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Paula Jacobi

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PHARMACEUTICAL TORT LIABILITY: A JUSTIFIABLE NEMESIS TO DRUG INNOVATION AND ACCESS?

PAULA JACOBI*

*"States Ration Low Supply of 5 Vaccines for Children"*¹

*"Schering-Plough to Start Wait List for
Hepatitis Drug"*²

*"Drug Shortages Impacting Trauma Centers"*³

*"Contraceptive Research Has Been Stalled for over a Generation in
the United States"*⁴

INTRODUCTION

These headlines tell a story of the persistent and growing shortage of critical drugs and vaccines in America.⁵ The threat of uncertain tort liability has led pharmaceutical manufacturers to either selectively or completely abandon the drug and vaccine

* J.D., January 2005.

1. Robert Pear, *States Ration Low Supply of 5 Vaccines for Children*, N.Y. TIMES, Sept. 17, 2002, at A20.

2. Geeta Anand, *Schering-Plough to Start Wait List for Hepatitis Drug*, WALL ST. J., Jan 16, 2002, at B14.

3. *Drug Shortages Impacting Trauma Centers*, J. OF TRAUMA NURSING, Apr. 1, 2003, at 50.

4. William M. Brown, *Déjà vu All over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1, 32-33 (2001) (discussing the fear of product liability and punitive damage awards driving pharmaceutical manufacturers out of contraceptive research).

5. For a bulletin of drugs in shortage, see the Drug Shortage Resource Center website maintained by the American Society of Health-System Pharmacists, at <http://www.ashp.org/shortage> (last visited May 25, 2005). The website identifies the short and "long-term unavailability" of common drugs as increasing significantly in the 1990's. Consequences include increases in medication errors and adverse reactions, sub-optimal treatment alternatives and procedure delays. These compromises generate an "economic drain" from the additional staff time involved in tracking shortages and resolving their ultimate impact on patient care.

market.⁶ Research has halted, consumer costs have escalated⁷ and drug access problems reign.⁸ From a public policy perspective, this is a situation with far reaching societal implications.⁹

Part I of this Comment examines historical and present day drug shortages, including factors which contribute to this problem—most notably tort liability. Part II discusses dual regulation of the pharmaceutical industry through the legislative mandates of the Federal Food, Drug and Cosmetic Act (“FDCA”)¹⁰ and state tort drug product liability. Part III considers three alternatives to minimize the impact pharmaceutical tort liability has on the drug industry. Finally, Part IV recommends implementation of a narrowly defined regulatory compliance

6. See Gary J. Spahn & Dabney J. Carr IV, *Runaway Jury Verdicts in Pharmaceutical, Device Cases: A Message Worth Listening to*, PHARMACEUTICAL & MED. DEVICE L. BULL., Feb. 2002, at 1 (citing as examples \$100 million verdict against a manufacturer for “severe gastroesophageal disease,” \$56.5 million and \$13.3 million verdicts involving diet drugs and supplements and a \$6.4 million verdict against a manufacturer of an antidepressant). Even where courts recognize inappropriate damage awards, the cost of appealing verdicts justifies settling out of court for manufacturers unwilling to risk “the legal and financial uncertainties involved.” W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 STAN. L. REV. 547, 584-85 (2000).

7. Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203, 234 (1997) (comparing drug prices in Canada and the United States and positing that the large price differentials observed were explained by the cost of actual and potential liability). This GAO finding demonstrated that the cost of tort liability increased the median price of a drug by one third and doubled the average drug price differential. *Id.*

8. *Drug Access: Shortages of Key Drugs Give Hospitals Headaches*, MED. LETTER ON CDC & FDA, Jan. 19, 2003, at 14 [hereinafter *Shortages Give Hospitals Headaches*]. See also *Drug Shortages Impacting Trauma Centers*, *supra* note 3, at 50 (describing as examples recent shortages of methylprednisolone, hydrocortisone and all vaccines containing tetanus).

9. Public policy implications are seen with common childhood illnesses that are often treated “off-label.” Lauren Hammer Breslow, *The Best Pharmaceuticals for Children Act of 2002: The Rise of the Voluntary Incentive Structure and Congressional Refusal to Require Pediatric Testing*, 40 HARV. J. ON LEGIS. 133, 146 (2003). “We are operating in a vacuum . . . I might be able to treat [children’s] cancer more aggressively, but I don’t know how to safely do that.” *Id.* at 146 (quoting Sheryl Gay Stolberg, *Children Test New Medicines Despite Doubts*, N.Y. TIMES, Feb. 11, 2001, § 1, at 1). See also 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, 206 (1992) (discussing the social costs attributed to the deferral by manufacturers of testing of an HIV vaccine due to the product liability climate); David C. Mowery & Violaine Mitchell, *Improving the Reliability of the U.S. Vaccine Supply: An Evaluation of Alternatives*, 20 J. HEALTH POL. POLY & L. 973, 974 (1995) (citing the importance of an effective immunization program to avoid the cost of responding to an infectious disease outbreak and to general maintenance of the public health).

10. 21 U.S.C. §§ 301-399 (2000).

defense coupled with expansion of incentive programs where research has stalled or liability exposure has driven drug product lines off the market.

I. SIGNS, SYMPTOMS AND THE CULPRIT

The casualties in research and development resulting from tort liability and dual regulation of the pharmaceutical industry span the broad spectrum of drugs and biologicals. Three classes of pharmaceuticals clearly demonstrate the magnitude of this problem: vaccines, reproductive and pediatric drugs.¹¹ Although not limited to these categories, drug shortages, including total abandonment of production, are routine obstacles for physicians and pharmacists in the treatment of patients.¹²

A. *The Vaccine Experience*

Serious injuries from vaccines are rare, but unavoidable.¹³ In spite of this risk, the “undeniable health benefits achieved through [immunization]” make vaccination “among the single most effective [means] of health intervention.”¹⁴ A public health emergency arose in the 1970’s and early 1980’s when the pharmaceutical industry was hit with \$3.5 billion in tort suits alleging injury to children under a mandated immunization program.¹⁵ The exposure to large damage awards provided the economic justification for companies to stop research and production.¹⁶ As a result, vaccine stockpiles declined, prices rose dramatically and industry consolidation occurred.¹⁷ The industry’s

11. See Breslow, *supra* note 9, at 141-42 (discussing the problems surrounding each class of pharmaceuticals).

12. Lars Noah, *Triage in the Nation’s Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 371, 373 (2002); Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 775 (1990) [hereinafter *A Question of Competence*].

