full reports of investigations” regarding safety and effectiveness).

Pioneers generally apply for new drug patents before seeking Agency approval.<sup>51</sup> Before 1984, Pioneers alleged the Act was deficient because safety testing and Agency review took years, effectively reducing the new drug's patent life and Pioneer profit.<sup>52</sup> The pre-1984 Act was also problematic for consumers because after drug patents expired, few manufacturers made generics of those off-patent drugs.<sup>53</sup> During Congressional hearings on these problems, drug industry representatives agreed that the expense of repeating the Pioneers' human safety tests prevented manufacturers applying for generic drug approval.<sup>54</sup> Repeating drug tests on human subjects just to receive generic approval was also not ethically justified because the Pioneer's pre-market tests and post-market monitoring arguably established drug safety.<sup>55</sup>

The 1984 Hatch-Waxman Amendments made concessions to Pioneer and generic manufacturers. The Act now gives Pioneers additional years of exclusivity that tack onto the end of new drug patents, as compensation for the cost of safety testing drugs and waiting for Agency approval.<sup>56</sup> The revised Act permits generic manufacturers to rely upon the Pioneers' safety and effectiveness tests so the tests' high costs do not prevent cheaper drugs from reaching consumers.<sup>57</sup>

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51. FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 4 (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

52. 35 U.S.C. § 154(a)(2) (2006) (providing twenty-year patent dating from application to U.S. Patent & Trademark Office); *Hearings, supra* note 7, at 7–8 (statement of Mark Novitch, Acting Comm'r, Food and Drug Administration); Richard A. Merrill, *Regulation of Drugs and Devices: An Evolution*, 48 HEALTH AFFAIRS 52, 53 (1994).

53. *Hearings, supra* note 7, at 1 (statement of Rep. Waxman) (noting for most off-patent Pioneer drugs, only one generic manufacturer would seek approval, usually charging a high price).

54. *Id.* at 30–39 (statement of Milton Bass, general counsel to the National Association [Generic] Pharmaceutical Manufacturers) (claiming generic manufacturers' inability to afford expensive safety trials effectively extended Pioneers' new drug monopolies).

55. *Id.* at 7, 19 (statement of Mark Novitch, Acting Comm'r, Food and Drug Administration) (alleging Act revisions to restore a Pioneer's drug patent life were needed, and that patent restoration would also benefit public health by allowing Pioneers to collect serious but "low incidence" side effect reports after drugs were on the market).

56. 21 U.S.C. § 355(c)(3)(E) (2006); 35 U.S.C. §§ 154–156 (2006).

57. 21 U.S.C. § 355(j)(2)(A) (2006); *Hearings, supra* note 7, at 1 (statement of Rep. Waxman); Joseph H. Meltzer et al., *Fighting the High Cost of Health Care*, 43:10 TRIAL 44, 45 (2007).

2009]

THE EXTINCT DISTINCTION OF PRIVILEGE

*B. Generic Drugs and How They Enter, or Are Prevented From Entering, the Market*

People might mistakenly believe generic manufacturers receive a Pioneer's permission to make generic drugs. Pioneers do sell licensing, distribution, and other rights to generic companies, but generic manufacturers might have no business relationship at all with a drug's Pioneer.<sup>58</sup> Regardless of whether a generic company has, or does not have, a business relationship with a drug's Pioneer, entering the market can be fraught with peril even if the generic company complies with the Act and receives Agency approval.<sup>59</sup>

To comply with the Act, generics must be bioequivalent to the name-brand drug, and the Agency tests generics to confirm bioequivalency.<sup>60</sup> The generic manufacturer must certify the warning label will be "the same as" the name-brand drug's warning.<sup>61</sup> The generic manufacturer must also certify that its drug and warning label do not violate any Pioneer patents.<sup>62</sup>

The first manufacturer that obtains generic approval receives a six-month exclusivity period, to encourage creation of generic drugs.<sup>63</sup> After the six months expire, any manufacturer may apply to

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58. FED. TRADE COMM'N, *supra* note 51, at 27 (describing agreements between Pioneers and generics, such as supply, distribution, licensing, royalty, and non-compete); Stephen M. Goodman, *Beyond Frankenstein: Guiding Genetic Engineering Companies to Money, Regulatory Approval, and Public Acceptance*, 5:3 A.B.A. SEC. SCI. & TECH. L. 21 (2009) (stating prescription drugs tend to have small numbers of molecular ingredients and can easily be reverse-engineered).

59. 21 U.S.C. § 355(j)(2)(A) (2006) (containing the application requirements for generic drug approval); Terry G. Mahn, *Drug Labels: The New Orange Book*, UPDATE, July–Aug. 2006, at 8, available at <http://www.fr.com/news/DrugLabels.pdf> (alleging Pioneers have developed methods to ensure generics will not compete with higher priced name-brand drugs).

60. 21 U.S.C. § 355(j)(2)(A)(iv) (2006). The Agency considers generic drugs equivalent to the Pioneer drugs they copy. STUART L. NIGHTINGALE, U.S. FOOD & DRUG ADMIN., THERAPEUTIC EQUIVALENCE OF GENERIC DRUGS (1998), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm073182.htm>.

61. 21 U.S.C. § 355(j)(2)(A)(v) (2006).

62. *Id.* § 355(j)(2)(A)(vii); Mahn, *supra* note 59, at 1 (alleging Pioneers are patenting portions of their drugs' warning labels). Using a warning label the Agency has not approved is misbranding and criminal penalties can apply, in addition to removing a generic from the market. 21 U.S.C. §§ 331, 352 (2006).

63. 21 U.S.C. § 355(j)(5)(B)(iv) (2006). A Federal Trade Commission study determined that Pioneers brought patent infringement suits against 72% of these first generic applicants. FED. TRADE COMM'N, *supra* note 51, at 14.

sell generic versions of that drug.<sup>64</sup> Thus, for every new drug that loses patent protection, numerous generic versions could exist, each made by a different manufacturer.<sup>65</sup>

If a Pioneer believes a generic violates any of its patents, it can sue for infringement; the infringement suit prevents the generic manufacturer from selling its bioequivalent for up to 30 months.<sup>66</sup> Sometimes, Pioneers sue for infringement and offer to withdraw their suits in return for an agreement by the generic manufacturer to refrain from selling their drug for a number of years.<sup>67</sup> While the Federal Trade Commission finds this anti-competitive practice illegal, most U.S. circuit courts of appeals permit it, and the Supreme Court refuses to consider the issue.<sup>68</sup>

### C. Prescription Drug Prices and the Need for Generic Drugs

For manufacturers, the prescription drug industry is highly profitable.<sup>69</sup> American-owned conglomerates sold \$291.5 billion in prescription drugs during 2008 and foreign-owned companies sold billions more, for a combined world market of \$773 billion.<sup>70</sup> Americans consume “approximately 45%” of the world supply of prescription drugs each year.<sup>71</sup>

Pioneers contend research and development costs cut deeply into drug profits; however, the new drug industry is heavily subsidized.<sup>72</sup> Years of tax benefits are available to manufacturers engaging in innovative enterprises.<sup>73</sup> Taxpayer money also funds public research

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64. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

65. *Id.*

66. *Id.* § 355(j)(5)(B)(iii).

67. FED. TRADE COMM’N, *supra* note 51, at 27–29 (reporting on patent settlements between generics and Pioneers).

68. *E.g., In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, at \*2 (F.T.C. Dec. 8, 2003), *rev’d*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

69. IMS HEALTH, TOP CORPORATIONS BY U.S. SALES (2008), [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/2008\\_Top\\_Corp\\_by\\_U.S.\\_Sales.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/2008_Top_Corp_by_U.S._Sales.pdf).

70. *Id.*; IMS HEALTH, GLOBAL PHARMACEUTICAL SALES 2000–2007 (2008), [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/GlobalSales.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/GlobalSales.pdf).

71. Meltzer, *supra* note 57, at 44.

72. Mahn, *supra* note 59.

73. *Hearings*, *supra* note 7, at 70 (statement of Fred Wegner, pharmaceutical specialist, American Association of Retired Persons) (claiming federal law grants

2009]

THE EXTINCT DISTINCTION OF PRIVACY

institutions and if those institutions sell new drug discoveries to Pioneers, no money flows back to taxpayers for their support of innovation.<sup>74</sup>

Instead, for consumers, name-brand drug prices increased 14%–18% a year on average from 1997 to 2005.<sup>75</sup> Generics lessen that expense, selling for 30%–80% less than the name-brand drugs they copy.<sup>76</sup> Nearly 500 million name-brand prescriptions were filled by generics in 2008, saving the American public, insurers, and government agencies billions of dollars in health care costs.<sup>77</sup>

## II. THE DOCTRINE OF STRICT LIABILITY APPLIES, IN PARTICULAR, TO HIGHLY TECHNICAL AND TRADE SECRET PRODUCTS LIKE PRESCRIPTION DRUGS

Strict liability applies to harmful products so that businesses purporting to have superior technical knowledge do not gain unjust windfalls from selling goods that injure human beings.<sup>78</sup> Strict liability is quasi-contractual because it draws on warranty,

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Pioneers decades of tax credit and “73%” in tax discounts to compensate for innovation and research costs).

74. Patent and Trademark Act Amendments of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended in 35 U.S.C. §§ 200–212 and known as the Bayh-Dole Act). The Bayh-Dole Act denies taxpayers “the fruits of technological progress” and amounts to corporate subsidy. Donald G. Richards, *INTELLECTUAL PROPERTY RIGHTS AND GLOBAL CAPITALISM* 50 (M.E. Sharpe, Inc. 2004). After Pioneers purchase new drugs from taxpayer-funded research, “such as AZT for the treatment of AIDS,” Pioneers charge “excessively high prices” for the medicine. *Id.* at 51. Since healthcare is a vital societal concern, “there is an especially urgent need for this science to be conducted in a manner appropriate to our interests as a species and not narrowly in the interests of profit.” *Id.*

75. Meltzer, *supra* note 57, at 44.

76. Linda A. Johnson, *Aurobindo, Pfizer Sign Generic Drug Deal*, Mar. 3, 2009, <http://www.manufacturing.net/News-Aurobindo-Pfizer-Sign-Generic-Drug-Deal-030309.aspx?menuid=256>.

77. IMS HEALTH, *TOP 15 U.S. PHARMACEUTICAL PRODUCTS BY DISPENSED PRESCRIPTIONS* (2008), [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/2008\\_Top\\_15\\_Products\\_by\\_U.S.\\_RXs.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/2008_Top_15_Products_by_U.S._RXs.pdf) [hereinafter *IMS HEALTH, TOP PRODUCTS*].

78. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963) (“Implicit in the machine’s presence on the market . . . was a representation that it would safely do the jobs for which it was built.”); *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 443 (Cal. 1944) (Traynor, J., concurring) (noting consumer “vigilance has been lulled by the steady efforts of manufacturers to build up confidence by advertising”).

misrepresentation, and unjust enrichment theories.<sup>79</sup> Tort law furthers the applicability of these theories to ensure that risks of product failure, and the burden of proving same, are not borne by injured consumers regardless of fault, privity, statutes of limitations, or other contractual concepts.<sup>80</sup>

An underlying purpose for strict liability is ensuring that the product itself pays for the harmful consequences it causes, out of the profit it earns.<sup>81</sup> The doctrine is necessary to guard against manufacturers using trade secrets, clever advertising, and a cultivated appearance of superior knowledge to shift the manufacturers' risk of loss onto an unwary public.<sup>82</sup>

Strict liability is also based upon the reality of an increasingly technological age.<sup>83</sup> Manufacturers cannot expect consumers to inspect every piece of a complicated, assembled good to determine which part of the good will fail and cause an injury.<sup>84</sup> Even if people could inspect every piece of a complex product, consumers are not experts in the manufacturer's business and cannot be: Trade secret law protects a product's safety testing and design from public disclosure.<sup>85</sup>

This link between trade secrets and strict liability must not be disregarded when it comes to technical, "esoteric" goods.<sup>86</sup> Strict liability was intended to apply with particular force to technical and esoteric goods because a manufacturer's right to shield its product's

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79. *Greenman*, 377 P.2d at 901; *Baxter v. Ford Motor Co.*, 35 P.2d 1090, 1092 (Wash. 1934) (holding breach of warranty action for shatterproof car windshield properly proceeded as tort claim for innocent misrepresentation).

80. *Greenman*, 377 P.2d at 901 ("The remedies of injured consumers ought not to be made to depend upon the intricacies of the law of sales." (internal quotation marks omitted)).

81. *See id.* (stating "the costs of injuries resulting from defective products [should be] borne by the manufacturers that put such products on the market" rather than injured consumers).

82. *Id.*

83. *Escola*, 150 P.2d at 443 ("The consumer no longer has means or skill enough to investigate for himself the soundness of a product . . .").

84. *Id.*

85. *Id.* ("Manufacturing processes, frequently valuable secrets, are ordinarily either inaccessible to or beyond the ken of the general public.").

86. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (calling prescription drugs "complex medicines, esoteric in formula and varied in effect" in discussing learned intermediary doctrine), *cert. denied*, 419 U.S. 1096 (1974).

2009]

THE EXTINCT DISTINCTION OF PRIVACY

design and safety qualities also means the public cannot verify if the product has defects.<sup>87</sup>

Despite the origin and purpose of strict liability, courts have changed the doctrine's failure-to-warn standard to require proof a manufacturer knew or could have known a particular risk of harm existed (the "knowability burden").<sup>88</sup> Imposing a knowability burden upon injured plaintiffs when manufacturers have wide latitude to operate in secret disrupts the fundamental basis of strict liability.

The knowability burden also harms product innovation.<sup>89</sup> When courts allow product innovators to avoid liability based upon a policy of encouraging invention, it reduces innovation to a pure profit enterprise.<sup>90</sup> Goods cloaked by trade secret law, immune from fault-piercing strict liability, cannot properly be considered innovative without factoring in the goods' actual safety and effectiveness.<sup>91</sup> Any policy encouraging invention should be balanced with other policies protecting public safety lest manufacturers benefit simply from creating goods so complex and cloaked as to reflect the mere appearance of innovation.

Research shows that innovation suffers when unsafe or impotent goods garner massive profit with no checks against their true value.<sup>92</sup> Failure to impose strict liability on technical goods rewards manufacturers for aggressive marketing instead of rewarding cautious advertising, full disclosure, and the creation of products that are as

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87. *Escola*, 150 P.2d at 443; *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963).

88. *E.g.*, *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 423 n.6 (Cal. Ct. App. 2009). For a thorough list of states that have codified the knowability burden (also called the state of the art defense—a misnomer since plaintiffs often bear the burden of proving knowability), see Ellen Wertheimer, *Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes Back*, 60 U. CIN. L. REV. 1183, 1261 n.318 (1992).

89. See Donald W. Light, *Global Drug Discovery: Europe is Ahead*, 28:5 HEALTH AFFAIRS 969, 975 (2009) (referring to dearth of new drugs that provide greater therapeutic advantages versus risks as an "innovation crisis for patients and society").

90. *Id.* (reporting "the vast majority of new drugs that constitute 80 percent of U.S. pharmaceutical costs offer few therapeutic advantages and greater risks than good drugs discovered in prior years").

91. *Id.*

92. *Id.* ("High prices for [new drugs] enable companies to spend two and a half times more on marketing than on [research and development], to persuade physicians to prescribe them and patients to want them.").

beneficial and safe as possible.<sup>93</sup> Releasing innovators of harmful products from liability also hurts the potentially innovative competitor, who may have an idea for making the product safer, but cannot change the item due to strict patent protection or lack of finances. An innovator receiving pure profit from its harmful product is unlikely to take the item off the market to improve the good's safety, or to bring in a competitor to work with its company to improve the product.

Allocating the risk of financial loss upon a manufacturer also encourages truthful advertising. When sophisticated manufacturers use advertising to invoke public demand and confidence, the risk that a product is actually less safe than represented should not fall upon people who buy into the product's represented scientific prowess.<sup>94</sup>

Strict liability levels the playing field between consumers and manufacturers, ensuring that profit is not unjustly gained at the expense of an increasingly unhealthy populace. The doctrine encourages natural removal of unsafe goods from the market without burdening state or federal agencies. Strict liability fosters innovation by motivating companies to outdo each other in making goods as safe as possible under a risk-utility test.<sup>95</sup> Finally, the doctrine shifts the monetary risk to where it properly lies—into the bottom line of any given product and away from the pockets of injured families, governments, and third party payors.<sup>96</sup> Those parties already paid for the product once, and should not have to subsidize its risks too.

### III. WHEN CONSUMERS ARE INJURED BY A DEFECTIVE WARNING LABEL ON A GENERIC DRUG, STRICT LIABILITY SHOULD APPLY TO THE PIONEER BECAUSE THE DEFECTIVE WARNING IS THE PIONEER'S PRODUCT

Strict liability requires proof that the defendant manufacturer supplied the stream of commerce with a defective component part that caused or created a risk of physical injury when used as intended.<sup>97</sup>

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93. *Id.* (concluding "current . . . incentives reward better marketing more than better value").

94. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963).

95. *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 544 (N.J. 1982) (describing risk-utility test).

96. *See id.*

97. *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 421, 426 (Cal. Ct. App. 2009). For purposes of this Note, the requirement that plaintiff suffered a physical, as opposed to economic, injury is presumed.

2009]

THE EXTINCT DISTINCTION OF PRIVILEGE

The threshold question is whether a Pioneer is a component part manufacturer of generic drugs.<sup>98</sup> A component part manufacturer is any entity that sells, supplies, or otherwise distributes its product to the stream of commerce (also called the chain of distribution).<sup>99</sup>

*A. Pioneers Are Component Part Manufacturers of Generic Drugs Because They Supply the Stream of Commerce With the Warning Labels Generic Drugs Must Use*

Component part manufacturers that can control or substantially influence other manufacturers in an assembled product's distribution chain have a duty to warn product users if the component part creates an inherent danger in the assembled product.<sup>100</sup> Some jurisdictions only use this control test.<sup>101</sup> California uses a *control plus* test—the component part manufacturer must have an intimate nexus or “participatory connection” with the assembled product before a duty to warn is created.<sup>102</sup>

A plaintiff must prove three elements to establish a participatory connection. First, the component part manufacturer must have control over, or the power to substantially influence, other chain of distribution manufacturers to make the assembled product safer.<sup>103</sup> Second, the component part manufacturer must be integral to the assembled product, such that the good would never reach the market without the component part manufacturer's conduct.<sup>104</sup> Third, the component part manufacturer must receive direct financial benefit

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98. Component parts are items, such as raw materials or complicated computer boards, incorporated by other manufacturers into an assembled product. *Id.*

99. *Greenman*, 377 P.2d at 901; *accord* *Francioni v. Gibsonia Truck Corp.*, 372 A.2d 736, 740 (Pa. 1977) (holding lessors are subject to strict products liability); *Trent v. Brasch Mfg. Co.*, 477 N.E.2d 1312, 1315 (Ill. App. Ct. 1985) (applying component part liability for defective air conditioning unit even though unit was affixed to real property); *see also* *Nelson v. Superior Court*, 50 Cal. Rptr. 3d 684, 687 (Cal. Ct. App. 2006) (finding strict liability extends to foreseeable bystanders since a retail sale is not required).

100. *Taylor*, 90 Cal. Rptr. 3d at 422.

101. *Simonetta v. Viad Corp.*, 197 P.3d 127, 134 (Wash. 2008) (noting strict liability applies to component part manufacturers that have control over other manufacturers in the distribution chain); *accord* *Peterson v. Lou Bachrodt Chevrolet Co.*, 329 N.E.2d 785, 786–87 (Ill. 1975) (ruling used car dealer was not liable for defective brakes because dealer could not pressure and control new car manufacturer to make the brakes safer).

102. *Taylor*, 90 Cal. Rptr. 3d at 422.

103. *Id.*

104. *Id.*

from entering its product to the chain of distribution.<sup>105</sup> These elements are not factors for weighing liability; they are a bright-line test “tied to the injury-producing product.”<sup>106</sup>

California courts have used the participatory connection test to analyze the duty of asbestos part manufacturers and for other situations where an injured consumer lacked exposure to a remote manufacturer’s product.<sup>107</sup> No jurisdiction has applied the participatory connection test to a Pioneer in a generic drug failure-to-warn case. A close analysis of each element demonstrates, however, that Pioneers have an intimate participatory connection to generic drugs.

