

“INSURING” THE CONTINUED SOLVENCY OF
PHARMACEUTICAL COMPANIES IN THE FACE OF
PRODUCT LIABILITY CLASS ACTIONS

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Costly product liability lawsuits continue to plague the pharmaceutical industry, and insurance to cover these losses is severely inadequate. Furthermore, questionable regulation of drugs exists once a pharmaceutical has passed FDA approval. This article describes a plan that uses a capitalistic, rather than a governmental, approach to solve both the insurance and the quality control problems. Although the proposed plan has never been used to insure pharmaceutical companies, different permutations of it have been used to insure other litigation-prone industries. Success from the proposed insurance entity results from the combined knowledge of scientists and actuaries to provide both protection from product liability lawsuits for the pharmaceutical industry and enhanced post-market surveillance of pharmaceuticals.

I. INTRODUCTION

After the disclosure that the use of Vioxx contributed to an increased risk of heart attacks and strokes, Merck and Company decided voluntarily to withdraw its arthritis medication from the market on September 30, 2004. Now, Merck is preparing itself for anticipated product liability class action lawsuits.

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These developments have already begun to threaten the company's future ability to function as an independent entity,¹ and are among the latest examples of class actions being brought against companies for faulty medical drugs or devices.² While class action litigation has become widespread in the past two decades,³ the ramifications for the pharmaceutical industry are particularly profound and long lasting, for manufacturer and consumer alike.⁴

There are few industries as widely reviled as the pharmaceutical trade. A recent Harris survey found that only 13 percent of respondents believed that drug companies are "generally honest and trustworthy."⁵ Notwithstanding the lack of public sympathy for the pharmaceutical industry's plight, it is alarming that the mere threat of liability, together with the unpredictability of litigation and unreasonable transaction costs, have been asserted as deterrents to pharmaceutical companies from actively engaging in the research and development of new products.⁶ This chilling effect on innovation has social costs in lost therapies and foregone research.⁷

1. See Alex Berenson, *Merck Offering Top Executives a Rich Way Out*, N.Y. TIMES, NOV. 30, 2004, at A1 (reporting that with Merck's "ability to thrive as an independent company uncertain, the drug giant . . . has adopted a plan that could give its top executives big bonuses if the company is taken over").

2. See generally ADVISORY COMM. ON CIVIL RULES & WORKING GROUP ON MASS TORTS, REPORT ON MASS TORT LITIGATION, APP. D (Feb. 15, 1999) (gathering the "Individual Characteristics of Mass Tort Congregations" and compiling data relating to product liability cases generally and medical drugs and devices specifically).

3. See, e.g., *High Flyers*, Editorial, WALL ST. J., June 26, 2000, at A46 (noting that a 1999 study found that in the decade between 1988 and 1998, the number of class actions rose by 338% in the federal courts and by more than 1,000% in state courts); Michael A. Pope, *Mass Tort Cases Are Swamping Courts*, NAT'L L.J., Oct. 11, 1999, at B14. *But cf.* Claire Andre & Manuel Velazquez, *Who Should Pay? The Product Liability Debate*, available at www.scu.edu/ethics/publications/iie/v4n1/pay.html (1991) (noting that the RAND Corp. found that although the number of product liability lawsuits had increased nearly eight-fold during the last decade, more than half of these lawsuits involved only a handful of companies, reflecting mass litigation against a few asbestos and pharmaceutical companies; a report by the Government Accounting Office also concluded that, except for cases involving a few drug or asbestos companies, product liability suits "do not appear to have been rapidly accelerating or explosive").

4. See, e.g., Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199 (1992) (arguing that the current product liability regime is costly both to pharmaceutical manufacturers and consumers, and concluding that the adoption of a no-fault system of drug injury compensation addresses these inefficiencies).

5. David J. Rothman, *Strong Medicine*, NEW REPUBLIC (Sept. 27, 2004) (finding, in a related Gallop survey, that positive public attitudes toward the pharmaceutical industry surpassed only that of the federal government and, alas, the "legal field" (which finished last)).

6. See PRODUCT LIABILITY AND THE PHARMACEUTICAL INDUSTRY, in U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS, OTA-H-522 (1993) (discussing the implications of product liability for the pharmaceutical industry) (hereinafter PHARMACEUTICAL R&D).

7. *Id.* A number of commentators have noted, for example, that liability concerns have slowed and now threaten the development of a vaccine for the human immunodeficiency virus

The example of the prescription drug Bendectin is instructive.⁸ It was taken by pregnant women beginning in 1956 to combat morning sickness, but was later linked in the medical literature to reported cases of congenital defects in babies. Although causation was never established, even after countless lawsuits and a \$120 million settlement offer,⁹ the drug manufacturer, Merrell Dow, eventually abandoned its marketing efforts. In 1985, Merrell Dow voluntarily “decided to set a limit on its liability by removing Bendectin from the market.”¹⁰ Thus, even though the U.S. Food and Drug Administration (“FDA”) concluded in 1980 that there was not enough evidence to ban Bendectin from the marketplace,¹¹ the total cost to Merrell Dow in defending the drug exceeded the \$13 million in annual revenues that the company received from its sales.¹² As one commentator has noted, “More often than not the best anticipatory defense in the modern legal environment is to sit still. Age, familiarity and ubiquity provide the surest legal protection. When it encourages improvement at all, today’s liability system promotes the trivial and marginal change.”¹³ As a result, U.S. consumers do not have access to some drugs that have been repeatedly proven to be safe and to new pharmaceuticals that have never been released or developed, due to the threat of product liability lawsuits.

Exacerbating all of the above is the dramatic increase in product liability lawsuits¹⁴ and an increasing inability to procure product liability insurance

(“HIV”). See Jon Cohen, *Is Liability Slowing AIDS Vaccine?*, 256 Sci. 168 (1992); Allison J. Arnold, Comment, *Developing, Testing and Marketing an AIDS Vaccine: Legal Concerns for Manufacturers*, 139 U. Pa. L. Rev. 1077, 1084 (1991).

8. See generally Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301 (1992) (providing a comprehensive analysis of the Bendectin litigations and compiling statistical studies and a database of each distinct Bendectin trial).

9. See, e.g., *In re Richardson-Merrell, Inc. “Bendectin” MDL No. 486*, 624 F. Supp. 1212 (S.D. Ohio 1985) (holding that a new trial was improper after drug maker prevailed in class action claim that drug caused birth defects because individuals could not testify as to causation); PHARMACEUTICAL R&D, *supra* note 6, at 176.

10. See, e.g., PHARMACEUTICAL R&D, *supra* note 6, at 175–76; Louis Lasagna, *Chilling Effect of Product Liability*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION, 334, 337–40 (Peter W. Huber & Robert E. Litan eds., 1st ed. 1991) (finding that “drugs and medical devices are taken off the market because of the magnitude of the litigation threat against the manufacturers”); Peter Huber, *Litigation Thwarts Innovation in the U.S.*, Sci. Am., Mar. 1989, at 120.