13. See Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 313-14 (1999) (noting that fewer than 100 children suffered fatal adverse reactions in over 100 million doses of vaccine administered, with “nonfatal reactions . . . similarly scarce”).

14. Breen, *supra* note 13, at 311-12. Vaccine litigation is an example of a jury’s focus on individual plaintiffs rather than the statistical benefit of vaccines to the public in general. Viscusi, *supra* note 6, at 582. A CDC study concluded that in the “absence of the pertussis vaccine program,” over 320,000 cases of whooping cough would result in 400 deaths annually. *Id.*

15. Breslow, *supra* note 9, at 140-41.

16. Jackson, *supra* note 9, at 205. “There is little doubt that [the] decline in vaccine availability is due to the overwhelming burden of product liability.” *Id.* Jackson cites as one example a punitive damage award totaling two hundred times the vaccine’s annual revenues. *Id.*

17. Breslow, *supra* note 9, at 140-41. During the height of the vaccine crisis the cost of the DPT vaccine rose from \$0.11 to \$11.40; seventy-one percent of

response posed a serious threat to childhood vaccine supplies.¹⁸

To address this threat to pediatric immunization, Congress enacted the National Childhood Vaccine Injury Act ("NCVIA") in 1986.¹⁹ Even with the protection afforded by the NCVIA, today only two manufacturers of the DPT (diphtheria/pertussis/tetanus toxoid) vaccine remain; with a single U.S. supplier of vaccines for MMR (measles/mumps/rubella), influenza and pneumonia.²⁰ Industry consolidation leaves vital vaccine supplies vulnerable to physical plant issues such as maintenance, catastrophic accidents and regulatory compliance concerns.²¹ Limited supplies of certain vaccines have already resulted in "rationing schemes."²²

B. Bendectin—Serving the High-Risk Consumer

Bendectin litigation illustrates why pharmaceutical manufacturers avoid drug development and marketing to one category of high-risk consumers—pregnant women.²³ Bendectin was the only drug marketed to treat morning sickness.²⁴ After allegations arose of birth defects in children born to mothers taking the drug, its manufacturer, Merrell Dow, had to defend over 2,100 lawsuits.²⁵ The Food and Drug Administration ("FDA") launched an investigation into Bendectin's safety but failed to reveal evidence that the drug was a teratogen.²⁶ Consequently, the

this price increase was due to insurance. Noah, *supra* note 12, at 373.

18. Viscusi, *supra* note 6, at 582-83.

19. 42 U.S.C. §§ 300aa-1 to -34. See also Breslow, *supra* note 9, at 141.

20. Noah, *supra* note 12, at 374-75.

21. *Id.*

22. *Id.* at 387-88. The high cost and limited supply of Hepatitis B vaccine, when first introduced, restricted its use to "high-risk groups." *Id.* Physicians have also been advised by the CDC to defer booster immunizations for DPT and tetanus due to short supply. *Id.* Rationing schemes have posed controversial social questions. *Id.* at 386. Where resources are scarce—in this case drugs—society must choose which individuals should get treatment based on such factors as medical need, age or ability to pay. *Id.* To date, medical criteria have formed the basis for handling most "micro allocation problems." *Id.* at 386-87.

23. W. Kip Viscusi et al., *The Effect of Products Liability Litigation on Innovation: Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1474-75 (1994). The withdrawal of Bendectin reaches beyond the singular loss of this drug. *Id.* at 1473-74. It represents the risk that a manufacturer can be held liable in court for products used in pregnancy in spite of an FDA judgment of a drug's safety. *Id.* There is a significant incentive for companies to choose product lines that avoid this degree of risk. *Id.* at 1474-75.

24. See *Brown v. Superior Court of S.F.*, 751 P.2d 470, 479 (Cal. 1988) (citing examples of products which have greatly increased in price or have been withdrawn from the market).

25. Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 319 (1992).

26. A teratogen is an agent causing the development of congenital

drug remained on the market.²⁷

Even with the backing of the scientific community, which found no causal connection between Bendectin's use and fetal deformity, a jury awarded "\$20 million in compensatory and \$75 million in punitive damages" in one case.²⁸ Although Merrell Dow prevailed in its defense of this and other suits on appeal, the manufacturer ultimately elected to withdraw the drug from the market in 1983.²⁹ The costs incurred in securing tort victories accrued to the point where Merrell Dow agreed to a class action settlement of \$120 million.³⁰

C. Other Casualties

Bendectin is not an isolated failure.³¹ For example, the sole manufacturer of Wydase, a treatment for I.V. infiltration, discontinued production and left patients without a comparable alternative treatment.³² Similarly, patients suffering from eye muscle spasm previously aided by Oculinum are now without its benefits.³³ The drug's clinical testing stopped because the manufacturer could not obtain affordable liability insurance.³⁴ These examples demonstrate that where insurance costs exceed a drug's potential value, the balance tips in favor of abandoning the drug and the patients it could help.³⁵

Pharmaceuticals manufactured and marketed for children represent an equally disenfranchised segment of the drug market.³⁶ The size of the pediatric market, the sensitivity

deformities in a fetus. *TABER'S CYCLOPEDIA MEDICAL DICTIONARY*, T-17 (12th ed. 1973).

27. Sanders, *supra* note 25, at 318-19. See also *Richardson ex rel. Richardson v. Richardson-Merrell Inc.*, 857 F.2d 823, 824 (D.C. Cir. 1988) (affirming *j.n.o.v.* for defendant of a \$1 million-plus verdict, noting "FDA approval has never been rescinded").

28. Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits from Driving Good Drugs off the Market*, 40 *CAS. W. RES. L. REV.* 413, 427-28 (1990).

29. *Id.* at 427-28; Sanders, *supra* note 25, at 319. A General Counsel of one manufacturer stated: "There has to come a point with a particular product, even a good product, where you say, that's enough, and you get out of the market." Marc Galanter, *Case Congregations and Their Careers*, 24 *LAW & SOC'Y REV.* 371, 381 (1990) (internal quotations omitted).

30. *A Question of Competence*, *supra* note 12, at 774.

31. Denemark, *supra* note 28, at 428.

32. *Shortages Give Hospitals Headaches*, *supra* note 8, at 15.

33. *A Question of Competence*, *supra* note 12, at 774.