*1. The Pioneer Controls Its Drug Warning and Can Substantially Influence Generic Manufacturers to Keep Drugs Safely Labeled*

Three realities prove a Pioneer can control generic manufacturers to make drugs safer. First, only the Pioneer can change its approved drug warning without Agency permission; once changed, generic manufacturers must change their warnings accordingly.<sup>108</sup> Second, a Pioneer has a post-market duty to strengthen its warning label at all times the drug is on the market.<sup>109</sup> Third, a Pioneer controls its drug’s master file and can prevent the file’s full disclosure under the Act.<sup>110</sup>

*a. The Pioneer Can Change a Drug Warning Without Agency Approval but Generics Cannot*

Some courts have held that the Changes Being Effected provision of the Act (“CBE”), which allows a Pioneer to change its warning without Agency approval, also allows a generic manufacturer

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105. *Id.*

106. *Id.*

107. *Id.* at 418 (finding that widow of man who developed mesothelioma from asbestos gaskets could not prove strict liability because her husband was never exposed to the asbestos gaskets defendant manufactured).

108. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008). These sections apply only to Pioneers. *See id.* § 201.56(a)(2)–(b)(1); *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2009 U.S. Dist. LEXIS 13274, at \*19–20 (W.D. Ky. Feb. 20, 2009).

109. *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at \*4 (U.S. Mar. 4, 2009) (holding Pioneer had duty to strengthen its drug’s warning, over 50 years after initial Agency approval of the warning label); 21 C.F.R. § 201.57(c)(6)(i) (2008). 21 C.F.R. § 201.57(c)(6)(i) applies only to Pioneers. *Id.* § 201.56(a)(2)–(b)(1).

110. 21 C.F.R. § 314.430(a)–(g)(1) (2008) (stating Pioneer can block disclosure of its drug’s safety test protocols, analytical procedures, and manufacturing processes by claiming trade secret protection).

2009]

THE EXTINCT DISTINCTION OF PRIVILEGE

to change its warning without Agency approval.<sup>111</sup> Those decisions are in error, both legally and practically.

The Act expressly states that a generic manufacturer must not change its drug warning without Agency permission.<sup>112</sup> The Agency has advised that the CBE does not apply to generic manufacturers.<sup>113</sup> The District Court for the Western District of Kentucky recently acknowledged that the Act does not permit a generic manufacturer to unilaterally change its drug warning.<sup>114</sup> The Agency stands between generic manufacturers and the public when it comes to prescription drug labels.<sup>115</sup>

Courts appear confused about the degree of power generic companies have over their copied drug labels.<sup>116</sup> Generic manufacturers do not have the same power as Pioneers.<sup>117</sup> Before receiving Agency approval, a generic manufacturer must petition the Agency to use a different warning.<sup>118</sup> After receiving Agency

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111. *Id.* § 314.70(c)(3)–(6) (containing the CBE); *e.g.*, *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (misstating generic manufacturer could change its warning under the CBE “even without prior FDA approval”); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at \*3–4 (N.D.N.Y. July 19, 2006).

112. 21 C.F.R. § 201.56(a)(2)–(b)(1) (2008) (specifying that certain provisions of the Act only apply to Pioneers).

113. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 n.1 (Jan. 16, 2008) (“CBE changes are not available for generic drugs approved under . . . U.S.C. 355(j). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug.”).

114. *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2009 U.S. Dist. LEXIS 13274, at \*19–20 (W.D. Ky. Feb. 20, 2009).

115. *See* 21 C.F.R. § 314.150(b)(10) (2008) (advising Agency may withdraw a generic if its warning label is “no longer consistent” with the Pioneer’s label).

116. *E.g.*, *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1169 (W.D. Wash. 2006) (misstating generic manufacturers “have the same power” to add to or strengthen drug warnings as Pioneers).

117. *Morris*, 2009 U.S. Dist. LEXIS 13274, at \*10 (stating, correctly, “federal regulation of brand and generic drug labeling differs significantly”).

118. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17957 (Apr. 28, 1992).

FDA reminds applicants that the labeling for an ANDA product [a generic drug] must be the same as the labeling for the listed drug product [the name-brand drug] except for differences due to different manufacturers, exclusivity, etc. (See 21 U.S.C. 355(j)(3)(G).) An ANDA applicant who believes that the labeling for a proposed drug product should differ from that approved for the reference-listed drug should contact FDA to discuss whether labeling for both generic and listed drugs should be revised.

*Id.*

approval, a generic manufacturer must petition the Agency and provide information supporting the requested change.<sup>119</sup> No matter which point in time a generic manufacturer requests a change, Agency review and approval is required.

In contrast, the CBE permits the Pioneer, and only the Pioneer, to immediately revise its approved warning without Agency approval.<sup>120</sup> Once the Pioneer changes its name-brand warning, every generic manufacturer of that drug across the country must accordingly change its label or face penalties under the Act.<sup>121</sup> This comports with the Agency's viewpoint that Pioneers know their drugs better than generic companies, and that Pioneers vitally assist the Agency in protecting public health.<sup>122</sup>

b. The Pioneer Has a Continuing Duty to Strengthen Its Warning Label at All Times a Drug Is On the Market

Generally, a manufacturer's post-market duty to warn under strict liability is continuous.<sup>123</sup> A component part manufacturer's duty to warn ordinarily ends, however, when the component part leaves the manufacturer's control.<sup>124</sup> This latter rule does not apply to Pioneers because the component part at issue—the warning label—remains within the Pioneer's control at all times its drug is in the stream of commerce.

Under the Act, a Pioneer must strengthen its drug's warning “as soon as there is reasonable evidence of a causal association” between the drug and a serious side effect.<sup>125</sup> The United States Supreme

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119. *Id.* at 17961 (“After approval of an ANDA [generic drug application], 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 [name-brand] drugs should be revised.”).

120. 21 C.F.R. § 314.70(c)(3)–(c)(6)(iii) (2008).

121. *Id.* §§ 314.97, 314.150(b)(3), 314.150(b)(10).

122. *Hearings, supra* note 7, at 7, 10–11 (statements of Mark Novitch, Acting Comm’r, Food and Drug Administration) (noting Pioneers are familiar with their own drug safety trials and assist the Agency by providing better evaluation of severe drug side effect reports).

123. *Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 262 (Cal. Ct. App. 1999) (“[A]s more information about adverse effects develops over time, the manufacturer must continue to provide physicians with warnings, at least so long as it is manufacturing and distributing the product.”).

124. *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 430 (Cal. Ct. App. 2009).

125. 21 C.F.R. § 201.57(c)(6)(i) (2008) (stating that in accord with 21 C.F.R. § 314.70 the Pioneer must strengthen the warning to notify of “a clinically significant

2009]

THE EXTINCT DISTINCTION OF PRIVILEGE

Court recently held that Wyeth, a Pioneer, had a duty to strengthen its drug's warning "at all times" its drug was "in the stream of commerce."<sup>126</sup> Since a Pioneer has a post-market duty to keep its warning label accurate, a Pioneer's duty regarding copied generic labels does not end simply because there is generic competition on the market.<sup>127</sup> The warning remains within the Pioneer's control after entering the stream of commerce because the Pioneer has the substantial ability and the ongoing duty to unilaterally strengthen the warning as soon as there is a nexus between a serious side effect and its drug.<sup>128</sup>

The Act's requirements make practical sense. If every generic manufacturer across the nation could change its label on its own, many warning variants would be on the market. Consumers might receive a lesser warning than neighbors, or see warnings that vary in degree within their own drug cabinets, depending on which company manufactured the drug product. Doctors in one state could be aware of a new severe side effect but doctors in other states would simultaneously be prescribing without that knowledge. This would create a tangle of conflicting warnings that the Agency would constantly have to sort out for every generic drug on the market.

Different warnings would also undermine the purpose of the Hatch-Waxman Amendments to lower prescription drug costs for the public.<sup>129</sup> More severe warnings might lead people to believe generics are more dangerous than name-brand drugs: for example, if a generic has the strongest warning, a black box advisory, but the Pioneer's drug does not.<sup>130</sup>

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hazard"); *id.* § 201.56(a)–(b) (indicating § 314.70 only applies to a Pioneer). Compare *id.* § 314.150(b)(10) (requiring the generic drug label be "consistent" with the Pioneer's drug label).

126. *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at \*10 (U.S. Mar. 4, 2009) ("[T]he manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."). The Pioneer drug at issue in this case had been on the market for over fifty years. *Id.* at \*5. Generic manufacturers do not craft their own warning labels—they must use the Pioneers' labels. 21 U.S.C. § 355(j)(2)(A)(v) (2006).

127. See *supra* notes 125–126 and accompanying text.

128. See *id.*

129. *Hearings, supra* note 7, at 1 (statement of Rep. Waxman).

130. 21 C.F.R. § 201.57 (2008) (listing the required sections for a warning label, including the black box advisory).

Multiple versions of a warning would also make it confusing to track severe side effects in relation to the approved warning.<sup>131</sup> For example, it is possible that the only way the Agency could learn of a new risk of harm is from generic reports of severe side effects that accompany requests to change the warning.<sup>132</sup> Generic companies provide a valuable benefit to the public and the Agency, and should not be negatively impacted by the Act's requirement they wait for approval before changing the Pioneer's warning.

c. The Pioneer Controls Its Drug Master File and Can Prevent the File's Disclosure to the Public

The Agency maintains a "master file" for every new drug.<sup>133</sup> Trade secret law and the Act allow Pioneers to block disclosure of the files' contents, including the initial protocols the Pioneers used to test the safety of their drugs.<sup>134</sup> Trade secret also protects other master file details such as post-market side effects.<sup>135</sup>

Hidden data makes it difficult for a generic manufacturer to determine how the side effect reports it receives fit with what is already known about a drug.<sup>136</sup> The Pioneers' control over drug master files supports a finding that Pioneers have control over generic manufacturers and can substantially influence whether or not generic manufacturers are able to make drug warnings safer.<sup>137</sup>

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131. *See Hearings, supra* note 7, at 48 (statement of Rep. Waxman) (asking whether the Hatch-Waxman Amendments would assist the Agency in tracking adverse reaction events).

132. *Id.* at 50 (statement of Bill Haddad, executive officer and president, Generic Pharmaceutical Industry Association) (asserting generic manufacturers had a good track record of reporting adverse drug reactions to the Agency and, in fact, over-report out of an abundance of caution).

133. 21 C.F.R. § 314.430 (2008).

134. *Id.* § 314.430(a)–(g)(1) (stating a Pioneer can block disclosure of safety test protocols, analytical procedures, and manufacturing processes by claiming trade secret protection).

135. *Id.* § 314.430(e)(4).