11. See *Obstetrics: Morning Sickness Drug May Return*, MEDICAL LETTER ON THE CDC & FDA 8–10 (Nov. 5, 2000), at www.NewsRx.net. The FDA did force the manufacturer to change its package insert to indicate that while the drug had been carefully studied, it was impossible to prove that it was without risk.

12. *High court hears views on Bendectin*, CHEM. MKTG. REP., Apr. 5, 1993, at 13 (describing a case where Jason Daubert and Eric Schuller alleged having birth defects caused by their mothers’ taking Bendectin while pregnant).

13. Huber, *supra* note 10, at 120.

14. Jack A. Chambless, *Capitalists Have Only Themselves to Blame*, ORLANDO SENTINEL, May 2, 2004, at G1 (stating that product liability lawsuits are increasing in number every year); see also Christiane Truelove, *The pharma industry is changing: is your company keeping up?*, MED AD NEWS (Dec. 1, 2003), at 37.

for pharmaceutical companies.¹⁵ The Pharmaceutical Manufacturer's Association, an industry trade group supporting systemic tort reform, submits that "insurance underwriters have no way to predict the kinds or amounts of claims they may have to pay. The result: broad classes of liability insurance are now unavailable or unaffordable."¹⁶ As one insurance expert has noted, "the pharmaceutical industry presents one of the most volatile risk management challenges in the world of business today."¹⁷ In this environment, most pharmaceutical companies have extreme difficulty obtaining basic insurance coverage in the traditional liability insurance market.¹⁸ The policies available today carry higher deductibles and higher premiums and often exclude specific products or types of products that carry a higher than average risk of product liability loss.¹⁹

This article proposes a plan that aids the pharmaceutical industry's ability to respond to, and recover from, the specter of future class action litigation. The plan does not advocate a vast overhaul of the current tort system. It is a more narrowly tailored proposal centering on a private, insurance-based framework that would work to (1) minimize tort exposure prospectively, and (2) allow companies to remain fiscally solvent even in the face of a class action. Specifically, the plan envisions an opt-in system in which pharmaceutical companies would form a private insurance company funded by premiums provided by the companies themselves. This indemnity plan, as detailed below, has analogues and offers a unique system of checks and balances between the actors working as both adversaries and allies: the pharmaceutical companies, the independent insurance entity (comprised of both scientists and highly trained underwriters), and the FDA. To augment this network, Congress will indemnify the pharmaceutical companies from catastrophic exposure by way of legislation that will

15. Lorraine Iannello, *Product Liability Reform Gathers Some Momentum*, J. COM., Nov. 4, 1991, at 1A (reporting that the impact of product liability litigation can be seen in the lack of insurance for products such as pharmaceuticals).

16. Judith P. Swazey, *Prescription Drug Safety and Product Liability*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION*, 291, 294 (Peter W. Huber & Robert E. Litan eds., 1st ed. 1991).

17. Mindy W. Toran, *Industry Risk Report: The Life Sciences*, RISK & INS., Dec. 2003 (quoting Bruce C. Belzak, the managing director of Marsh, Inc., as stating that "[i]n today's increasingly litigious society, the cost of product liability insurance has dramatically increased . . . the limits of liability and available capacity have significantly declined, while the number of claims continues to increase").

18. Steven B. Hantler, *The mounting assault by trial lawyers*, CHIEF EXECUTIVE (U.S.), July 1, 2004, at 16 (stating that the pharmaceutical industry is seeing a five-fold increase in its product liability insurance premiums and adding that companies have to put hundreds of millions of dollars in reserve just to handle legal expenses because if tort costs continue to escalate, today's insurance coverage cannot possibly cover the actual costs of lawsuits brought a decade from now).

19. PHARMACEUTICAL R&D, *supra* note 6, at 172.

largely model previous safety nets cast by Congress in response to terrorism, vaccination disease, and nuclear disaster.

The current regulatory regime skews disproportionately on the side of new-drug approvals, while often neglecting careful study of post-market safety.²⁰ The current system of FDA regulation has been widely derided as rife with potential conflicts of interest. Our plan, in contrast, emphasizes the advantages of a more transparent and more powerful regulatory approach. Part II of this article briefly reviews the legal background of product liability class actions, explores the present regime of post-marketing surveillance, and discusses some of its inefficiencies. Part III reviews past proposed solutions to insuring industries fraught with lawsuits, including governmental involvement in the insurance industry to indemnify companies engaged in risky, but necessary, commercial activity. Part IV details the proposed plan for an insurance entity-based system, and outlines the benefits of such a system for the pharmaceutical industry. The plan pays particular attention to a new classification: Needed, but Uninsurable, Drugs (“NBNIs”), such as thalidomide or a potential anthrax or Acquired Immunodeficiency Syndrome (“AIDS”) vaccine. Finally, Part V addresses some of the legal ramifications that arise from such a plan.

II. DEFINING THE PROBLEM: A CONTEXTUAL BACKGROUND

The number of filings, claimants, and monetary awards appear to have greatly increased since the 1960 withdrawal of thalidomide from the U.S. market.²¹ Thalidomide, described by one commentator as the “most maligned drug in the history of pharmaceutical medicine,”²² has been thought to be linked to birth defects in *ten* individuals in the United States.²³ From that start, the size of class actions increased over the next forty years. By August 2004, for example, over 100,000 former users of the diet drugs collectively known as Fen-Phen had filed lawsuits against American Home Products (now Wyeth) after concerns were raised that the drugs were

20. Ted Agres, *FDA's Ability to Protect Questioned*, DRUG DISCOVERY & DEV. (Feb. 1, 2005), at 16 (quoting the *Journal of American Medical Association* editors as stating that the FDA's existing post-marketing surveillance system is rife with “shortcomings and failures”); Eve E. Slater, *Today's FDA*, NEW ENG. J. MED., Jan. 20, 2005, at 293 (stating that the current reporting and review of post-marketing data create many opportunities for human error).

21. Alison Kittrell, *3 industries face bulk of product suits*, BUS. INS., Jan. 23, 1989, at 3 (stating that product liability case filings increased 733% to 12,666 in 1986 from 1,520 in 1974); see also Chambless, *supra* note 14, at G1.