34. *Id.*

35. *Shortages Give Hospitals Headaches*, *supra* note 8, at 14.

36. Karena J. Cooper, *Pediatric Marketing Exclusivity—As Altered by the Best Pharmaceuticals for Children Act of 2002*, 57 *FOOD & DRUG L.J.* 519, 520 (2002). The lack of pediatric studies and corresponding labeling of drugs for pediatric use is premised on several factors. *Id.* In addition to the ethical

associated with testing in children and the level of liability exposure involved are all sufficient incentives to focus the industry on "safer," more lucrative product lines.³⁷ Similar to the exodus that occurred in the contraceptive market,³⁸ drug companies learned a lesson from the vaccine experience. "The industry would be resoundingly punished in the courtroom for injuring women's reproductive capabilities, their fetuses, or their children."³⁹

A quote from the director of pharmacy services at the New Jersey Hospital Association reflects the everyday experience of hospitals dealing with shortages of injectible anesthetics, painkillers, antibiotics and steroids.⁴⁰ "At any given time, it seems there are about four dozen drug items that are near-impossible to get."⁴¹ Therapeutic drug equivalents are not always available. One example of the threat drug shortages pose to patient safety occurred when three San Francisco patients died of bacterial meningitis when a local pharmacy prepared a contaminated mixture as a substitute for an unavailable steroid that the patients required.⁴²

The infrastructure and coping mechanisms available to assist healthcare providers in managing shortages highlights the prevalence of the access problem.⁴³ There is a department in the FDA devoted entirely to managing drug and vaccine supplies.⁴⁴ The FDA and the American Society of Health-System Pharmacists maintain web sites for tracking drug shortages.⁴⁵ The sites also

issues raised with studies involving children, the industry is also concerned with the legal liability associated with pediatric research and the risk of "long-term adverse effects." *Id.* The lack of available pediatric "safety and dosing information" forces physicians into "off-label" prescribing. *Id.* at 520. Of the top ten drugs prescribed for children, six have not been tested in pediatric clinical trials. Breslow, *supra* note 9, at 148. This poses special risks for children as evidenced by instances of teeth staining, seizure reactions, cardiac arrest and even death. *Id.*

37. Breslow, *supra* note 9, at 140-44.

38. Jackson, *supra* note 9, at 204. Investment in fertility and contraception research declined by ninety percent from its peak in the early 1970's. *Id.* A National Academy of Science study confirmed this flight of the pharmaceutical industry from research and development. Breslow, *supra* note 9, at 142. Of eight firms actively involved in this area in the 1970's, within the next decade only Ortho Pharmaceutical Corporation remained. *Id.* Medical injury claims from "defective reproductive drugs and devices" were the largest source of tort recoveries in women. *Id.* at 141-42.

39. Breslow, *supra* note 9, at 142.

40. *Shortages Give Hospitals Headaches*, *supra* note 8, at 14.

41. *Id.*

42. Jillene Magill-Lewis, *Running on Empty: What's Behind the Current Rampant Drug Shortages? Pharmacists Want to Know*, DRUG TOPICS, Sept. 17, 2001, at 36, 44.

43. *Shortages Give Hospitals Headaches*, *supra* note 8, at 15.

44. Magill-Lewis, *supra* note 42, at 37.

45. See the drug shortage bulletin, *supra* note 5, which lists thirty-seven

provide guidelines and information to assist in securing alternative drugs. The Joint Commission on Accreditation of Healthcare Organizations, the body responsible for accrediting U.S. hospitals, requires in its new standards that hospitals have medication management plans for handling drug shortages.⁴⁶

D. *The Culprit*

The scarcity of some drugs, and the stifling of research and development, stems from several sources. Outside the realm of tort liability, manufacturers cite aging physical plants, difficulty securing raw materials, industry regulatory concerns and expiration of patent protections as factors contributing to the current problem.⁴⁷ In addition, there are also a number of issues within the realm of tort liability generating unwelcome risk exposure. Contributors to high damage awards include the rise of mass tort class action suits,⁴⁸ the admissibility and use of scientific evidence⁴⁹ and a system of dual regulation imposed by the FDA and common law.⁵⁰

While several of these factors are worthy of mention to avoid the suggestion that tort liability is the sole precipitating cause of

drugs in short supply as of January 31, 2005. For another listing of drugs in shortage, see the FDA Center for Drug Evaluation & Research webpage at <http://www.fda.gov/cder/drug/shortages/default.htm> (last visited on May 25, 2005).

46. Kathi Gannon, *JCAHO Plans Major Change for Hospital Surveys in 2004*, DRUG TOPICS, Feb. 17, 2003, at HSE23.

47. See Noah, *supra* note 12, at 377-78 (noting that strict control of manufacturing facilities and expiration of patents drive profits down and foster decisions to cease production of certain products); *Shortages Give Hospitals Headaches*, *supra* note 8, at 14 (naming among other contributing factors to shortages: demand spikes, manufacturing interruptions and lack of raw materials); Magill-Lewis, *supra* note 42, at 37 (indicating vulnerability of raw materials due to dependence on foreign suppliers, as occurred with the outbreak of mad cow disease and the interruption of the supply of beef protein needed for manufacture of dexamethasone).

48. Manning, *supra* note 7, at 208. The availability of class action suits in the United States was identified as one difference between the American and Canadian legal systems, which contributes to the greater product liability costs being observed in the United States. *Id.* This is exemplified by the request of plaintiffs' counsel for \$550 million in fees for the handling of the class action litigation of the diet drug fen-phen. *Fen-Phen Plaintiff Attorneys Seek \$550 Million in Fees*, ANDREWS MED. DEVICES LITIG. REP., Mar. 8, 2002, at 1. More recently a trend toward denial of class certification in pharmaceutical tort actions has been seen. Bruce Kaufman, *Emerging Trends in Drug Suits, Combating Punitive Damages*, 31 PROD. SAFETY & LIAB. REP. (BNA) No. 434 (May 19, 2003).

49. See Denmark, *supra* note 28, at 423-25 (discussing the role of expert testimony in finding causation in drug liability cases and the circumstances under which expert testimony may be suspect in those cases).

50. See Manning, *supra* note 7, at 208; Viscusi et al., *supra* note 23, at 1438.

drug and vaccine shortages, it is beyond the scope of this Comment to address them in further detail.⁵¹ The remainder of this Comment focuses on the conflicts created by dual regulation and a comparison of three mechanisms to address pharmaceutical company liability risk.