136. *Hearings, supra* note 7, at 7, 10–11 (statements of Mark Novitch, Acting Comm'r, Food and Drug Administration) (noting Pioneers are familiar with the clinical safety trials and better able to evaluate serious drug side effects). Although Congress recently passed the Food and Drug Administration Amendments Act of 2007, requiring online posting of clinical research trial results for public review, the system still depends on good faith Pioneer and researcher reporting. *See* Pub. L. No. 110-85, 121 Stat. 823; Clinical Trials Protocol Registration System, <http://prsinfo.clinicaltrials.gov/fdaaa.html> (last visited Dec. 18, 2009).

137. *See Hearings, supra* note 7, at 142–43 (statement of [Pioneer] Pharmaceutical Manufacturers Association) (claiming nonpublic safety and

2009]

THE EXTINCT DISTINCTION OF PRIVACY

## 2. *Pioneers Are Integral to the Generic Drug Distribution Chain*

### *Because Generics Would Not Be On the Market Without Pioneers*

A component part manufacturer is integral to an assembled product if the part manufacturer's conduct within the stream of commerce is closely linked to the assembled product's presence on the market.<sup>138</sup> Evidence that a component part manufacturer designed and tested a harmful product, allowed the product to bear its trademark, or created consumer demand for the product are relevant factors for proving a component part manufacturer is integral to an injury-producing good.<sup>139</sup>

Generics would not be on the market without Pioneer conduct. Pioneers design new drugs, purchase new drugs from public research institutions, and test the safety of those drugs' chemical compounds.<sup>140</sup> Pioneers write drug-warning labels based upon their own safety and effectiveness data, and move new drugs through the Agency approval process. A drug's proprietary name, as trademarked by the Pioneer, must be included on generic warning labels.<sup>141</sup>

Pioneers also keep name-brand drugs on the market long enough for generic manufacturers to consider copying the drug and its warning label. In fact, Pioneers have always made and sold their own generic drugs.<sup>142</sup> Pioneers are increasingly entering the generic market to copy their own drugs and those of competing Pioneers, when those drugs lose their patent protection.<sup>143</sup>

Finally, Pioneers are closely linked to the overall enterprise of creating high consumer demand for name-brand drugs. Even after new drug patents expire, Pioneer sales personnel attend medical

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effectiveness data in the Agency's drug master files is Pioneer property worth millions of dollars, and cannot be given away by the government to a private party).

138. *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 422 (Cal. Ct. App. 2009).

139. *Id.* at 425 (requiring a close link to the "overall producing and marketing enterprise" of the harmful product).

140. *See* discussion *supra* Part I. *See generally* 21 U.S.C. § 355(j)(8) (2006) (defining bioequivalency).

141. 21 C.F.R. § 201.57(a)(2) (2008).

142. *Hearings, supra* note 7, at 18 (statement of Mark Novitch, Acting Comm'r, Food and Drug Administration, and Marvin Seife, Director, Division of Generic Drug Monographs, National Center for Drugs and Biologics, Department of Health and Human Services).

143. Johnson, *supra* note 76 (reporting Pfizer sells over 300 generic versions of its own off-patent drugs through its subsidiary, Greenstone, and recently purchased "one of the world's biggest generic drugmakers").

seminars to shower doctors with expensive gifts.<sup>144</sup> Pioneer advertising in medical journals and direct mail further encourages doctors to prescribe name-brand drugs.<sup>145</sup> Pioneers also conduct extensive, mass marketing campaigns directly to consumers that feed on a highly vulnerable aspect of human nature to seek wellness and a longer or happier life.<sup>146</sup>

In a failure-to-warn case against Pfizer, Pioneer of psychiatric drug Zoloft, the U.S. District Court for Minnesota observed that modern drug marketing required courts to impose “enhanced consumer protection” on behalf of the public.<sup>147</sup> The court held Pfizer strictly liable for failing to warn about Zoloft’s risk of suicide, in part, because of the Pioneer’s heavy-handed marketing tactics, “personifying [the drug] as a happy, bouncing-oval cartoon character.”<sup>148</sup>

In *Foster v. American Home Products*, the Fourth Circuit Court of Appeals opined that generic companies benefit from Pioneer advertising.<sup>149</sup> This might be true if the advertising does not mislead consumers. The California First District Court of Appeal refused to follow *Foster*, observing in *Conte v. Wyeth* that generics do not benefit when Pioneers misrepresent drug risks to consumers.<sup>150</sup> The

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144. See Press Release, U.S. Dep’t of Justice, Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), [http://www.justice.gov/opa/pr/2007/September/07\\_civ\\_782.html](http://www.justice.gov/opa/pr/2007/September/07_civ_782.html) (alleging Pioneer illegally gave doctors “financial inducements” and “lavish entertainment” to encourage them to prescribe Abilify).

145. IMS HEALTH, PROMOTION, *supra* note 15 (stating Pioneers spent over \$11.2 billion in the U.S. during 2008 on drug promotion to consumers and doctors).

146. See *id.*

147. *Witzak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005).

148. *Id.*

[P]rescription drugs were once marketed primarily to trained health care providers—sophisticated and discerning intermediaries. Today, on the other hand, pill-rolling apothecaries and the mortar and pestle have disappeared. They have been replaced by drug manufacturers who urge the use of their drugs in mass-market print and television advertisements targeted directly at the public.

*Id.*

149. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (asserting generic manufacturers ride the coattails of Pioneer advertising).

150. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 316–17 (Cal. Ct. App. 2008) (finding Reglan’s Pioneer liable for negligent misrepresentation to generic Reglan consumer because plaintiff’s doctor relied upon Pioneer’s warning).

2009]

THE EXTINCT DISTINCTION OF PRIVILEGE

*Conte* court also noted joint tortfeasor liability still applies when two defendants cause human injury.<sup>151</sup>

In *Miles Laboratories, Inc. v. Superior Court*, the Pioneer and all generic manufacturers of the drug DES were found jointly liable for false promotion even though only a few manufacturers misrepresented the drug's appropriateness for preventing miscarriage.<sup>152</sup> The California Fourth District Court of Appeal found that dedicated sales efforts by several DES manufacturers supported negligence against all the DES manufacturers.<sup>153</sup> The court applied market share theory, where all manufacturers that have made a particular drug share in paying damages, regardless of fault.<sup>154</sup> Market share theory unfairly burdens drug manufacturers who do not violate the Act when promoting a drug.<sup>155</sup> The better approach is one that preserves consumer safety but only applies to the manufacturer best suited to keeping drug warnings safe: Pioneer component part manufacturer liability.

3. *Pioneers Receive Direct Profit from Patent Extensions, Agreements With Generic Companies, and the Consumer Right to Demand Name-Brand Drugs After Generics Are On the Market*

Several realities prove Pioneers realize direct profit from entering their warning labels to the stream of commerce. First, by receiving patent extensions Pioneers directly profit, by potentially billions of dollars, from the Act.<sup>156</sup> Second, the participatory connection test requires direct profit from the manufacturer's conduct within the stream of commerce, not a direct sale to a consumer.<sup>157</sup> Third, Pioneers still profit from name-brand sales after generics begin

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151. *Id.*

152. *Miles Labs., Inc. v. Superior Court*, 184 Cal. Rptr. 98, 103 (Cal. Ct. App. 1982) (concerning illegal promotion of DES (diethylstilbestrol) for preventing miscarriage).

153. *Id.* (DES allegedly caused reproductive organ cancer in daughters of women who took the drug while pregnant).

154. *Id.*

155. *Id.* at 105 (Kaufman, J., concurring and dissenting).

156. Hatch-Waxman Amendments, *supra* note 4 (codifying patent extensions at 35 U.S.C. §§ 154–156).

157. *See Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 422 (Cal. Ct. App. 2009).

using Pioneer warning labels, as proven by the language of generic drug substitution statutes.<sup>158</sup>

a. The Consequence of Patent Extensions Is Direct Profit

Patent extensions under the Act can arise permissibly, or effectively by stalling generic drug competition on the market.<sup>159</sup> In 2002, the Federal Trade Commission (“FTC”) investigated claims Pioneers were filing meritless patent infringement suits against certain approved generic applicants.<sup>160</sup> The FTC found evidence of abusive patent litigation because generic manufacturers prevailed in approximately 73% of the patent infringement lawsuits studied.<sup>161</sup>

Each Pioneer patent extension may generate billions of dollars, profit the Pioneers would not receive but for their conduct within the generic drug stream of commerce.<sup>162</sup> If a Pioneer uses its patent extension—whether received permissibly under the Act or through an abusive patent suit—only to realize capital gain and not to appropriately strengthen a drug warning, the Pioneer has directly profited from its involvement with the generic drug distribution chain.<sup>163</sup>

b. When a Pioneer Sells Its Drug Rights to Another Manufacturer

Before an Alleged Injury Occurs, the Pioneer Has Realized Direct Profit from Its Participation in the Chain of Distribution

Courts often focus on the sale between consumer and pharmacy, but the direct profit requirement is without regard to who enriches the

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158. See, e.g., CAL. BUS. & PROF. CODE § 4073 (West 2003) (indicating generic substitution is permissible if the generic costs less than the name-brand, and if the prescribing doctor has not indicated only the name-brand be used to fill the prescription by writing “Do Not Substitute” or similar on the prescription).

159. 35 U.S.C. §§ 154–156 (2006) (containing the Act’s Pioneer patent extensions); Mahn, *supra* note 59, at 1 (claiming Pioneers have found ways to use the Hatch-Waxman Amendments to their direct financial advantage).

160. FED. TRADE COMM’N, *supra* note 51, at ii, 27–29 (reporting abusive patent litigation had delayed entry of “Paragraph IV” generic drugs on the market). Paragraph IV refers to a section of the Act that permits certain generic applicants to market their generic before the Pioneer’s patent expires. *Id.* at ii.

161. *Id.* at 13, 29 tbl.3-2 (stating research indicated Pioneers prefer to sue the first Paragraph IV generic applicant).