22. Lasagna, *supra* note 10, at 345.

23. Dale H. Gieringer, Editorial, *The FDA Continues to Commit Regulator Malpractice*, WALL ST. J., Mar. 27, 1985. However, thalidomide has been found to be effective in many other medical conditions, but fear of liability and the legacy of the Bendectin story have largely kept the drug off the market, even as a “safe” isomer. See Lasagna, *supra* note 10, at 347.

associated with heart valve leakage.²⁴ As another example, over 12,000 lawsuits have been brought against Bayer Pharmaceutical Division after Baycol, a cholesterol lowering drug, was reported to cause sometimes fatal rhabdomyolysis.²⁵

As noted above, these suits may pale in comparison to the Vioxx class action. Already, attorneys in Cook County Circuit Court have filed a class action complaint that covers the estimated 300,000 people in Illinois who took Vioxx.²⁶ This will be only one of numerous class action filings because Merck estimates that approximately 20 million patients took Vioxx between May 1999 and August 2004.²⁷ Of that group, Dr. David Graham from the FDA's Office of Drug Safety has declared Vioxx to be the cause of heart attacks and strokes in an estimated 88,000 to 139,000 people in the United States.²⁸

Product liability lawsuits have been very costly—financially, reputationally, and productively—to the pharmaceutical industry. Wyeth set aside \$16.6 billion in reserves for the Fen-Phen litigation and only \$3.3 billion of that remains.²⁹ Wyeth recently submitted an agreement to U.S. District Court Judge Harvey Bartle III in Philadelphia whereby a \$1.275 billion fund would cover payments to about 40,170 people with nonlife-threatening valve damage, the biggest group of claimants.³⁰ As of January 13, 2004, Bayer AG had reached approximately 2,825 settlements and paid \$1.084 billion out of court as a result of Baycol lawsuits.³¹

After Merck's decision to pull Vioxx off the market, the company's stock immediately fell 27 percent, precipitating a \$28 billion loss in market value.³² Vioxx accounted for 11 percent of Merck's global sales in 2003,

24. See, e.g., *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, Nos. 1203, 99-20593 2000 WL 1222042 (E.D.Pa. Aug. 28, 2000) (providing background information relating to the Fen-Phen class actions, and noting the consolidation of claims and the Nov. 18, 1999, settlement in which Wyeth agreed to pay \$3.75 billion into a trust to be used to provide benefits to members of the *Brown* class). For more recent developments in state court cases, see *Wyeth Agrees to a Fen-Phen Pact*, WALL ST. J., Aug. 12, 2004, at B2 (reporting that more than 40,000 former Fen-Phen users who contend that the diet drugs caused minor heart valve damage would be compensated faster—but get substantially less money—under a proposed deal to speed review of less-serious cases in the protracted litigation).

25. *Bayer Settles Cases Related to Baycol*, WALL ST. J., Jan. 13, 2004, at D10.

26. *House Call with Dr. Sanjay Gupta* (CNN television broadcast, Oct. 9, 2004).

27. Andi Atwater, *Patients left worrying about pain relief*, NEWS-PRESS, Dec. 28, 2004, at A1.

28. Gardiner Harris, *F.D.A. Failing in Drug Safety, Official Asserts*, N.Y. TIMES, Nov. 19, 2004, at A1.

29. *Wyeth Agrees to a Fen-Phen Pact*, *supra* note 24.

30. *Id.*

31. Barbara Martinez, *Vioxx Lawsuits May Focus on FDA Warning in 2001*, WALL ST. J., Oct. 5, 2004, at B1.

32. See, e.g., *A Vioxx Elegy*, WALL ST. J., Oct. 1, 2001, at A14; Berenson, *supra* note 1.

and its loss is expected to decrease Merck's 2004 profit by 20 percent.³³ Furthermore, Merck has set aside more than \$600 million to defend the Vioxx lawsuits.³⁴

The pharmaceutical industry was once described as one of the "most tightly regulated industries in the United States . . . unique among American industries in having both its marketed products and its research on new products under federal regulation."³⁵ Since 1992, however, when an agreement was reached between the White House, Congress, and the pharmaceutical industry, a deal that has survived three administrations, the FDA has almost completely abdicated its role in ensuring the safety of drugs already on the market, in favor of new-drug reviews.³⁶ Under the terms of the agreement, the industry promised to give the FDA financial backing, \$200 million in 2003 alone, if the agency spent a specified amount of money on new-drug approvals.

The results of this conflict-ridden marriage have been devastating for post-market monitoring by the FDA. Now, 79 percent of the FDA's budget goes solely to approving new drugs. As the *New York Times* has reported, "everything else has gotten squeezed. Since the 1992 agreement, agency officials have eliminated half of the scientists in the drug center's laboratories, and starved them of new equipment. They have ended many of the agency's collaborations with academic groups that scrutinize problems of marketed drugs."³⁷ As a result of this dramatic shift in resources, the FDA's mechanisms for uncovering the dangers of drugs, post-market, are now described as a "woefully inadequate, underfunded, understaffed, haphazard system."³⁸

Because of these systemic failures, exacerbated in the last decade, the FDA's oversight authority has not created a uniformly safer marketplace for consumers. Consistent with its historic mandate,³⁹ the FDA should

33. Barbara Martinez, *Merck Pulls Vioxx from Market After Link to Heart Problems*, WALL ST. J., Oct. 1, 2004, at A1.

34. Christopher Bowe, *Merck sets aside \$600m for Vioxx legal costs*, FIN. TIMES, Jan. 26, 2005.

35. Swazey, *supra* note 16, at 292.

36. See, e.g., Gardiner Harris, *At F.D.A., Strong Drug Ties and Less Monitoring*, N.Y. TIMES, Dec. 6, 2004, at A1 (describing the FDA as "increasingly reliant on and bound by drug company money"); Editorial, *Industry Distortion of the F.D.A.*, N.Y. TIMES, Dec. 8, 2004, at A30 (calling attention to the Harris article, and urging an "increase in federal support for the F.D.A. so safety monitoring would be adequately financed and the [pharmaceutical] industry's influence would be proportionally reduced") (hereinafter Editorial, *Industry Distortion*).

37. Editorial, *Industry Distortion*, *supra* note 36.

38. See Phil B. Fontanarosa, Drummond Rennie, & Catherine DeAngelis, *Postmarketing Surveillance—Lack of Vigilance, Lack of Trust*, JAMA, Dec. 1, 2004, at 2647 (arguing that the FDA's post-marketing surveillance system "requires a long overdue major restructuring," and predicting that until that occurs, the United States will remain "far short of having an effective, vigilant, trustworthy system").

39. The FDA derives its authority from the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301–393 (1982), and is charged with the dual role of being "both a public health promoter . . . and a public health protector." 50 Fed. Reg. 7452–01 (1985).

more diligently monitor drugs post-market by using its bully pulpit to demand that manufacturers conduct more testing, increase warnings on drug packages, or recall drugs that pose material risks unrecognized prior to market approval. Moreover, the FDA's current role as the sole regulator of drug safety must be revamped along the lines of the following proposals, as too many people have died or been seriously injured, in spite of the agency's external oversight responsibilities. The FDA's Dr. David Graham has acknowledged the agency's impotence in post-market surveillance. When testifying before the Senate Finance Committee, he stated that the FDA is simply incapable of protecting the public.⁴⁰ Dr. Graham also told the Senate panel "that his agency discounts recommendations from its own safety researchers and doesn't give sufficient weight to safety concerns once drugs are approved."⁴¹ In a related interview, Dr. Graham noted, "the agency is far too focused on approvals and not on safety. If this problem isn't fixed, future Vioxx-like catastrophes are inevitable."⁴² Moreover, Sandra Kweder, deputy director of the FDA's office of new drugs, has stated that "[t]here is clearly concern that somehow the system is not working as well as it could."⁴³ If the leaders and managers of the FDA lack basic trust in the current efficacy of its regulatory capacity, it is regrettable and dangerous that the American public believes that the FDA can protect it from the next devastating pharmaceutical product.