II. DUAL REGULATION—THE “DOUBLE-EDGED” SWORD

A. The FDA Scheme—“Edge One”

The Federal Food, Drug and Cosmetic Act of 1938 and its subsequent amendments vests the authority to regulate all pharmaceuticals in the FDA.⁵² Through this agency, pharmaceutical manufacturers must submit extensive information to enable the FDA to determine whether the drug in question is safe—that is, whether the drug’s potential benefits outweigh any risks associated with its use.⁵³ Only with an affirmative finding can a drug be licensed for sale.⁵⁴ Completion of the entire approval process for a single new drug costs, on average, \$200 million, and can require as long as twelve years to complete.⁵⁵

In addition to clinical trials, manufacturers must also submit a proposed label in conformance with the FDA’s labeling standards for approval.⁵⁶ The FDA’s control over this aspect of bringing a drug to market is critical to findings of liability.⁵⁷

Regulation of a drug by the FDA does not stop with its approval for sale. The FDA also conducts post-market surveillance to overcome limitations inherent in all pre-market

51. Noah, *supra* note 12, at 377.

52. *A Question of Competence*, *supra* note 12, at 775.

53. *Id.* at 776; Brown, *supra* note 4, at 6.

54. See Vicusi, *supra* note 6, at 580 (commenting that the FDA’s risk-benefit analysis recognizes that drugs are not “risk-free” and their availability rests on what is in “society’s best health interest”).

55. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 486 (1997).

56. FDA regulation requires a drug label to contain the following information: a description, clinical pharmacology, indications and usage, contraindications, warnings, precautions, adverse reactions, drug abuse and dependence, overdosage, dosage and administration and how supplied. 21 C.F.R. § 201.56(d)(1)(2005). By standardizing drug labeling, the FDA assists the physician in processing information on a drug’s known risks through a uniform format and language. Viscusi et al., *supra* note 23, at 1442.

57. The modification of FDA rules now allow a manufacturer to include a warning of an adverse side effect without prior agency approval. 21 C.F.R. § 201.57(e). On a practical basis, this mechanism is seldom utilized out of concern on the part of manufacturers of the need to maintain the FDA’s “goodwill.” Denemark, *supra* note 28, at 431. Additionally, FDA regulations specifically restrict the addition of warnings to known, not theoretical, risks. 21 C.F.R. §201.57(d).

clinical trials.⁵⁸ Pharmaceutical companies and physicians are required to report any adverse drug reactions (“ADRs”) to the FDA.⁵⁹ The submission of ADRs may lead to labeling changes, use restrictions or market withdrawal of the drug.⁶⁰

B. Drug Product Liability—“Edge Two”

Pharmaceutical product liability litigation has historically been treated somewhat differently than the strict liability standard established in section 402A of the *Restatement (Second) of Torts*.⁶¹ Comment (k)⁶² provides an exception to strict liability where a product is deemed to be “unavoidably unsafe.”⁶³ Some courts adopt comment (k) where pharmaceuticals are involved; others confer immunity from strict liability only where adequate warnings are provided; still others decide the issue “on a case-by-case basis.”⁶⁴

The more recently adopted *Restatement (Third) of Torts* section 6 provides another framework for courts to apply.⁶⁵ A

58. Brown, *supra* note 4, at 7; *A Question of Competence*, *supra* note 12, at 777. The limitations of clinical trials to identify all potential “risks associated with use of a drug” include the homogeneity of the population comprising the study group as compared to the population who will use the drug; the rare frequency of some complications which may not occur during the testing period; and the difficulty in anticipating certain side effects and a mechanism to detect these during the investigation. Green, *supra* note 55, at 496.

59. Viscusi et al., *supra* note 23, at 1446-47.

60. *See id.* at 1447-48 (discussing “post-marketing labeling changes”).

61. *Id.* at 1457-59.

62. Comment (k), entitled “Unavoidably unsafe products,” provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use [B]ecause of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or . . . purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending to their use.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

63. Viscusi et al., *supra* note 23, at 1457-58.

64. Brown, *supra* note 4, at 17-18. The lack of predictability under varying liability rules has contributed to an increase in the cost and complexity of litigation. “As a result, the total transaction costs of litigation now exceed the total recoveries of all claimants.” Viscusi et al., *supra* note 23, at 1461. *Compare Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) (adopting comment (k) defense where a drug is properly manufactured and includes proper warnings), *with Feldman v. Lederle Labs.*, 479 A.2d 374, 383 (N.J. 1984) (holding that as a “matter of law and policy” that all prescription drugs are not unavoidably unsafe; it is instead a case-by-case determination).

65. The section provides:

(a) A manufacturer of a prescription drug . . . who sells or otherwise distributes a defective drug . . . is subject to liability for harm to persons caused by the defect

(b) For purposes of liability under Subsection (a), a prescription drug . . .

manufacturer's compliance with FDA requirements would be "relevant and admissible" concerning the proper standard of care to be met, but "not dispositive."⁶⁶ Under section 7, comment (e), courts may selectively treat compliance with a specific regulation in a products liability action as conclusive if it is "current, protective, salient and the product of untainted regulatory expertise."⁶⁷

As with any product liability action, drugs may be considered defective in design, manufacture or for failure to warn.⁶⁸ On a practical basis, compliance with FDA required good manufacturing practice⁶⁹ standards limits litigation in the area of drug design and manufacturing defects.⁷⁰ The very nature of drug composition does not lend itself to alternative design, as might be expected with

is defective if at the time of sale or other distribution the drug . . . :

- (1) contains a manufacturing defect . . . or
- (2) is not reasonably safe due to defective design . . . or
- (3) is not reasonably safe due to inadequate instructions or warnings . . .

(c) A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers . . . would not prescribe the drug . . . for any class of patients.

(d) A prescription drug . . . is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- (1) prescribing . . . health-care providers . . . or
- (2) the patient . . .

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998). See *Stahl v. Novartis Pharm.*, 283 F.3d 254, 267 (5th Cir. 2002) (citing section 6 of the *Restatement (Third) of Torts* and Louisiana product liability requirement that a warning must be "adequate to reasonably inform the recipient" of the risks). But see *Vitanza v. Upjohn Co.*, 48 F. Supp. 2d 124, 129 n.6 (D. Conn. 1999) (discussing Connecticut drug product liability law and the court's adherence to section 402A of the *Restatement (Second)* over *Restatement (Third)*).