162. See IMS HEALTH, TOP 15, *supra* note 24.

163. It is inevitable generics will eventually come on the market despite Pioneer patent games because after the first generic manufacturer’s six-month exclusivity period expires, any company may apply to make a generic of that drug. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

2009]

THE EXTINCT DISTINCTION OF PRIVITY

Pioneer.<sup>164</sup> A defendant directly profits when it receives financial gain or other personal benefit from the overall enterprise that created a harmful good.<sup>165</sup> If a Pioneer sells its drug rights to another manufacturer before an injury occurs and the warning was inadequate at that point in time, the Pioneer has directly profited from distributing an inadequate warning to the stream of commerce. When statutes use terms like direct sale, courts should first determine whether the statute is testing for direct profit or whether the statute is impermissibly attempting to resurrect privity for tort claims.<sup>166</sup>

In *Swicegood v. Pliva*, plaintiff alleged she developed permanent neurological damage after taking generic Reglan.<sup>167</sup> The applicable products liability statute required a sale, but the sale could have occurred directly or through “any other person,” regardless of privity.<sup>168</sup> The statute also required that the warning was defective when “sold by the manufacturer.”<sup>169</sup> The District Court for the Northern District of Georgia found that there was no sale by the Pioneer.<sup>170</sup> In dicta, however, the court stated that the Pioneer sold its rights in Reglan to another manufacturer in 2001, before plaintiff’s alleged injury.<sup>171</sup>

In a separate Massachusetts suit by another generic Reglan consumer, a different plaintiff presented credible evidence that in the 1980s and 1990s reports indicated Reglan caused neurological damage “one hundred times” more frequently than the drug label warned.<sup>172</sup> Since the *Swicegood* plaintiff’s injury arose in 2005, and

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164. *Kasel v. Remington Arms Co.*, 101 Cal. Rptr. 314, 321–22 (Cal. Ct. App. 1972) (ruling defendant need not actually manufacture the harmful product nor have “an agency relationship” with other stream of commerce manufacturers for strict liability to apply).

165. *Id.* at 323 (“It is the defendant’s participatory connection, for his personal profit or other benefit, with the injury-producing product and with the enterprise that created consumer demand for and reliance upon the product . . . which calls for imposition of strict liability.”).

166. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1056 (N.Y. 1916) (removing the privity requirement from tort claims made by injured consumers).

167. *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1354 (N.D. Ga. 2008).

168. *Id.* (citing to undated edition of GA. CODE ANN. § 51-1-11(b)(1)).

169. *Id.* at 1354-55.

170. *Id.* at 1355.

171. *Id.* 1354.

172. *Kelly v. Wyeth*, No. 20033314F, 2007 WL 1302589, at \*2 n.7 (Mass. Dist. Ct. Apr. 12, 2007) (regarding two scientific experts who testified Reglan caused neurological problems much more often than 1 out of 500, as warned on the drug’s label).

credible evidence of a serious risk existed as early as the 1980s, the Reglan warning label was defective when sold by the Pioneer to another drug manufacturer in 2001.

The 2001 sale in *Swicegood* should have satisfied a direct profit requirement or Georgia's products liability statute, neither of which require privity, yet Ms. Swicegood did not prevail under any theories of liability.<sup>173</sup> Ms. Swicegood's permanent neurological injury and resulting financial loss fall solely upon her, her family, a government disability program, and her private insurance, if any.

Courts should not permit Pioneers to sell their liability away for inadequate drug warnings. Even a manufacturer that *gives away* a defective good or service can be liable in negligence.<sup>174</sup> But a manufacturer that sells a defective good—to anyone—should be strictly liable because it is profiting from submitting a dangerous product to the realm of public commerce.

c. Generic Drug Substitution Statutes Prove Pioneers Continue to Receive Direct Profit After Generic Sales Begin

Every state has a generic substitution statute that permits pharmacies to dispense cheaper generics, most of which also give doctors the ability to demand name-brand drugs for their patients.<sup>175</sup> These statutes prove Pioneers receive direct profit from submitting their warning labels to the stream of commerce because the statutes can only apply after generics enter the market.

All three parts of California's participatory connection test are met, demonstrating Pioneers owe a duty to consumers of generic drugs. Pioneers are able to control or substantially influence generic manufacturers to make drug warnings safer, are integral to the generic

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173. Some practitioners allege Georgia is notoriously "favorable to the pharmaceutical industry." Ciaran McEvoy, *Pharma Hails Venue Change in Patent Case*, L.A. DAILY J., at A2 (Apr. 16, 2009).

174. *Fisher v. Morrison Homes, Inc.*, 167 Cal. Rptr. 133, 137 (Cal. Ct. App. 1980) (finding home developer that gave an allegedly dangerous pathway to the city was subject to negligence for its defective gift). The court was persuaded that "where defendant's motivation for dedicating property to public use was not altogether charitable, but rather was prompted by the desire to enlarge the profitability of its enterprise," negligence would apply. *Id.*

175. *Bristol-Meyers Squibb Co. v. Shalala*, 91 F.3d 1493, 1497 (D.C. Cir. 1996); e.g., CAL. BUS. & PROF. CODE § 4073 (West 2003).

2009]

THE EXTINGUISHED DISTINCTION OF PRIVILEGE

drug industry, and receive ongoing direct profit from supplying their warning labels to the generic drug chain of distribution.<sup>176</sup>

But additional realities, above and beyond the participatory connection test, also demonstrate that Pioneers are component part manufacturers of generic drugs. First, Pioneers are patenting portions of their drug warnings, showing they believe they own, and want to own, their drug labels.<sup>177</sup> Second, policy supports a duty upon Pioneers regarding the warning labels on generic drugs.

#### *4. Pioneers Are Patenting Portions of Their Drug Labels, Demonstrating Their Belief They Own the Warnings*

There are several parts to a drug warning, such as instructions to “take two hours before bedtime.”<sup>178</sup> Attorneys allege Pioneers are patenting these and other portions of their drug warning labels.<sup>179</sup> The Act allows for these patents.<sup>180</sup> Since a generic cannot infringe upon a Pioneer’s patent, a generic manufacturer may be forced to omit certain indications on its drug’s warning.<sup>181</sup>

Even though the Act allows this Pioneer conduct, the focus here is not whether the Act is valid or practical; the focus is who owns the drug label. A Pioneer’s desire and ability to patent warning indications on its drug label supports a finding that the label is the Pioneer’s own product.

Further, if omission of a patented indication on a generic warning label causes the drug to be more dangerous than it would be if the Pioneer had not patented the text, the Pioneer should be liable for any harm that arises. Under this analysis, it is not what the Pioneer allowed its component part to contain, but what the Pioneer would not allow it to contain, that caused the risk of harm.

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176. *See generally* Taylor v. Elliott Turbomachinery Co., 90 Cal. Rptr. 3d 414, 422 (Cal. Ct. App. 2009) (containing participatory connection test).

177. Mahn, *supra* note 59, at 8.

178. *Id.*; 21 C.F.R. § 201.57 (2008) (a drug label must include dosage, indications on how to use the drug, contraindications, over-dose information, possible side effects, warnings in general, and warnings for children, pregnant women and geriatrics, among other sections).

179. Mahn, *supra* note 59, at 8.

180. 21 C.F.R. § 314.430(a)–(g)(1) (2008); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17953 (Apr. 28, 1992).

181. 21 U.S.C. § 355(j)(2)(A) (2006).

5. *Policy Supports a Duty upon Pioneers for Generic Drug Labels Because Pioneers Can Effectively Reduce Harm and Spread the Risk of Loss in New Drug Pricing*

Ultimately, the court decides whether a duty exists as a matter of law.<sup>182</sup> Policy requires courts to place the duty on the manufacturer best positioned to effectively reduce the hazard of defective goods ever reaching consumers.<sup>183</sup> The duty to warn should lie with Pioneers because, as discussed previously, it is easier and faster for Pioneers to change an approved drug warning.

Policy also requires courts to assign responsibility to the manufacturer in the distribution chain best able to spread the risk of loss.<sup>184</sup> Pioneers can better absorb the financial risk from harmful drugs, and are already spreading that risk of loss among the public through name-brand drug pricing.<sup>185</sup> The top-selling drug in the United States, Lipitor, earns its Pioneer around \$8 billion a year.<sup>186</sup> In 2007, Pioneers were sufficiently well funded to spend \$11.5 billion on drug advertising alone.<sup>187</sup> In 2009, as other major businesses crumbled under the weight of a troubled financial market, Pioneer Pfizer purchased Pioneer Wyeth for \$68 billion.<sup>188</sup>

Name-brand drugs potentially bring innovative relief, but the public pays high prices for these brand products. Generic drugs ease that expense only after Pioneers have dominated the market for many years. Holding that Pioneers have a duty regarding the condition of

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182. *E.g.*, *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 731 (D. Minn. 2005).

183. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440-41 (Cal. 1944) (Traynor, J., concurring).

184. *Id.* at 441.

185. The largest criminal fine ever levied against a corporation in the history of the United States occurred in 2009. Press Release, U.S. Dep't of Justice, *Eli Lilly & Co. Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa* (Jan. 15, 2009), <http://www.usdoj.gov/opa/pr/2009/January/09-civ-038.html>. Accused of violating the Act's label laws, Eli Lilly agreed to pay \$1.6 billion to federal and state governments to settle allegations it falsely promoted Zyprexa. *Id.* This case did not involve warning defect but did involve promotion of Zyprexa for a use not approved by the Agency or the drug's approved label, demonstrating that Pioneers may have little regard for the Agency or the Act's labeling rules. *Id.*

186. IMS HEALTH, TOP 15, *supra* note 24.

187. IMS HEALTH, PROMOTION, *supra* note 15.

188. Andrew R. Sorkin, et al., *Pfizer Agrees to Pay \$68 Billion for Rival Drug Maker Wyeth*, N.Y. TIMES, Jan. 26, 2009, at A1 (noting Pfizer and Wyeth are large drug Pioneers and that half of the \$68 billion was borrowed from banks receiving taxpayer money under the Troubled Asset Relief Program).

2009]

THE EXTINCT DISTINCTION OF PRIVACY

their warning labels after generics enter the market is the fair thing to do, in accord with long-standing, public protection principles.

*B. True Strict Liability Should Apply to Prescription Drug Labels, With Knowledge of Risk Imputed to the Pioneer*

Under current law, a drug label is defective if it inadequately warns about a risk of harm that was knowable under prevailing scientific practices when sold or distributed.<sup>189</sup> But the focus of defect for strict liability is supposed to be the product itself and not manufacturer conduct.<sup>190</sup> Since manufacturer conduct is irrelevant, whether the manufacturer knew or could have known of a product's risk of harm should not be part of a true strict liability analysis of defect.<sup>191</sup> If the risk must be knowable, the jurisdiction is applying a negligence standard by looking for manufacturer fault. Strict liability is not about fault; it is about the realities of trade secret law protecting the inherent qualities of esoteric goods from public disclosure, and requiring that the product itself absorb the risk of financial loss.<sup>192</sup>

*1. The Imputed Knowledge Test Is Appropriate Because Consumers Should Not Be Held to a Higher Standard Than Innocent Component Part Manufacturers*

In true strict liability, a warning defect is analyzed by imputing knowledge of the particular risk of harm to the manufacturer.<sup>193</sup> The trier of fact asks whether the product's continued sale was reasonable, assuming the manufacturer knew of the risk at the time of sale.<sup>194</sup> When courts claim to observe a strict liability standard yet inject knowability into the defect test, it imposes a cruel shell game upon

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189. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 310 (Cal. Ct. App. 2008) (noting differences between negligence and strict liability).