Further proof that the FDA does not adequately monitor drugs post-market was highlighted by evidence presented at the Baycol trials. By December 1999, it had become apparent that Baycol was causing severe adverse muscle reactions.⁴⁴ The FDA and Bayer first warned patients and doctors on how to avoid trouble. A little over a year later, a second warning was sent to doctors. However, patients continued to die, so Bayer decided to pull Baycol off the market. On August 8, 2001, Bayer announced the voluntary recall of Baycol.⁴⁵ Baycol was approved by the FDA at dosage levels of 0.2 and 0.3 milligrams in June 1997. From November 1997 to the date of the recall, the FDA processed 5,112 individual adverse case reports.⁴⁶ Despite this, in May 1999 the FDA approved Baycol at 0.4 milli-

40. See Gardiner Harris, *Man in the News; A Firebrand on Drug Safety; Dr. David J. Graham*, N.Y. TIMES, Nov. 20, 2004, at A16 (detailing the harsh criticism of Dr. Graham, a reviewer in the agency's office of drug safety, to the congressional panels). See also Gardiner Harris, *F.D.A.'s Drug Safety Program Will Get Outside Review*, N.Y. TIMES, Nov. 6, 2004, at A11.

41. Anna Wilde Mathews, *FDA Official Assails Agency on Monitoring of Risks*, WALL ST. J., Nov. 19, 2004, at A1 (noting further the comments of Dr. Kweder).

42. Harris, *supra* note 36.

43. *Id.*

44. Philip J. Hiltz, *Drug's Problems Raise Questions on Warnings*, N.Y. TIMES, Aug. 21, 2001, at F1.

45. Michael Lynch, *Baycol Litigation Just Beginning*, N.J.L.J., Dec. 3, 2001.

46. *Id.*

grams and in July 2000 the FDA approved Baycol at 0.8 milligrams. It was the quantity and seriousness of the side effects associated with the 0.8 milligrams dosage of Baycol that caused Bayer to voluntarily remove the product from the market in 2001.

Similar inadequacies in oversight by the FDA have allowed Vioxx to become, potentially, the largest pharmaceutical class action in history. Dr. Eric Topol wrote in the *New England Journal of Medicine* that the FDA approved Vioxx before reviewing peer-reviewed journal data.⁴⁷ It was almost two years after approval of Vioxx that the FDA met to determine the potential cardiovascular risks associated with the drug.⁴⁸ At this meeting the FDA determined that a trial specifically assessing the cardiovascular risk of Vioxx be commenced.⁴⁹ However, this was never done.

After the FDA meeting, Dr. Garret Fitzgerald published a paper with the primary purpose of studying the gastrointestinal effect of Vioxx, even though the paper noted that vascular effects increased with the use of Vioxx.⁵⁰ Merck allegedly continued marketing Vioxx as cardioprotective, refuted all allegations about cardiac side effects, and spent more than \$100 million per year in direct consumer advertising while the FDA did nothing.⁵¹ Since Vioxx's entry into the market in 1999, more than 100 million prescriptions have been written for it, and Dr. Graham estimates that the four-year delay in uncovering Vioxx's dangers cost 55,000 Americans their lives.⁵²

III. PROPOSED SOLUTIONS FOR THE PHARMACEUTICAL PRODUCT LIABILITY PROBLEM

A. *Critiquing the Current System*

Different suggestions have been contemplated to increase the efficacy of post-marketing surveillance, thereby decreasing the amount and severity of product liability class action lawsuits. We believe that improving post-market surveillance will decrease pharmaceutical product liability lawsuits since a major cost of a product liability lawsuit depends on the number of claimants involved. The claimant group size can be reduced by altering the pharmaceutical compound, changing the labeling on a marketed drug, or

47. Eric J. Topol, *Failing the Public Health—Rofecoxib, Merck, and the FDA*, NEW ENG. J. MED., Oct. 21, 2004, at 1707.

48. *Id.*

49. *Id.*

50. Garret A. Fitzgerald, *The Coxib, Selective Inhibitors of Cyclooxygenase-2*, NEW ENG. J. MED., Aug. 9, 2001, at 439.

51. Topol, *supra* note 47, at 1708.

52. Martinez, *supra* note 33, at A1; Harris, *supra* note 36.

discontinuing production of a deleterious pharmaceutical in the most timely manner.

Critics of the current regime, which has been described as full of institutional conflicts of interest, have proposed increasing the power of the FDA's safety office in monitoring drugs already on the market and strengthening the FDA's mandate for post-market surveillance.⁵³ However, with current budget deficits, it is unrealistic to assume that the FDA's budget would be increased sufficiently to perform effective post-market surveillance by itself. More forcefully, the editors of the influential *Journal of the American Medical Association* have recently proposed that a drug safety board or agency for drug safety should exist that operates independently of the FDA and the drug industry, arguing that it is unreasonable to expect the same agency that approves drugs to "also be committed to actively seek evidence to prove itself wrong."⁵⁴

While the FDA struggles with budgetary constraints and the influence of a demanding industry, the drug companies, in turn, have found it increasingly difficult to get product liability insurance coverage.⁵⁵ Through the 1970s, most pharmaceutical firms protected themselves against product liability losses with a three-phased insurance plan: a deductible for the first portion of each claim; a basic insurance policy to pay claims up to specified limits, once the deductible is met; and the procurement of excess insurance to pay claims above the basic policy up to another specified limit.⁵⁶

In such a system, the total cost to the company was largely known and predictable. It included deductibles, any losses not covered under the plan, legal and administrative costs, and the policy premium. Although much of the evidence has been anecdotal, as the liability insurance industry has been described as a "poor source of information,"⁵⁷ it is clear that starting in the early 1980s, losses notably exceeded premiums for U.S. insurers of phar-

53. See Editorial, *Looking for Adverse Drug Effects*, N.Y. TIMES, Nov. 27, 2004, at A14 (arguing, in light of the paper's critical reporting, that the agency "lacks enough power to ensure the safety of drugs after they are approved and on the market," and charging that the "agency is so impotent that manufacturers mostly fail to complete even the postmarketing trials they have pledged to conduct as a condition for their drug's approval").