66. Green, *supra* note 55, at 462.

67. *Id.* at 465-66.

68. Brown, *supra* note 4, at 18.

69. 21 C.F.R. §§ 211.1-.208. The FDA established comprehensive and detailed regulations described as "good manufacturing practice" standards for all pharmaceutical manufacturers to follow. *Id.* These regulations encompass standards for personnel, facilities, equipment, control of components, production and process control, packaging and distribution, laboratory controls, records and reports and returned and salvaged drug products. *Id.*

70. See Brown, *supra* note 4, at 18 (discussing the areas of design and manufacturing defects). Manufacturing defects in the scheme of drug product litigation seldom occur and are ordinarily not controversial; instead the drug simply "fail[s] the manufacturer's own standards." *Id.* "The Restatement Third § 8(b)(1) imposes strict liability for [pharmaceutical] manufacturing defects." Green, *supra* note 55, at 470-71. Design defect claims are similarly uncommon. *Id.* at 471-73.

other durable good “design claims.”⁷¹

Thus, the vast majority of drug product liability falls under the rubric of failure to warn; be it accuracy, adequacy or timeliness.⁷² Given the previously noted control of the FDA with regard to drug labeling, the tension between complying with FDA requirements and the decisions of a common law jury as to what is an adequate warning leave the industry grappling with this “double-edged sword.”⁷³

III. ALTERNATIVE APPROACHES: A CURE FOR WHAT AILS US

Having considered the background and impact of tort liability on drug access and innovation, an analysis of three different approaches for addressing this issue follows. Two alternatives, the regulatory compliance defense and the no-fault compensation model, limit liability by changing tort rules.⁷⁴ A third alternative, the voluntary incentives approach, works indirectly on the liability problem by providing financial incentives to stimulate

71. See Green, *supra*, note 55, at 471-72 (noting the *Restatement (Third)* does impose liability for a design defect “without proof of an alternative design” where a court determines a drug’s overall risks outweigh its benefits).

72. *Id.* at 472-73. The sufficiency of the label with respect to failure to warn liability provides a strong incentive for manufacturers to add any possible negative side effects. Jackson, *supra* note 9, at 212-13. FDA regulations are intended to control this tendency to avoid information overload and the potential for serious warnings to be glossed over. *Id.* See also Carlin v. Superior Court, 920 P.2d 1347, 1352 (Cal. 1996) (noting manufacturers are prevented by FDA regulation from including warnings concerning “every conceivable adverse reaction”).

73. Viscusi, *supra* note 6, at 585-86. A target for liability actions in the mid-80’s, pharmaceutical manufacturers were sued in federal court with “higher mean damages awards relative to sales than the rest of the U.S. manufacturing sector.” *Id.* at 585. Their “ratio of liability costs to sales . . . dwarfed that for the rest of the manufacturing industries in the U.S.” *Id.* In spite of more recent settlements, potentially destructive exposure exists. *Id.* at 586. An example of the tension created by dual regulation is evidenced in a jury award of \$3.1 million in compensatory and \$124.5 million in punitive damages to a plaintiff who was blinded when inadvertently injected in the eye with Depo-Medrol. Joseph A. Mahoney, *Senate Bill 640: Proposed Federal Product Liability Reform and Its Potential Effect on Pharmaceutical Cases and Punitive Damages*, 36 ST. LOUIS U. L.J. 475, 475 (1991). The trial judge precluded admissibility of evidence that the manufacturer had requested the inclusion of a disclaimer on the label that uses around the eye were not approved. *Id.* at 476. The FDA denied the requested label modification. *Id.* Here the manufacturer’s full compliance with the FDA’s labeling standards resulted in a failure to warn and tort liability as assessed by the court. *Id.* at 475-76.

74. Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994) (discussing the National Childhood Vaccine Injury Act as a no-fault remedial scheme). See also Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 SETON HALL L. REV. 1481, 1484 (1994) (discussing regulatory compliance and the limits on liability it should have).

pharmaceutical company investment in research, development and manufacture of otherwise financially unattractive drug product lines.⁷⁵ With a problem of this complexity, a cure requires more than one approach.

A. *Regulatory Compliance Defense—Preemption Revisited*

To eliminate the conflict existing between compliance with the FDA and state tort law, many legal commentators advocate adoption of an “FDA” or regulatory compliance defense⁷⁶ under the doctrine of preemption.⁷⁷ Where pharmaceutical manufacturers fully comply with FDA regulations, a regulatory compliance defense would “insulate” them from tort liability and exposure to punitive damages.⁷⁸

Current FDA regulations do not provide for express preemption of state tort liability.⁷⁹ The limited application of preemption thus far depends upon the actions of a few state legislatures⁸⁰ and the interpretation of the courts.⁸¹ In the latter

75. Cooper, *supra* note 36, at 519.

76. Jackson, *supra* note 9, at 224-25.

77. See John F. Del Giorno, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Product Liability Cases*, 22 J. MARSHALL L. REV. 629, 635-36 (1989)(stating that under authority of the Supremacy Clause, when Congress legislates “in a field of dominant federal interest,” state laws pertaining to this field are not enforceable, and are thus preempted).

78. Green, *supra* note 55, at 464-65.

79. *A Question of Competence*, *supra* note 12, at 786.

80. See ARIZ. REV. STAT. § 12-701 (2003) (providing protection from punitive damages where manufacturers receive approval from the FDA and have not misrepresented or withheld information known to be “relevant to the harm . . . plaintiff allegedly suffered”); UTAH CODE ANN. § 78-18-2 (2003) (providing that punitive damages may not be awarded where manufacturer has “received premarket approval or licensure” by the FDA and has not “knowingly withheld or misrepresented information . . . relevant to the claimant’s harm”); OR. REV. STAT. § 30.927 (2001) (providing no liability for punitive damages where drug is “recognized as safe and effective pursuant to . . . [FDA] regulations” and manufacturer did not knowingly withhold or misrepresent information to the FDA or physician); N.J. STAT. ANN. § 2A:58C-4 (West 2000) (precluding liability for “harm caused by a failure to warn if the product contains an adequate warning” and providing a rebuttable presumption that compliance with FDA standards is an adequate warning).