190. *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 546 (N.J. 1982).

191. *Id.* at 545 (deciding manufacturer's ability to know asbestos' danger was irrelevant for strict liability because knowledge would be imputed "as a matter of law"). The New Jersey Supreme Court dispensed with *Beshada's* imputed knowledge test in a later prescription drug case by applying comment j of the Restatement (Second) of Torts; but since comment j only concerns allergic drug reactions, it was inapplicable, its use was erroneous, and *Beshada* should be viewed as still valid on those grounds. See *Feldman v. Lederle Labs.*, 479 A.2d 374, 386 (N.J. 1984).

192. *Beshada*, 447 A.2d at 546–47.

193. *Id.* at 545.

194. *Id.* at 544–45.

plaintiffs, supplanting a negligence standard into a doctrine that is supposed to be responsibility without fault.<sup>195</sup>

Under the same principle that innocent component part manufacturers are not required to hire experts to determine the risks of other manufacturers' products, injured consumers should not be required to hire experts to determine the safety of all drugs before consuming them.<sup>196</sup> Arguably, Congress codified the innocent component part manufacturer rule into the Act by stating generic manufacturers need not repeat Pioneer safety tests so long as generic drugs use the name-brand warning.<sup>197</sup> A knowability standard is unconscionable because it imposes a higher burden on injured consumers than innocent component part manufacturers.

## 2. *Defect Is About Positive Conduct and Resulting Consequences, Not Knowability of Risk*

Failure-to-warn, as a concept, admittedly fails because manufacturer failure should not be at issue in a no-fault doctrine. If manufacturer conduct must be included in failure-to-warn cases, historically only two types of profit-related conduct were relevant: submitting a product to the stream of commerce, and knowing the product would not be inspected for harmful defects.<sup>198</sup> Both are positive actions, or feasancess, rather than omissions to act.

The original strict liability case of *Greenman v. Yuba* did not require plaintiff to prove the defendant knew its lathe screws were inadequate.<sup>199</sup> The only knowledge necessary was that consumers and possibly other stream of commerce manufacturers would use the lathe

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195. *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 423 n.6 (Cal. Ct. App. 2009) (purporting to impose strict liability for asbestos and drugs, but requiring plaintiff to prove the risk of harm was knowable). A shell game is a confidence ploy or "swindle" where something of "little or no value" is substituted for an item of great value. MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 1079 (10th ed. 1999).

196. See *Taylor*, 90 Cal. Rptr. 3d at 429 (limiting an innocent component part manufacturer's duty because manufacturers are not required to inspect other manufacturers' goods).

197. *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2009 U.S. Dist. LEXIS 13274, at \*11–12 (W.D. Ky. Feb. 20, 2009) (finding it significant that the Act states a Pioneer "must" tell the Agency a warning should be strengthened, as opposed to generic companies, which "should" ask the Agency to strengthen their drug's warning label).

198. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900–01 (Cal. 1963).

199. *Id.* (containing no discussion of the lathe manufacturer's reasonableness or its scienter that the bolts were defective).

2009]

THE EXTINCT DISTINCTION OF PRIVACY

without inspecting it for safety problems.<sup>200</sup> Knowability of risk is irrelevant because the doctrine is not concerned with what theoretically might be knowable—only that the manufacturer knew no further inspection would occur.

Pioneers know generic manufacturers will not repeat their human safety tests.<sup>201</sup> Requiring plaintiffs to also prove that Pioneers, who can hide their safety studies as trade secrets, must have scientifically been able to know the risks of injury (the “knowability burden”) forces consumers to prove what they cannot know. The knowability burden discourages Pioneers from increasing the amount of safety research they perform, and from openly disclosing the results of that research.<sup>202</sup> Removing the knowability burden will assist in the removal of unsafe and inefficient drugs from the market long before generic companies decide to step in and reproduce a particular medicine.

Finally, the knowability burden impermissibly allows manufacturers to define the scope of their own responsibilities.<sup>203</sup> The scope of responsibility is self-defined because Pioneers will make ever-decreasing investments in product safety to avoid having a risk be knowable.<sup>204</sup>

The other historical feausance necessary for strict liability is the manufacturer submitting its product to the stream of commerce.<sup>205</sup> Pioneers do more than submit their drug warning labels to the stream of commerce—they heavily market drug benefits in print, radio, and television, invoking public confidence in their companies’ skills, and the safety of their products.

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200. *Id.*

201. Hatch-Waxman Amendments, *supra* note 4.

202. *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 548 (N.J. 1982) (“Fairness suggests that manufacturers not be excused from liability because their prior inadequate investment in safety rendered the hazards of their product unknowable.”).

203. *See, e.g., Simonetta v. Viad Corp.*, 197 P.3d 127, 131 (Wash. 2008) (noting that whether a duty exists is a question of law for the court to decide).

204. *Beshada*, 447 A.2d at 548 (observing that knowability of a risk depends on “how much industry invests in safety research”).

205. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900–01 (Cal. 1963).

3. *Advertising Is Part of a Drug Warning and Must Be Part of a Defect Analysis, to Ensure Utility of a Drug Is Not Over-Promoted, Nor Risks Unreasonably Downplayed*

A drug warning includes package inserts given to consumers, information provided to doctors, and advertisements, whether or not attached to the drug.<sup>206</sup> Even an adequate warning can become defective; counterrepresentations such as pictures or marketing statements that downplay a product's risks can negate an adequate warning.<sup>207</sup> Slick marketing ploys may be part of why a doctor prescribed or a consumer requested a drug in the first place. A Pioneer may have disproportionately marketed a drug's benefits and downplayed its risks. Triers of fact should therefore inquire whether adequate Pioneer warnings became inadequate by advertising.<sup>208</sup> After all, a generic company cannot control Pioneer advertising.

When prescription drug manufacturers advertise directly to consumers, the learned intermediary doctrine vanishes and a duty to directly warn consumers of newly discovered risks is created.<sup>209</sup> Once doctors no longer stand between drug companies and consumers to interpret the risks versus the benefits, a defect standard lower than knowability is warranted.<sup>210</sup>

4. *The Imputed Knowledge Test Prevents Manufacturers Being Insurers of Their Products by Including Reasonableness and a Risk-Utility Balancing Test*

Under the imputed knowledge rule, the trier of fact assumes the manufacturer knew about the alleged risk of injury; then asks whether the product's continued sale was reasonable in light of the product's

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206. 21 U.S.C. § 321(k)-(m) (2006); *Kordel v. United States*, 335 U.S. 345, 346–50 (1948) (finding the Act applies to drug warning labels and drug marketing literature even if not physically attached to drug packaging).

207. *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971) (holding that even if the drug warning was adequate, the warning was “in effect cancelled out and rendered meaningless” by sales efforts to doctors minimizing the warning).

208. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1273 (5th Cir. 1974) (“[T]he circumstances of marketing themselves can amount to a defect; . . .”).

209. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1257 (N.J. 1999) (noting that advertising was key to the “fall of the citadel of privity” in New Jersey (quoting *Prosser*, *supra* note 5)).

210. *Witzak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (finding Zolof Pioneer's mass marketing of psychiatric drug as bouncing cartoon character supported the court's imposition of “enhanced consumer protection” on behalf of decedent drug consumer's heir).

2009]

THE EXTINCT DISTINCTION OF PRIVACY

risks and benefits when the plaintiff's injury occurred.<sup>211</sup> The imputed knowledge test slightly misses the mark by drawing a line beyond which liability will not extend, drawn in terms of defect rather than proximate cause, where such lines have historically been drawn.<sup>212</sup> The test is fair, however, because it limits liability.

The imputed knowledge test does not turn the manufacturer into an insurer of its wares because it is a balancing test with a standard of reasonability.<sup>213</sup> For example, even if a drug warning did not highlight a risk with the best method, such as a black box warning, a jury could nevertheless find that the warning did not unreasonably overstate the benefits nor downplay the risks, and that the label was therefore not defective. A jury could similarly find that the generic had been selling its drug copy long enough to request and receive a stronger warning on its own.

### *C. Drug Warning Labels Are Products, Subject to Strict Liability*

Failure-to-warn necessarily analyzes a product warning separately from the product itself.<sup>214</sup> Even though a drug label consists of text and potentially has free speech protection, the warning label is analogous to airplane navigation charts and should be deemed a product, subject to strict liability.<sup>215</sup>

#### *1. State and Federal Law Defines Warnings, Instructions, and Labels as Separate Products*

The United States Supreme Court and the Agency both confirm that a prescription drug's warning determines whether or not the drug

211. *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 544 (N.J. 1982).

212. *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 104 (N.Y. 1928) (Andrews, J., dissenting) (suggesting proximate cause is found where "a direct connection between [cause and effect], without too many intervening causes," exists).

213. *Beshada*, 447 A.2d at 544.

214. *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991) (claiming failure-to-warn cases require analysis of manufacturer conduct). The *Anderson* court mistakenly found that negligent misrepresentation was the foundation of strict liability, but innocent misrepresentation is the more likely progenitor. *Id.*; see *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897 (Cal. 1963) (containing no discussion of the manufacturer's reasonableness, merely that the product's presence on the market was a representation it could safely do the job it was created for); *Baxter v. Ford Motor Co.*, 35 P.2d 1090, 1092 (Wash. 1934) (holding breach of warranty action for "shatterproof" car windshield that shattered and injured purchaser properly proceeded as tort claim for innocent misrepresentation).

215. *E.g.*, *Brocklesby v. United States*, 767 F.2d 1288, 1294–95 (9th Cir. 1985) (ruling airport approach charts were products because they were mass marketed).

is safe.<sup>216</sup> Adequate warnings prevent doctors from prescribing drugs to patients if the drugs' use is inadvisable due to pregnancy, allergy, other illness, or a patient's age. Warnings also prevent a person from opening a drug bottle and transferring medicine into their stomach, for example with alcohol or without food. Since a prescription drug must contact the body before injury can arise, the unreasonably dangerous item in a prescription drug failure-to-warn case is the warning.