54. See Fontanarosa, *supra* note 38. See also Denise Grady, *Medical Journal Calls for a New Drug Watchdog*, N.Y. TIMES, Nov. 23, 2004, at A18; Anna W. Mathews, *FDA Establishes Board to Review Approved Drugs*, WALL ST. J., Feb. 16, 2005, at A1 (reporting that most of the members of the new Drug Safety Center Oversight Board will come from the FDA and the safety board will be fully funded by the FDA).

55. See *European drug makers mull own insurance pool: Schwarz Pharma*, AGENCE FRANCE-PRESS, Feb. 27, 2003 (quoting a spokeswoman for the German firm Schwarz Pharma stating that pharmaceutical companies in Europe do not rule out setting up their own insurance pool to cover risks connected with their products in view of the sharp rise in premiums demanded by insurance companies).

56. PHARMACEUTICAL R&D, *supra* note 6, at 172.

57. *Id.* at 170.

maceuticals.⁵⁸ As one commentator has noted, “[i]nsurance companies are no more eager to lose their shirts to unpredictably generous juries than are . . . the manufactures themselves.”⁵⁹ As such, traditional insurance indemnification is no longer a reality for pharmaceutical companies.

In order to calculate the cost of insuring an entity, underwriters need to know exposure, residence, and manifestation. These variables are extremely hard to determine in pharmaceutical product liability class actions since the potential risks of drugs are often unknown at the time of FDA approval. The time period for establishing a potential adverse effect is independent for each drug and nearly impossible to calculate, and the initial signs and symptoms of a potential health consequence vary widely. Furthermore, unlike the majority of nonpharmaceutical products, all pharmaceuticals inherently can produce adverse consequences. Accordingly, the insurance industry has been hesitant to indemnify pharmaceutical companies in liability class actions, thereby creating a vacuum of the type of insurance needed to cover liability suits and settlements.

For example, insurance companies are only expected to cover \$1.2 billion of costs in the Baycol lawsuit.⁶⁰ Merck’s liability insurance will offset only \$650 million of the cost of the Vioxx lawsuits.⁶¹

This article proposes that only an entity with a financial incentive to decrease the number and magnitude of class action lawsuits would have the proper motivation to consistently and adequately perform post-market drug surveillance. Specifically, the establishment of a pharmaceutical insurance entity will accomplish this goal.

B. *Past Models of Governmental Involvement in the Insurance Industry*

Congress has historically approved and funded multiple societal insurance schemes, in effect fashioning social safety nets, in response to catastrophes. The most recent Congressional endeavor, the Air Transportation Safety and System Stabilization Act (“ATSSSA”), was an emergency bill passed to aid the airlines in the immediate aftermath of the September 11th attacks, creating, in Title IV, the September 11th Victim Compensation Fund

58. See, e.g., W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION*, 81–119 (Peter W. Huber & Robert E. Litan eds., 1st ed. 1991) (arguing that the roots of the “liability premium crisis” and “evidence of liability insurance markets in disarray” can be found in the early 1980s, as “insurance companies [were] not able to raise premiums sufficiently to reflect the change in their loss experience”).

59. Peter W. Huber, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 287 (1988).

60. *Philadelphia Judge OKs Suit Against Bayer*, *PITT. POST GAZETTE*, Mar. 30, 2004, at C12.

61. Richard Irving, *Merck vows to fight claims for Vioxx ‘deaths,’* *TIMES (UK)*, Jan. 26, 2005, at 52.

of 2001.⁶² Some question whether the unprecedented nature of September 11th, and the extraordinary largesse of the federal government's immediate response, is simply too idiosyncratic to provide real lessons for tort reform generally.⁶³

In a more closely related context, Congress enacted the National Childhood Vaccine Injury Act of 1986 ("NCVIA") in response to the threatened shortage of childhood vaccines because of dire liability problems.⁶⁴ In an earlier example, Congress passed the National Swine Flu Immunization Program of 1976 to encourage manufacturers to produce a vaccine for swine flu, a new deadly strain of the influenza virus that caused twenty million deaths worldwide in 1918 and ominously reappeared in Fort Dix, New Jersey.⁶⁵ Absent this federal intervention, in which the government rather than the pharmaceutical companies agreed to accept liability for all vaccine-related injuries except manufacturing errors, manufacturers were unwilling to supply the needed vaccine because insurers had categorically excluded it from product liability coverage.⁶⁶ Under this law, 45 million people received the vaccine and most gained effective protection against swine flu. Those injured could not sue, but were permitted to make claims against the United States within two years of the vaccination according to the theories of liability in practice in the state where the injury took place.⁶⁷

Also, in 1969, Congress authorized the Black Lung Benefits Act to compensate underground coal miners suffering from work-related pneumo-

62. Pub. L. No. 107-42 (2001); see generally Linda S. Mullenix & Kristen B. Stewart, *The September 11th Victim Compensation Fund: Fund Approaches to Resolving Mass Tort Litigation*, 9 CONN. INS. L.J. 123, 126 (2002) (reporting that ninety-five percent of eligible claimants chose the no-fault victim compensation fund over tort litigation, apparently based upon a conviction that the money awarded under the fund approach appeared fair and reasonable in comparison to the risks associated with litigating the claims in court).

63. See, e.g., Gary R. Smith, *The Future of Tort Reform: Reforming the Remedy, Rebalancing the Scales*, 53 EMORY L.J. 1219, 1223 (2004); John C. Culhane, *Tort, Compensation, and Two Kinds of Justice*, 55 RUTGERS L. REV. 1027 (2003) (posing a broader question of the Fund's equitable fairness in light of those bereaved by misfortunes and tragedies other than terrorism).

64. 42 U.S.C. § 300aa (as amended 2000) (providing a no-fault alternative to product liability litigation for people seeking compensation for injuries related to childhood vaccines administered up to eight years prior to the enactment of the legislation, and empowering the Secretary of the Department of Health and Human Services to determine what types of injuries are eligible for compensation).

65. Pub. L. No. 94-380, 28 U.S.C. §§ 2671-2680 (as amended 2000).

66. See Huber, *supra* note 59 (finding that the country's emergency national immunization program was about to be derailed by insurance companies that "refused to touch the swine flu vaccine in any way or form." Outraged, Congress substituted the U.S. Treasury Department as the insurer, and Sen. Ted Kennedy accused the insurance companies of "cupidity and [lacking] social obligation").

67. *Id.* However, by 1986, the government had settled 704 cases emanating from the swine flu vaccine, with total payments amounting to over \$100 million, sixty times that of original government estimates, suggesting that private insurers' circumspection may have been well founded.

coniosis, or black lung disease. The legislation was later extended in 1977 to include additional mining industry workers and to encompass a broader array of pneumoconiosis-related injuries.⁶⁸

The funds approved by Congress have been financed by many means. The U.S. Treasury Department has financed the uncapped September 11th Victim Compensation Fund, with a total cost to taxpayers that has been estimated at \$5 billion.⁶⁹ A mandatory broad-based excise tax on each dose of vaccine funded the NCVIA compensation fund,⁷⁰ and an excise tax on coal financed the Black Lung Benefits Act. Congress has also established payment schedules by which to manage many of the funds outside of the courtroom.