81. The court in *Ehlis v. Shire Richwood, Inc.* granted summary judgment for a manufacturer on a products liability claim stating “[t]he FDA dictates the contents of the label for Adderall(R) and defendants were prohibited from changing it without prior approval from the FDA This concept sounds in preemption.” 233 F. Supp. 2d 1189, 1197-98 (D.N.D. 2002). In a products liability action involving implantable contraceptive capsules, the court stated “[f]or all practical purposes, absent deliberate concealment or nondisclosure of . . . harmful effects, compliance with FDA standards should be virtually dispositive of such claims.” *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1259 (N.J. 1999).

case, common law precedents follow an anti-preemption presumption in areas of public health and safety—traditional state concerns.⁸² Even in cases where courts acknowledge that tort liability exposure may have detrimental effects on drug access and cost, they dismiss this impact as “too speculative for judicial consideration.”⁸³

Critics of the FDA defense, in relying on the common law, claim that FDA regulations are designed only as minimum standards.⁸⁴ Further, the resources of the FDA are insufficient to meet the demands of the agency functioning as the sole protector of the healthcare consumer.⁸⁵ Without the overarching deterrence provided by tort liability, the FDA is more vulnerable to agency capture—where the FDA is “controlled” by the industry it is charged with regulating.⁸⁶

Lastly, opponents of a regulatory compliance defense point to the differing goals of dual regulation. Imposition of an FDA defense would defeat the objective of a tort system which focuses on compensating the individual victim injured by a defective drug.⁸⁷ In contrast, the FDA makes global risk-benefit determinations to insure the safety of a drug for use by the general public.⁸⁸

Proponents of preemption cite the pervasiveness of the FDA’s regulation and challenge those who characterize compliance as meeting only minimum standards.⁸⁹ Given the general exclusion

82. *Caraker v. Sandoz*, 172 F. Supp. 2d 1018, 1032 (S.D. Ill. 2001) (“In the absence of express preemption, there is a strong ‘basic assumption’ that Congress did not intend to displace state law.”).

83. *A Question of Competence*, *supra* note 12, at 787.

84. *See Gilhooley*, *supra* note 74, at 1485 (claiming that even courts view FDA labeling as minimal); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO L.J. 2147, 2152 (2000) (arguing that courts should take safety standards more seriously, even though there is no obligation to do so).

85. *See Gilhooley*, *supra* note 74, at 1488 (discussing the ALI Reporters Study finding that a compliance defense should apply only where there are adequate resources within the FDA to receive and evaluate product information from the industry); Green, *supra* note 55, at 476 (citing a 1991 FDA study finding that the agency’s mandate for regulation of drugs far exceeds its funding).

86. *Gilhooley*, *supra* note 74, at 1489.

87. *Jackson*, *supra* note 9, at 221-22 (commenting that the state’s interest in compensating drug related injury in a tort action is in opposition to the federal interest of insuring a safe drug supply).

88. *Id.* The broader focus on “safety questions” by the FDA is preferable to regulatory impact created by a jury “fixated” on a “needy plaintiff” and awarding damages without, in some cases, regard for product defect or causation. Noah, *supra* note 84, at 2163.

89. *Viscusi et al.*, *supra* note 23, at 1478 (commenting “the FDCA does not establish minimum standards for prescription drug[s]”); *Jackson*, *supra* note 9, at 217-18 (noting “the FDA and manufacturers . . . regard regulatory oversight

of drugs from strict liability, a manufacturer's compliance with FDA requirements effectively negates any "conscious, flagrant indifference" on the part of the manufacturer in the design, manufacture and labeling of the drug.⁹⁰ Advocates of preemption also emphasize that where a manufacturer is guilty of fraud or misrepresentation, the protections of an FDA defense are lost.⁹¹

A jury finding of negligence is, in effect, saying the "thorough and painstaking" review and approval of the FDA is wrong.⁹² The ability of a lay jury to assess complex information required in determining the safety and efficacy of a drug as compared to the institutional competence of the FDA is questionable at best.⁹³ Somewhat paradoxically, courts consider failure to comply with FDA regulations as negligence per se.⁹⁴ This failure equates to an absence of reasonable care.⁹⁵ It is inconsistent to hold that a manufacturer's compliance with FDA requirements is merely "some evidence," but not presumptive of reasonable care.⁹⁶

B. No-Fault Compensation—The National Childhood Vaccine Injury Act

Congressional response to the vaccine crisis of the 1970's and 1980's resulted in the passage of the NCVIA in 1986.⁹⁷ The Act sought to stabilize the vaccine market and encourage further research and development through a no-fault compensation scheme that modified traditional tort actions.⁹⁸ The Act established special claims procedures requiring an injured party to seek redress through the "Vaccine Court" before pursuing any other civil remedy.⁹⁹ An advantage for plaintiffs is the expedited processing of claims without the need to prove causation where an

as a comprehensive determination of safety").

90. Mahoney, *supra* note 73, at 512.

91. Viscusi et al., *supra* note 23, at 1478 (seeing tort liability as an effective regulatory measure only in situations where a drug manufacturer has misrepresented information or behaved fraudulently with respect to its obligations under the FDCA).

92. Mahoney, *supra* note 73, at 512.

93. Jackson, *supra* note 9, at 218-19. Jackson discusses the incongruity of case-by-case jury determinations made with the "bright light of hindsight" on small samples of data with the complex, multidisciplinary FDA evaluation that a new drug application must complete to determine the safety and efficacy of the product. *Id.* Where jury findings contradict the FDA's labeling requirements the scientific basis for adequate warning to physicians is supplanted. *Id.* at 219-20.

94. Mahoney, *supra* note 73, at 513 & n.320.

95. *Id.*

96. *Id.*

97. Breslow, *supra* note 9, at 141.

98. Schafer, 20 F.3d at 2-3.

99. *Id.*

“on-table” injury exists.¹⁰⁰ The calculation of damages follows a formula provided in the Act and are paid out of a fund created from excise taxes assessed on vaccines administered and covered under the program.¹⁰¹

The Act provides a presumption of adequate warning when a manufacturer complies with the FDA’s requirements.¹⁰² It limits punitive damages and precludes compensation for injuries resulting from “unavoidable side effects.”¹⁰³ Following NCVIA’s implementation, vaccine prices stabilized, immunization rates improved and vaccine development resumed.¹⁰⁴ The large vaccine jury awards of the past disappeared under the more predictable exposure of this no-fault program.¹⁰⁵