A manufacturer that controls the ability to warn can be independently liable even if another manufacturer supplies the chemical product that actually injures people.<sup>217</sup> In *Blackwell v. Phelps Dodge*, a sulfuric acid supplier loaded its product into a leased railroad tank car.<sup>218</sup> Pressure built up inside the tank car from the acid and when workers opened the car, the acid rapidly escaped, injuring the workers.<sup>219</sup> California's Second District Court of Appeal observed that the acid was not unreasonably dangerous by itself: The unreasonably dangerous product was the tank car, by failing to adequately warn about how to safely release the chemical inside.<sup>220</sup> Because a contractual provision prevented anyone other than the tank car owner from modifying the car's exterior, the acid seller was not liable to the injured workers; although the tank car owner would have been.<sup>221</sup>

The *Blackwell* circumstances are analogous to Pioneer and generic drug manufacturers. First, federal law prohibits a generic company modifying its label without Agency permission unless the Pioneer changes the warning itself, similar to the chemical supplier's

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216. *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at \*26 (U.S. Mar. 4, 2009) (Alito, J., dissenting) (noting the standard for whether a prescription drug is safe depends upon its warning label); New Drug and Antibiotic Regulations, 50 Fed. Reg. 7470 ¶67 (Feb. 22, 1985) ("Drug labeling serves as the standard under which FDA determines whether a product is safe and effective."); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3934 (Jan. 24, 2006) ("The centerpiece of risk management for prescription drugs generally is the labeling . . .").

217. *Blackwell v. Phelps Dodge Corp.*, 203 Cal. Rptr. 706, 710–12 (Cal. Ct. App. 1984) (involving railroad tank car loaded with potentially dangerous acid).

218. *Id.* at 709.

219. *Id.*

220. *Id.* at 710 (finding "it was not the [acid product] supplied by defendant," but the tank car that was defective, by lacking adequate warnings and instructions).

221. *Id.* at 711–12 (ruling the lack of warning on how to safely disburse the chemical "made the car a defective product").

2009]

THE EXTINCT DISTINCTION OF PRIVACY

limits in *Blackwell*. Second, prescription drugs can be dangerous but only if people are exposed to drugs when they should not be. Thus, a drug by itself may not be unreasonably dangerous, just like sulfuric acid is not.<sup>222</sup> The unreasonably dangerous product is the warning because an adequate warning prevents drug contact with the body.

A modern analogy might be an Agency-approved combination product, such as a syringe prefilled with a prescription drug that requires refrigeration. If the syringe fails to warn that the plastic becomes warm in a doctor's hand after an inordinately short time, or inverting the syringe affects how much of the drug enters the body, strict liability should apply to the syringe manufacturer and not the drug maker.

2. *Pioneer Drug Warnings Are Used by Trained Professionals to Guide Other People to Safety, and the Potential Harm Outweighs the Warning's Commercial Intellect Protection*

Written text created for a profit motive is commercial intellect.<sup>223</sup> Commercial intellect generally has free speech protection.<sup>224</sup> One exception exists, however: Navigation charts sold to commercial airplane pilots are products, subject to strict liability, and do not have commercial intellect protection.<sup>225</sup> The doctor-patient duty is sufficiently analogous to the pilot-passenger duty to warrant a second commercial intellect exception for drug warning labels.

The decision to define a good as a product is fundamentally a policy issue, based upon a good's use.<sup>226</sup> Drug warnings are used in a

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222. *See id.* at 710.

223. BLACK'S LAW DICTIONARY 271 (6th ed. 1990).

224. U.S. CONST. amend. I; *Watters v. TSR, Inc.*, 904 F.2d 378, 381 (6th Cir. 1990) (finding writers and publishers of imaginary Dungeons & Dragons parlor game were not liable for man committing suicide after his character was killed in-game because the game was creative commercial intellect consisting of ideas and expressions).

225. *Brocklesby v. United States*, 767 F.2d 1288, 1294–95 (9th Cir. 1985) (ruling airport approach charts were products because they were mass marketed); *accord Salomey v. Jeppesen & Co.*, 707 F.2d 671, 676–77 (2d Cir. 1983) (applying Colorado law) (holding that airplane navigational charts were products, and not a service); *Fluor Corp. v. Jeppesen & Co.*, 216 Cal. Rptr. 68, 71 (Cal. Ct. App. 1985) (deciding navigation charts sold to pilots were not a service but a product).

226. *Lowrie v. City of Evanston*, 365 N.E.2d 923, 925, 928 (Ill. App. Ct. 1977) (ruling that parking garage lacking guard rails to keep people from falling out was not a product); *see also Kaneko v. Hilo Coast Processing*, 654 P.2d 343, 348 (Haw. 1982) (stating a product must be moveable, have intrinsic value, and can be either an assembled good or its component parts).

similar manner as airplane navigation charts because both items instruct trained professionals in safely guiding people entrusted to the professionals' care.<sup>227</sup> Just as faulty instruction charts interfere with the legal duties of trained pilots, inadequate drug warnings interfere with doctors' duties of care to their patients. Prescription drugs themselves are powerful and potentially dangerous, like airplanes. Drugs have an even further reach than aircraft, since millions take generic drugs every day.<sup>228</sup>

Intruding into free speech laws that protect commercial intellect should not occur lightly.<sup>229</sup> Prescription drug warnings, however, should be deemed products for the same policy reasons the charts lost commercial intellect protection: to place the burden of injuries onto the manufacturer who created them, mass marketed them, and controlled their text.<sup>230</sup>

Drug labels remain the Pioneer's product despite the Agency requiring changes to the text because it is foreseeable that government agencies make mistakes, and joint tortfeasor liability would apply in any event.<sup>231</sup> An aeronautical chart manufacturer argued against strict liability for its charts because it received all its airport approach information from the Federal Aviation Administration ("FAA").<sup>232</sup> The Ninth Circuit Court of Appeals, applying "the literal requirements" of strict liability, found it irrelevant whether or not the FAA's data was wrong.<sup>233</sup> Refusing to permit fault into its analysis, the Ninth Circuit held that the fundamental policies underlying strict liability supported responsibility lying with the chart manufacturer.<sup>234</sup>

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227. See *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1036 (9th Cir. 1991) ("The best analogy to an aeronautical chart is a compass. Both may be used to guide an individual who is engaged in an activity requiring certain knowledge . . .").

228. IMS HEALTH, TOP PRODUCTS, *supra* note 77 (showing generics fill approximately 500 million prescriptions each year).

229. *Winter*, 938 F.2d at 1037 (refusing to apply strict liability to encyclopedia publisher because publisher, who did not create the book, had no duty to "independently investigate the accuracy of the text").

230. See cases cited *supra* note 225.

231. See *Brocklesby v. United States*, 767 F.2d 1288, 1295 (9th Cir. 1985).

232. *Id.*

233. *Id.* at 1296 (applying strict liability to aeronautical charts even though the FAA gave the chart manufacturer all the data used to create the charts).

234. *Id.* (citing *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900 (Cal. 1963); *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436, 440-44 (Cal. 1944) (Traynor, J., concurring); *REST. 2D - TORTS*, 402A cmt. c (1965); and *PROSSER AND KEETON ON THE LAW OF TORTS* § 100, at 705 (W. Keeton 5th ed. 1984)).

2009]

THE EXTINCT DISTINCTION OF PRIVACY

The Agency has even less input to drug warnings than the FAA has to aeronautical charts. Pioneers supply the Agency with all the safety and effectiveness data on new drugs.<sup>235</sup> The Agency conducts no independent investigation of its own.<sup>236</sup> The original policy purposes of strict liability, used to find aeronautical charts are products subject to strict liability, should also apply to drug labels.

Finally, the same free speech provision that protects commercial text also protects a consumer's right to information.<sup>237</sup> Free market choices are not possible if a manufacturer does not provide the public with access to complete information.<sup>238</sup> The choice between protecting free speech for commercial intellect versus protecting the right of the purchasing public to make informed choices weighs in favor of informed choice.

*D. An Inadequate Drug Warning Causes and Creates the Risk of Serious Side Effects Because the Drug Would Not Have Been Prescribed or Consumed if the Warning Fulfilled Its Purpose*

For the final element of strict liability, a component part must cause or create the risk of harm in the assembled product.<sup>239</sup> No specific test exists, but factors relevant to assessing causation include the manufacturer's expertise and the component part's characteristics, function, and foreseeable use.<sup>240</sup>

*1. Pioneers Are Experts in Drug Research and Their Own Name-Brand Drugs' Risks*

Pioneers must inspect, safety test, and monitor the side effects of their drugs.<sup>241</sup> Pioneers have a continuous duty to update a drug

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235. 21 U.S.C. § 355(b) (2006) (requiring "full reports of investigations" regarding drug safety and effectiveness); *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 283 (E.D. Pa. 2006) (Ambro, J., dissenting) (stating the Agency "relies on" full safety and effectiveness information provided to it by the Pioneer), *vacated on other grounds*, No. 08-437, 2009 U.S. LEXIS 1818, at \*1 (U.S. Mar. 9, 2009).

236. *Colacicco*, 521 F.3d at 283.

237. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 756 (1976).

238. *Id.* at 771 n.24 (noting government can regulate informational advertising since its message is durable and verifiable).

239. *Taylor v. Elliott Turbomachinery Co.*, 90 Cal. Rptr. 3d 414, 426 (Cal. Ct. App. 2009).

240. *Id.* at 425–26.

241. 21 U.S.C. § 355(b) (2006).

warning without waiting for definite proof of a causal connection.<sup>242</sup> Since the name-brand warning can only be included with proven bioequivalents of the Pioneer's drug, there is no reason to claim a Pioneer lacks expertise in the risks of a generic copy of its own drug.

### *2. The Characteristics and Function of a Drug Warning Label Are Gatekeeping and Informed Choice*

A drug-warning label's characteristics are to inform of risks, promote for certain uses, and advise against other uses, leaving the final decision up to doctors and their patients. The warning's essential function is to provide informed choice to doctors and patients. The label serves a gatekeeping purpose because the drug cannot be exposed to the body until the decisions to prescribe and consume occur.