For instance, ATSSSA has a three-part formula to determine the amount of compensation to those who choose a claim through the September 11th Victim Compensation Fund. First, ATSSSA provides for a determination of the amount that a victim would have earned over his or her lifetime, subject to some limitations.⁷¹ Second, compensation for pain and suffering is added to the projected earnings.⁷² Finally, each award is adjusted for amounts received from collateral sources, excluding money received from charities.⁷³

In order to create a standardized method for determining who would be eligible for compensation under NCVIA, a Vaccine Injury Table was devised to define compensation based on injuries within a given period of time.⁷⁴ A \$250,000 limit was imposed for damages, pain, suffering, and emotional distress.⁷⁵ The Fund paid a monthly allotment to victims based on the number of dependents that the claimant had. Benefits were decreased by the amount received by the victim from the state compensation fund.⁷⁶

C. *The Price-Anderson Act*

Congress passed the Price-Anderson Act in 1957 to encourage the entry of private industry into the field of nuclear energy.⁷⁷ The Price-Anderson

68. Pub. L. No. 95-239, § 2, 92 Stat. 95, 95 (1978) (codified as amended by 30 U.S.C. § 902 (2002)) (intending to “provide benefits, in cooperation with the states, to coal miners who are totally disabled due to pneumoconiosis and to the surviving dependents of miners whose death was due to such disease”). *Id.* § 901(a).

69. See Mullenix & Stewart, *supra* note 62, at 127; David W. Chen, 7 *Families Sue Administrator of 9/11 Fund*, N.Y. TIMES, Jan. 27, 2003, at B1.

70. Mullenix & Stewart, *supra* note 62, at 134.

71. September 11th Victim Compensation Fund of 2001, 28 C.F.R. § 104.44 (2002).

72. *Id.*

73. Air Transportation Safety and System Stabilization Act, Pub. L. No. 107-42, 115 Stat. 230 (codified at 49 U.S.C.A. § 40101.405(b)(6) (Note)).

74. *Id.*

75. Mullenix & Stewart, *supra* note 62, at 135.

76. *Id.* at 146.

77. Pub. L. No. 85-256, 71 Stat. 576 (codified at 42 U.S.C. § 2210 (2000) (Price-Anderson Indemnity Amendments to the Atomic Energy Act of 1954)).

Act was amended three times, in 1965, 1975, and 1988, and allowed for constraints on possible catastrophic tort liability in the event of a nuclear accident. Congress designed the Act as a protective measure to ensure participation in the nuclear energy field at a time when the insurance industry did not provide such insurance.⁷⁸ The Act granted protection once the Nuclear Regulatory Commission declared an extraordinary nuclear event.⁷⁹ Plaintiffs had the burden of proving injury from the nuclear power plant accident.⁸⁰ Importantly, claimants indemnified by the fund were required to waive all of their legal defenses.⁸¹

The compensation plan established by the Act is funded through a pooling mechanism in which "each nuclear licensee is required to purchase \$160 million in private liability insurance and to contribute a maximum of \$10 million yearly (up to a maximum of \$63 million) to the compensation fund when there is a nuclear incident at any plant."⁸² Each civilian nuclear power plant was initially granted \$60 million in coverage, and a \$560 million cap was imposed on all liability for nuclear accidents. Furthermore, subsequent to an event exceeding \$560 million in damages, Congress would decide whether or not to provide greater public compensation.⁸³ The U.S. Supreme Court found the \$560 million ceiling on liability to be constitutional.⁸⁴

IV. PROPOSED INSURANCE ENTITY PLAN

Under this article's plan, an insurance entity would be formed, funded by premiums paid by the pool of pharmaceutical companies that opted to buy the insurance. Pharmaceutical companies would have an incentive to participate in the program because it would provide needed product liability insurance currently not available in the marketplace. The insurance entity would have fixed liability, with the federal government establishing an alternative remedy akin to Congress's other compensation programs,⁸⁵ that would cover any catastrophic product liability disasters. Paralleling the governmental insurance funds described above, specifically NCVIA, an excise tax would be imposed on pharmaceutical manufacturers for each product that they marketed in the United States. This would shield the Amer-

78. Mullenix & Stewart, *supra* note 62, at 139.

79. Janet Behnshoof, *Protecting Consumers, Prodding Companies, and Preventing Conception: Toward a Model Act for No Fault Liability for Contraceptives*, 23 N.Y.U. REV. L. & SOC. CHANGE 403, 418 (1997).

80. *Id.* at 419.

81. Mullenix & Stewart, *supra* note 62, at 140.

82. Behnshoof, *supra* note 79, at 419.

83. *Id.* at 420.

84. *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59 (1978).

85. See Part IIIA *infra*.

ican taxpayer from directly funding the system and allocate risk to members of the industry in some proportion to their market share of drug sales.

The FDA would still have primary responsibility for premarket approval of drugs, and would continue its post-market surveillance of drugs, but with a more powerful legislative mandate and a broader budget specifically allotted for post-market drug safety. In consideration for the government covering excess liability, the insurance entity would be mandated to insure all FDA-approved drugs. Finally, NBNIIs,⁸⁶ those drugs that the FDA determines are medically necessary but practically uninsurable because of the degree of risk exposure, would be insured by the insurance entity through a fixed schedule of payments.

The insurance entity would be established similar to a self-regulatory organization whereby it would have a board of directors and internal governance independent of the pharmaceutical companies and the FDA. Because the insurance entity would be a privately held company and a non-governmental agency, the insurance entity would have autonomy from the pharmaceutical industry, the FDA, and the federal government. The FDA's revamped post-market testing would be supplemented by and have contact with the insurance entity's self-regulating Drug Safety Center, which would be comprised of scientists working in conjunction with the entity's underwriters. In addition to having the appropriate business background, the underwriters would preferably also have completed a formal education in the basic sciences. The scientists would do post-approval surveillance of drugs via on-going clinical research trials aimed at flagging potentially harmful side effects before they grow into full-blown liability disasters. Moreover, after completion of extensive testing by the Drug Safety Center, any company that opted in would be able to advertise its higher degree of product safety by way of a certification label noting its participation in the program. This could be placed on its packaging, thus indicating another form of consumer protection.