Notwithstanding NCVIA’s accomplishments, this no-fault system is not a panacea. While claim processing is faster, as compared with traditional tort litigation, the program still struggles with proof of causation and inherent limits to the vaccine injury table that attempts to deal with this issue.¹⁰⁶ Petitioners see more than two-thirds of filed claims dismissed,¹⁰⁷ while the industry remains cautious of risk exposure for vaccines not covered under the legislation.¹⁰⁸ Further manufacturer consolidation and economic decisions to abandon these product lines in favor of more profitable classes of drugs eroded the early gains made by NCVIA with respect to stabilizing the vaccine market.¹⁰⁹

The government’s involvement in providing an alternative to tort liability is unique for vaccines because of mandated immunization.¹¹⁰ Declines in immunization rates have significant public health implications and provide a strong incentive for

100. Derry Ridgway, *No Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL’Y & L. 59, 63 (1999). The statute provides a rebuttable presumption of causation where the vaccine is included in the table and the type of injury occurred within the specified time period from inoculation. *Id.*

101. *Id.* at 64. Compensation under the NCVIA “includes nonreimbursable medical expenses, rehabilitation, lost wages, and a pain and suffering award that may not exceed \$250,000.” Jackson, *supra* note 9, at 224.

102. *Schafer*, 20 F.3d at 3.

103. *Id.*

104. Ridgway, *supra* note 100, at 76-77.

105. *Id.* at 77-78.

106. *See* Breen, *supra* note 13, at 326-28 (claiming the “system of recovery” is unfair with respect to the discretion of the special master, timing requirements and the structure of the table); Ridgway, *supra* note 100, at 71, 73-74 (discussing differences and difficulties of “legal and scientific causal reasoning” under the NCVIA).

107. Breen, *supra* note 13, at 320.

108. Noah, *supra* note 12, at 393.

109. *Id.* at 374 (commenting “[t]he [NCVIA] helped to stabilize the pediatric vaccine market, but supply problems persist”).

110. *Schafer*, 20 F.3d at 2.

government protection of the vaccine supply.¹¹¹ Unlike other drugs that are taken or administered voluntarily, the mandate of immunization creates a “societal obligation” to compensate those unavoidably injured by vaccination.¹¹²

The question remains whether the legislature is willing to intervene and provide liability protection mechanisms for other classes of drugs where there is a choice whether to “consume” the product.¹¹³ With an industry that today is viewed by many as profit driven, and more than able to afford the risk attendant to its sales, public perception of drug manufacturers is not as favorable as it once was.¹¹⁴

C. Voluntary Financial Incentives—The Best Pharmaceuticals for Children Act

To avoid the significant risk of tort liability in a small market segment of pharmaceuticals, drug companies avoided testing and marketing their products for children.¹¹⁵ This condones a practice of “off-label” prescribing and leaves physicians guessing as to proper pediatric dosing.¹¹⁶ Rather than tackle tort exposure directly as a solution, legislation focused on an incentive system

111. Noah, *supra* note 12, at 375 (noting that vaccine shortages have the potential to undue the “gains made against infectious disease” in the last fifty years).

112. Ridgway, *supra* note 100, at 79; Schafer, 20 F.3d at 2 (stating that the government’s vaccination mandate imposed a concomitant responsibility to provide compensation to those injured as a result of complying).

113. Ridgway, *supra* note 100, at 83. In discussing the applicability of the NCVIA as a model for other no-fault coverage, Ridgway remarks that vaccines are the only product whose use is mandated by law and that this status creates a powerful argument for their “special treatment.” *Id.*

114. Spahn & Carr, *supra* note 6, at 2. Pharmaceutical manufacturers have been swept along in the tarnishing of healthcare’s image as a result of managed care and “exploding” costs. *Id.* The media, politicians, attorneys and consumer groups have “regularly accuse[d] the pharmaceutical and medical device industry . . . of sacrificing safety for the sake of large, ‘unfair’ profits.” *Id.* The industry has responded through direct-to-consumer public relations efforts of their own. *Id.* at 3. The FDA and the drug industry are currently attempting to thwart the implementation of an internet-based prescription service that allows employees of Springfield, Massachusetts to buy their drugs from Canada at savings of thirty-five to sixty percent. Mike Dorning, *Town Leaps at Canadian Drugs*, CHI. TRIB., Oct. 14, 2003, § 1, at 1. The plan is projected to save the city \$9 million annually in drug expenditures. *Id.*

115. Breslow, *supra* note 9, at 140-42. In addition to the industry’s unfavorable tort experience with pediatric vaccines, the unwillingness of pharmaceutical manufacturers to test drugs in children is linked to a similar high-risk exposure involving “women’s reproductive systems.” *Id.* at 141-42. Pharmaceutical manufacturers avoid pediatric testing and labeling of their products due to legal liability from clinical trials; perceived delays in the approval process; ethical issues where children are study participants and the supply of qualified pediatric investigators. Cooper, *supra* note 36, at 520.

116. Breslow, *supra* note 9, at 140-41, 146-47.

for pharmaceutical manufacturers.¹¹⁷

The Best Pharmaceuticals for Children Act of 2002 ("BPCA"), passed as successor legislation to the Food & Drug Administration Modernization Act of 1997 ("FDAMA").¹¹⁸ The BPCA continues a voluntary incentive program that began under the FDAMA for pharmaceutical manufacturers to conduct pediatric studies in exchange for six months of exclusivity or patent extensions for already marketed drugs.¹¹⁹ The BPCA also provides funding for public and private testing on drugs that pharmaceutical companies opt not to study.¹²⁰

Currently, incentive program results indicate that the BPCA has succeeded in building a more vigorous pediatric research infrastructure.¹²¹ Labeling of drugs for pediatric use increased.¹²² However, as with the no-fault compensation alternative, the incentive program approach has its drawbacks.¹²³

Critics of the BPCA take issue with the windfall profits garnered by pharmaceutical manufacturers through their participation.¹²⁴ The costs of conducting studies for pediatric applications are dwarfed by the return of profits in the hundreds of millions of dollars through patent extensions.¹²⁵ As an example, the value of patent extensions for several common drugs yielded as much as \$900 million to \$1.4 billion in additional revenue.¹²⁶ By contrast, the average cost to study a drug for pediatric use ranges from \$500,000 to \$20 million, with an average per study cost of

117. Cooper, *supra* note 36, at 519.

118. Breslow, *supra* note 9, at 133-34.

119. *Id.*

120. *Id.* at 134. "Congress appropriated \$200 million" in 2002 for taxpayer supported pediatric testing for studies that the pharmaceutical manufacturers elected not to conduct. *Id.* at 134.