A drug warning must provide all information necessary for doctors and their patients to decide whether to prescribe and ingest a drug.<sup>243</sup> "But for" the label failing to provide adequate information, the drug would never have entered the body where the harm not warned of could proceed unchecked.<sup>244</sup> If an inadequate warning fails its gatekeeping function, the warning creates the uninformed choices necessary before harm to human health could possibly occur.

### *3. Proximate Cause Is Met by the Act, Generic Drug Substitution Statutes, and Pioneer Mass Marketing*

Proximate cause exists if someone uses a component part in a foreseeable manner.<sup>245</sup> If a plaintiff alleges a misrepresentation theory of strict liability, proximate cause is met if a doctor relies upon the Pioneer's warning to prescribe a drug for a patient.<sup>246</sup> The Act makes it foreseeable that generic drugs will use name-brand

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242. *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at \*9 (U.S. Mar. 4, 2009); 21 C.F.R. § 201.57(c)(6)(i) (2008) (applying only to Pioneers per 21 C.F.R. § 201.56(a)–(b) (2008)).

243. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 310 (Cal. Ct. App. 2008).

244. *See id.* at 305 (holding Reglan's Pioneer was the actual cause of harm to plaintiff because plaintiff's doctor relied upon the Pioneer's warning to prescribe the drug).

245. *Id.* at 313 (finding it was foreseeable to Reglan's Pioneer that doctors would rely upon the Pioneer's warning information for purposes of prescribing the drug).

246. *Id.* at 312.

2009]

THE EXTINCT DISTINCTION OF PRIVACY

warnings.<sup>247</sup> Generic substitution statutes make it further foreseeable that pharmacies will occasionally fill prescriptions for name-brand drugs with generics.<sup>248</sup>

In *Foster v. American Home Products*, a Maryland drug substitution statute permitted a pharmacy to dispense generic promethazine syrup for six-week-old Brandy Foster, as substitute for the Phenergan syrup prescribed by Brandy's doctor.<sup>249</sup> Brandy died after taking the drug.<sup>250</sup> In response to the parents' negligence and strict liability claims, the Fourth Circuit U.S. Court of Appeals found that Pioneer Wyeth could not foresee that it would be responsible for the warning labels that accompany generic drugs.<sup>251</sup> The *Foster* court failed to ask why the Act and Maryland's generic drug substitution statute did not make it foreseeable that the Fosters would receive a generic substitute, and that it would carry Phenergan's warning label.

Regarding the parents' misrepresentation claim, the *Foster* court found it unnecessary to consider whether Brandy's doctor relied upon Phenergan's product information.<sup>252</sup> The Fourth Circuit was reviewing the case de novo, however, and could have asked why Brandy's doctor wrote a prescription for "Phenergan Syrup Plain" if the doctor did not rely upon Phenergan's drug information.<sup>253</sup>

In *Foster*, it seems clear that not just the drug, but also the Pioneer's defective warning, caused and created the risk of the infant's death. The coroner declared Brandy died from promethazine, but in order for her to die from promethazine, the drug had to first enter her body.<sup>254</sup> Prior to that, her doctor had to prescribe Phenergan

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247. 21 U.S.C. § 355(j)(2)(A)(v) (2006) (requiring generic drug labels be the same as the Pioneer's).

248. *E.g.*, CAL. BUS. & PROF. CODE § 4073 (West 2003) (containing the state's generic drug substitution statute).

249. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994). Phenergan was first approved in 1955 and slightly different rules apply to its Pioneer and generic manufacturers because the Hatch-Waxman Amendments only concerned post-1962 drugs. *Hearings, supra* note 7, at 1 (statement of Rep. Waxman). Nevertheless, the Pioneer's duty to warn was still continuous, as determined by the Supreme Court in another case against Wyeth involving Phenergan. *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at \*10 (U.S. Mar. 4, 2009).

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

251. *Id.* at 168–71 (failing to note the Act expressly states a Pioneer has a continuing duty to strengthen its drug warning with newly discovered risks).

252. *Id.* at 171.

253. *Id.* at 167.

254. *Id.*

for an infant. Ultimately, the infant's parents had to make the final decision to allow the drug to enter their daughter's body in light of the warnings given to them. Those decisions were unfortunately taken from the Fosters, and their doctor, by a deficient warning whose function was to inform, warn, and prevent risk of harm.

The *Foster* court also held that the generic manufacturer assumed the risk that the Pioneer's safety tests were faulty.<sup>255</sup> If this were true, the Legislature should not have granted Pioneers additional years of exclusivity in return for conducting the expensive safety tests. If generic drugs are to fulfill their purpose of making cheaper drugs available to the masses, the generic must rely upon the Pioneer. Otherwise, generic manufacturers would have to charge as much as Pioneers for their drugs.<sup>256</sup> The Act permits generics to rely, and Pioneers are compensated for that reliance.<sup>257</sup>

The *Foster* court should have ruled that Wyeth's product—the generic drug warning—potentially failed its gatekeeping role, and should have allowed a trier of fact to determine how much Wyeth knew about Phenergan's ability to cause infant mortality.<sup>258</sup> The doctor relied on the Pioneer's warning about Phenergan for infants; the Fosters relied on their doctor; and the inadequate label created the risk of the drug being prescribed for, and contacting, Brandy's stomach.

Pharmacies fill prescriptions from any number of brands when generics are available.<sup>259</sup> Generic substitution is not the cause of harm in failure-to-warn cases. Nor is the drug alone the cause, if at

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255. *Id.* at 169–70 (stating the “name brand manufacturer had no control” over the generic drug, neglecting to observe the Pioneer did have control over the drug's warning, and an ongoing duty with respect to the warning's text).

256. *Hearings, supra* note 7, at 38 (statement of Milton Bass, general counsel, National Association [Generic] Pharmaceutical Manufacturers) (reporting Agency-required safety tests are approximately 95% of a drug's Agency approval costs).

257. 21 U.S.C. § 355(j)(2)(A) (2006); *Hearings, supra* note 7, at 70 (statement of Fred Wegner, pharmaceutical specialist, American Association of Retired Persons) (disagreeing with Hatch-Waxman Amendments because it gave Pioneers a longer profit period, delayed affordable drugs for low-income people, and amounted to taxpayer subsidy of Pioneer innovation).

258. In *Wyeth v. Levine*, the Supreme Court found Pioneer Wyeth ignored decades of evidence that dangerous administrations of Phenergan caused irreversible gangrene. No. 06-1249, 2009 WL 529172, at \*9 (U.S. Mar. 4, 2009). It is possible similar circumstances existed in *Foster* regarding Phenergan in colic syrup for infants. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994).

259. *Miles Labs., Inc. v. Superior Court*, 184 Cal. Rptr. 98, 105 (Cal. Ct. App. 1982).

2009]

THE EXTINCT DISTINCTION OF PRIVITY

all.<sup>260</sup> A drug's potential danger cannot occur without an unreasonably dangerous warning. Therefore, inadequate Pioneer drug warnings are an actual and proximate cause of injury in generic drug failure-to-warn cases.

### CONCLUSION

The Agency and the public depend on Pioneers to create and strengthen drug-warning labels so the labels adequately fulfill their gatekeeping role. Maintaining Pioneers in generic drug failure-to-warn cases provides a legal solution that is not only practical, but serves the Act's purpose.

Imposing a duty on Pioneers as component part manufacturers will help prevent future harm and simplify claims by consumers, who lack the power to protect themselves against latent defects in mass marketed, trade secret products.<sup>261</sup> A consumer does not have to overcome arcane contractual distinctions such as privity to state a cause of action for strict liability.<sup>262</sup> Ruling that the Pioneer did not manufacture the generic drug when a claim involves an allegedly defective warning resurrects that privity concept by binding two products into a whole, and finding no sale occurred between Pioneer and consumer.<sup>263</sup> It also places the burden of loss where it unfairly lies—on the public.<sup>264</sup>

The burden of loss from harmful products should be on the manufacturer that enters a dangerous good to the stream of commerce and can control other manufacturers to make assembled products safer.<sup>265</sup> Courts should strive to place the duty to warn on the manufacturer best able to reduce risk of harm effectively, who can absorb the risk of loss through product pricing.<sup>266</sup>

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260. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 317 n.16 (Cal. Ct. App. 2008) (observing joint liability can apply when multiple tortfeasors cause injury).

261. *See Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963).

262. *Id.* (stating contract principles do not serve the public good, which tort law exists to protect).

263. *See Francioni v. Gibsonia Truck Corp.*, 372 A.2d 736, 739 (Pa. 1977) (“Where the fundamental principles [of strict liability] are applicable, the imposition of artificial distinctions will only frustrate the intended purpose.”).

264. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) (“Those who suffer injury from defective products are unprepared to meet its consequences.”).

265. *Id.* at 440–41 (observing, “the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot”).

266. *Id.* at 440.

Pioneers are not innocent component part manufacturers because they can control generic manufacturers. Pioneers are able to strengthen drug warnings without Agency approval, in turn forcing all generic copies of a name-brand drug to have stronger warnings. Simply by sending a notice of label change to the Agency, Pioneers can pressure generic manufacturers to make assembled drugs safer or to take a drug off the market. This is a minor burden for Pioneers, even if they have already sold their drug rights to an unsuspecting generic manufacturer.

With recent discoveries that Pioneers hid safety results, defective drug warning cases might reveal truths that would remain unknown if only the generic manufacturer remains in the case.<sup>267</sup> Courts should therefore not require plaintiffs to prove a risk was knowable because this further encourages Pioneers to hide safety results.

Instead of looking for privity in failure-to-warn cases, courts should ask which defective part in the assembled product caused or created the risk of harm.<sup>268</sup> For the millions of people who take generic drugs every day, whether by choice or because their insurance policy requires a cheaper substitute, it should not matter who manufactured the drug if the cause of action is what is on the drug label. Tort law removed the privity barrier long ago through component part liability and stream of commerce doctrine. As generic drugs increasingly fill name-brand prescriptions, now is not the time to resurrect privity and its extinct contractual distinctions. If a manufacturer with the power to pressure others to make a product safer fails in its duty to exert that control, strict component part liability should apply where it properly may.

*Beatrice Skye Resendes\**

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267. *E.g.*, Vedantam, *supra* note 12.

268. *Blackwell v. Phelps Dodge Corp.*, 203 Cal. Rptr. 706, 710–12 (Cal. Ct. App. 1984) (noting manufacturer who controlled ability to warn on a railroad tank car was distinguishable from, and potentially separately liable than, the seller of the goods inside the container).

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2009]

THE EXTINCT DISTINCTION OF PRIVACY

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