Transparency and communication would be hallmarks of the plan. Information learned by the scientists would be shared with the underwriters,

86. While this classification is a construct of the authors, it has similarities to the problems posed by "orphan drugs," a term used in the pharmaceutical industry to denote a potentially therapeutic treatment for a rare disease (affecting 200,000 or fewer persons in the United States). Since the target population for rare diseases is per se a small subset, it lacks a sponsor to conduct the clinical tests necessary for FDA approval. See David Duffield Rhode, *The Orphan Drug Act? An Engine of Innovation? At What Cost?*, 55 FOOD & DRUG L.J. 125 (2000) (examining Congress's legislative action in this regard, codified as amended at 21 U.S.C. § 360aa-ee (1998)); Lasagna, *supra* note 10, at 347 (citing the 1989 *Report of the National Commission on Orphan Diseases* that even six years after the Orphan Drug Act, concerns about liability have still led to serious delays in product development and to increased liability insurance costs).

the business arm of the insurance entity, who would utilize the information to determine the premiums owed by each pharmaceutical company.

The underlying goal of having both scientists and underwriters work for the same company is to enable the entity to ascertain an in-house, precise determination of exposure, residence, and manifestation. If during post-market surveillance, for instance, scientists found adverse problems related to a drug, the underwriters would inform the pharmaceutical company that it must either modify its product or accept a higher premium. The higher premium might cause a company to recall the pharmaceutical product or force the company to undertake a modification before producing future batches of the drug. Such information would be voluntarily shared with the FDA, as the entity would have an incentive to inform the FDA of any adverse consequences. The insurance entity, after all, must protect itself from class actions in order to remain financially viable. Therefore, the entity would desire to have as many litigation defenses as possible. Although adherence to FDA regulations on prescription drugs does not currently serve as a defense against, or otherwise preempt, a state common law failure-to-warn claim,⁸⁷ its evidentiary power would still be coveted by the insurance entity. Full compliance with FDA regulations would also be used as a bar to punitive damages, as is the case in a handful of states.⁸⁸

As noted above, the insurance entity would be mandated to insure every FDA-approved drug. This mandate would prevent industry cherry picking that might exclude the drug companies producing NBNIs from attaining insurance protection. However, in consideration for the insurance entity having a mandate to insure all FDA-approved drugs, the government would cover excess liability resulting from a catastrophic class action lawsuit. Together, executives from the state Department of Health and the Board of Directors of the insurance entity would set the upper dollar amount that the insurance company must indemnify for each drug before

87. The “government standards” defense—proffered by a drug manufacturer to show compliance with federal regulations—is but a “weak shield” in defending against a product liability action; courts regularly deem FDA standards to be a baseline or a floor, and not a ceiling. Noncompliance, of course, remains a “strong shield” for plaintiffs. *See, e.g.,* *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (“An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.”); *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1111–14 (4th Cir. 1988); *Mazer v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990); RESTATEMENT (SECOND) OF TORTS § 288C (1965) (“Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.”). *See also* James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 320 (1990) (“[F]or reasons that we find difficult to understand, courts have not deferred to the determinations of products safety agencies. . . . The analysis usually begins and ends with the statement that agency standards are minimum, not maximum, standards and that courts are therefore free to disregard them.”).

88. *See Lasagna, supra* note 10, at 356.

the government would begin covering the cost of a class action product liability catastrophe. The insurance entity would not insure against any off-label uses of pharmaceuticals. If appropriate, users could look to hospitals and doctors to be responsible in any tort action resulting from off-label uses. In addition, physicians would also be responsible for not performing tests used to monitor for FDA-noted side effects of drugs.

The insurance industry would use a fixed schedule to pay for claims resulting from NBNI drugs. An NBNI might be a pharmaceutical where an extreme public interest exists in its availability; however, the drug has a potential to cause extreme adverse consequences. Examples of NBNI would be thalidomide or an anthrax or AIDS vaccine. The underwriters of the insurance company would demonstrate to an FDA panel that the risk of insuring a drug would be a guaranteed loss for the company and hence the government must declare the drug an NBNI. Once the FDA determined a drug to be an NBNI, the insurance entity would use a schedule from which it would insure the NBNI. The schedule would be formulated by the NBNI Production Commission, comprised of scientists and underwriters from the insurance entity, and representatives of the FDA. As a gateway to NBNI access, patients would have to sign a waiver agreeing to the schedule, which would be administered outside of the federal and state judicial systems.

Multiple benefits flow from our insurance entity plan, which envisions a unique system of checks and balances that recasts the pharmaceutical industry, the FDA, and the federal government into intersecting relationships that are, at once, both adversarial and allied. This plan envisions a working system in which the perspectives of government, manufacturer, insurer, and, ultimately, consumer are taken into account. One faction would not determine outcomes based on its own interests.

The insurance entity would have an adversarial relationship with pharmaceutical companies because of the entity's goal of minimizing tort exposure. This could often conflict with the pharmaceutical company's desire to maintain low insurance premiums and keep drugs on the market. For example, the insurance entity would continue to engage rigorously in post-market surveillance in order to ensure that any adverse consequences were addressed as soon as possible. As noted previously, if scientists at the insurance entity discovered a drug's propensity for adverse side effects, the insurance company would immediately alert the pharmaceutical company. The pharmaceutical company could then decide to temporarily or permanently remove the drug from the market, thereby decreasing the number of potential claimants and the amount of liability exposure, or continue marketing it with a change in warning labels, but with a marked increase in its premium. If the adverse consequences proved too dangerous, the

FDA could take the step of last resort and force removal of the drug from the market.

In addition to having a sometimes adversarial relationship posture, the pharmaceutical companies and insurance entity would clearly also have aligned interests. Both the insurance entity and the pharmaceutical companies would want to avoid the loss of resources and adverse publicity resulting from a class action lawsuit. Pharmaceutical companies prize good publicity because, although they may appear to have a captive audience, they do not. For instance, even though each drug has its own method of functioning and therefore its own set of side effects and benefits, many drugs can still be interchanged for each other. In addition, patients maintain the option to abstain from treatment and to use nonallopathic forms of therapy. Furthermore, the insurance entity would have to rely on payments from the pharmaceutical companies to maintain its business, providing it with the financial motivation necessary to ensure the financial solvency of its clients. Conversely, the pharmaceutical companies presently have no other alternative for full insurance except from the proposed insurance entity. Therefore, the pharmaceutical companies do not want the insurance entity to become bankrupt, leaving them unprotected and with unlimited liability.

The FDA and the newly formed Drug Safety Center (composed of the insurance entity's scientific wing) would also have both an adversarial and a nonadversarial relationship. The FDA has the moral and legal authority to protect the public as its health guardian, and thus would want to update labels on drug products as adverse consequences become apparent. Even though a pharmaceutical company can choose to pay a higher premium once the insurance entity learns of increased drug risks, the insurance entity might not be able to fully underwrite its potential loss. Therefore, the recall of a drug by the FDA might financially benefit the insurance entity.

Although NBNIs can have devastating medical effects on a certain patient population, they might be extremely beneficial to another subset. For instance, thalidomide taken by a pregnant woman can result in children being born with extremely malformed extremities. However, thalidomide has shown to be extremely beneficial in patients with multiple myeloma, HIV, and cancer. Indeed, for this subset there has not been a drug found that could be substituted for thalidomide's beneficial effects. Hence, the FDA has a public policy interest that certain dangerous drugs remain on the market. The extremely high premiums that the insurance entity would have to charge to the drug companies in order to insure the NBNIs would force the pharmaceutical companies to remove the drugs from the market. Therefore, by limiting the risk of the insurance entity by way of a governmental underwrite, premiums stay low, the pharmaceutical industry would

continue to produce the NBNIs, and the public would have access to necessary treatments.

The FDA would be politically motivated and morally bound not to approve a plethora of NBNIs since the public would be outraged if an improperly classified NBNI caused devastating injuries. Since the FDA is an administrative agency under the executive branch of the government, the FDA has the incentive not to create political turmoil or upheaval.

The federal government would also be politically motivated to step up its post-market surveillance to ensure that class actions not exceed the caps that it has set for the insurance entity's liability, lest the public be responsible for underwriting the catastrophic financial loss. Accordingly, the scientists and underwriters in the insurance entity would work closely with executives in the state Department of Health to determine proper insurance limits. At every juncture, then, political accountability and transparency would replace the present regulatory system's timidity and vulnerability. These checks and balances, created by the establishment of an insurance entity, would provide the institutional vigilance not present in the current system of FDA and pharmaceutical company post-market surveillance.

Another benefit of the proposed plan lies with its ability to spur competition within the insurance industry. If the proposed insurance entity maintains sufficient profitability and effectiveness, additional entities may form to provide product liability insurance for the pharmaceutical industry. Moreover, existing insurance companies may once again choose to insure pharmaceutical companies against product liability lawsuits. Furthermore, success of the proposed insurance entity demonstrated by a decrease in the number and the size of payouts in product liability lawsuits could also provide for growth and competition within the reinsurance industry.

V. LEGAL RAMIFICATIONS

The system envisaged by this article offers a hybrid, third-way approach to product liability law. It does not advocate a complete overhaul of the tort system⁸⁹ or call for a uniform social insurance scheme along the lines of many European countries.⁹⁰ Rather, it more modestly proposes a few emendations to the current system of tort liability. Chief among these is the September 11th Victim Compensation Fund, to be earmarked by the

89. See, e.g., STEPHEN SUGARMAN, *DOING AWAY WITH PERSONAL INJURY LAW* (1989) (surveying contemporary attempts to reform tort law and advancing several new proposals); Jackson, *supra* note 4 (same, with regard specifically to the pharmaceutical industry).

90. See, e.g., Lotta Westerhall, *Disbursement of Indemnity for Injuries Related to Reproductive Drugs and Devices: A Swedish Prospective*, 23 N.Y.U. REV. L. & SOC. CHANGE 443 (1997) (summarizing the approach to compensation utilized by Sweden, a country with a historically weak tort liability system that was supplemented in 1978 by a system that seeks to compensate persons "on the basis of need rather than fault").

federal government for use only in the event of an unavoidable pharmaceutical catastrophe. Societal insurance is a more effective, efficient, and equitable avenue of compensation than the status quo as a response to future unpreventable disasters. Indeed, this country has already experimented with such programs in response to past catastrophes in related contexts. Given the added vigilance in post-market surveillance called for by this article, to be carried out concurrently, but independently, by the FDA and the private Drug Safety Center, a regulatory standards defense should be available for the manufacturers. Manufacturer liability would be limited to cases of fraud or deception, in which the company engaged in deceptive reporting, such as concealing or skewing data or withholding data relating to a drug's adverse effects. Compliance with FDA/Drug Safety Center regulations should protect manufacturers from punitive damages absent conscious withholding of data.⁹¹ A remedy at tort law would only exist, then, upon a finding that the manufacturer was negligent under this fraudulent information standard.

If, after proper warning of and adherence to regulatory standards is established, a drug were nonetheless found to result in drastic physical harm, a no-fault compensation system would be a better alternative to tort liability. Virtually no U.S. jurisdiction employs pure strict liability in the context of pharmaceutical litigation, as outlined in Section 402A of the *Restatement (Second) of Torts'* comment "k" exception.⁹² The *Restatement (Second)* comment recognizes that there

are many new or experimental drugs as to which, because of lack of time or sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredientsThe seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, *is not to be held in strict liability for unfortunate consequences attending their use.*⁹³

91. See 42 U.S.C. § 300aa-23(d)(2) (1988) (stating that punitive damages will be allowed if information was withheld prior to approval of vaccine or subsequent to approval of vaccine, or if manufacturer engaged in criminal or illegal activity).

92. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). For judicial conceptions of the *Restatement*, see *Brown v. Superior Court*, 751 P.2d 470, 480 (Cal. 1988) (limiting scope of product liability to design defects, extending the protections of comment k to all prescription drugs as a matter of law, and finding that public interest on the development, availability, and reasonable pricing of drugs outweighed consumer interest in strict liability principles). *But see Hill v. Searle Lab.*, 884 F.2d 1064, 1069 (8th Cir. 1989) (noting that drafters of comment k considered and rejected extension of strict liability exemption to all prescription drugs). Cf. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. f (1998) (stating that "[a] prescription drug or device manufacturer defeats a plaintiff's design claim by establishing one or more contexts in which its product would be prescribed by reasonable, informed health-care providers").

93. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) (emphasis added).

Furthermore, Congress, in passing NCVIA, created an explicit presumption that a vaccine is accompanied by proper direction and warning if the manufacturer shows that it complied with FDA regulations.⁹⁴ Similarly, under this article's plan, once the manufacturer opts into the coverage by the insurance entity and agrees to its higher standards of ongoing post-market surveillance and proper labeling, the company's drugs should be recognized judicially as "unavoidably unsafe." In such a case, the tort system could be bypassed in favor of the legislatively created, national compensation scheme, and all consumers, by entering the governmental system, would have to exhaust the governmental remedies before resorting to the tort system. Proving by a preponderance of the evidence that the injury suffered was pharmaceutical related, the injured party would be awarded compensation commensurate with the Vaccine Injury Table established by Congress.

This article does not propose a wholesale preemption of common law tort remedies. In recognizing the efficacy of a more certain and efficient dispute resolution process, the plan attempts to conserve judicial resources, absolve pharmaceuticals of never-ending liability and unpredictability, and assure that the American consumer is provided with continuing innovations in health care. A solution to the present insurance crisis will not only help pharmaceutical companies minimize class actions from their inception by instituting a higher standard of post-market surveillance, but will also help the FDA maintain its historic role as "public health guardian." Finally, the plan recognizes the realities of unavoidably unsafe drugs, and works to ensure that pharmaceutical companies are protected as long as they adhere to the heightened public protection regulations advocated here. Subject to that necessary caveat, the federal government, as it has before, would then indemnify the unavoidably unsafe drugs on behalf of society, protecting both the pharmaceuticals and the general public.

94. 42 U.S.C. § 300aa-22(b) (1988).

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