121. *Id.* at 164 (noting testing capacity for pediatric studies at the National Institute for Children's Health and Development increased from seven to thirteen units to accommodate need in working with pharmaceutical companies); Christopher-Paul Milne, *Exploring the Frontiers of Law and Science: FDAMA's Pediatric Studies Incentive*, 57 FOOD & DRUG L.J. 491, 499-500 (2002) (reporting results of the Tufts CSDD survey indicating a doubling in the number of pediatric studies to be initiated under BPCA as compared with studies begun under the FDAMA).

122. Breslow, *supra* note 9, at 164.

123. *Id.* at 165. (noting problems in exclusivity under FDAMA related to windfall profits from patent extensions, lack of incentives to ensure neonatal testing, "failure to address off-patent and off-exclusivity drugs" and insufficient means to require pediatric labeling). *Id.* at 165-66.

124. *Id.* at 167.

125. *Id.* at 168.

126. *Id.* (estimating revenue gains from pediatric exclusivity protection at: Claritin—\$975 million, Prozac—\$831 million, Glucophage—\$648 million, Pepcid—\$290 million, Vasotec—\$318 million and Buspar—\$284 million (citing Rachel Zimmerman, *Child Play: Pharmaceutical Firms Win Big on Plan to Test Adult Drugs on Kids*, WALL ST. J., Feb. 5, 2001, at A1)).

\$3.87 million.¹²⁷

Ultimately, the cost of incentives provided under the BPCA is shouldered by the consumer, most notably seniors, who pay higher drug prices while generic alternatives experience delayed introduction into the market.¹²⁸ With Congress' recent action to implement prescription drug coverage for seniors, this particular criticism of pediatric exclusivity may be somewhat mitigated.¹²⁹

Advocates of the BPCA, including the American Academy of Pediatrics, point to the program's favorable impact on pediatric research and testing.¹³⁰ An FDA study of five pediatric illnesses attributed a "substantial portion of th[e] higher hospitalization rate[s] [experienced in children] to the lack of informed drug treatment."¹³¹ The FDA projected that a twenty-five percent reduction in the disparity between adult and pediatric admissions for just those illnesses studied would yield annual savings of \$228 million.¹³²

In this example, the benefits of an industry incentive program can be measured with some reasonable degree of certainty. The un-quantified cost of drugs that are not available because of research and innovation abandoned or never undertaken due to unacceptable liability risk should also be considered in this equation.¹³³ Those who support the voluntary incentives offered under the BPCA consider what price to place on a child's health.¹³⁴ Opponents of an incentive approach claim consumers are paying the drug companies to do something, in this case pediatric testing, which is already their ethical and regulatory obligation.¹³⁵ Regardless of the merits of either argument, pharmaceutical

127. Milne, *supra* note 121, at 501.

128. Cooper, *supra* note 36, at 540-41. By granting or extending patent exclusivity under the BPCA, delays in the availability of generic substitutes occur. *Id.* This places a disproportionate cost burden on the elderly and those without health insurance. *Id.* at 541. See also *Nat'l Pharm. Alliance v. Henney*, 47 F. Supp. 2d 37, 41 (D.D.C. 1999). In a suit by manufacturers of generic drugs against the FDA, concerning the agency's interpretation of the FDAMA, the court held "the loss of six months" profit due to the grant of patent exclusivity to an innovator drug manufacturer would not result in "business failures" or insurmountable obstacles to introduction of generic producers' products to market. *Id.* Further, the court noted the detrimental impact on generic drug producers was considered by Congress at the time the FDAMA was enacted. *Id.*

129. Cooper, *supra* note 36, at 541; *Patches for the Drug Program*, N.Y. TIMES, Jan. 25, 2004, § 4, at 14.

130. Breslow, *supra* note 9, at 162-63.

131. *Id.* at 164.

132. *Id.*

133. Viscusi et al., *supra* note 23, at 1445.

134. Breslow, *supra* note 9, at 163 (describing pediatrician comments that industry benefits under the BPCA is justified in light of the gains in pediatric information and research realized).

135. *Id.* at 163, 192.

companies have the ultimate choice whether or not to produce a drug. If tort liability risk significantly compromises profitability, altruism will not trump shareholder accountability.¹³⁶

IV. A RECOMMENDED PRESCRIPTION

A multi-faceted approach is required to successfully address the unfavorable impact of tort liability on the pharmaceutical industry.¹³⁷ Implementation of an FDA defense coupled with appropriately tailored incentive programs can create the requisite business environment to a pharmaceutical company's decision to pursue development and marketing of otherwise unprofitable drugs and vaccines. The implementation of preemption legislation and incentive measures represent a substantial, though not total, solution to the drug access and innovation dilemma.¹³⁸ Like most complex problems, resolution must begin with incremental, yet significant, progress.

A. *Changing the Tort Rules*

The significant advantages of assigning decisions regarding drug safety to the institutional competence of the FDA far outweigh the usurpation of the jury in a common law action.¹³⁹ Pharmaceutical product liability has been a costly, inefficient and largely ineffective means of promoting the public health and the manufacture of safer drugs.¹⁴⁰ To avoid the conflicts of dual regulation,¹⁴¹ an FDA defense should be provided where

136. Magill-Lewis, *supra* note 42, at 36-38.

137. See Noah, *supra* note 12, at 403 (identifying steps the government could take to improve the "business climate" including tort liability protection, flexibility in regulation of manufacturing facilities, increasing emergency drug stockpiles and avoiding government cost containment through overly aggressive price controls).

138. *Id.* at 402-03.

139. See Viscusi, *supra* note 6, at 586, 589 (claiming jurors improperly assess risk and cost-benefit analyses, which provided further justification for deferring to regulatory agencies the responsibility of "detering corporate misbehavior"). An example of the uncertain liability in tort actions is seen in the decision in *Wells v. Ortho Pharm. Corp.*, 615 F. Supp 262 (1985). Ignoring scientific evidence which showed no connection between the use of spermicidal jelly and the alleged birth defect, the judge ruled against Ortho in a multi-million dollar judgment on the basis of the "demeanor and tone" of the expert witness. Brown, *supra* note 4, at 27-28. The case has not since been followed, even in the district rendering the decision. *Id.*

140. See *A Question of Competence*, *supra* note 12, at 784 (citing the inefficiency of the tort system and its failure to provide compensation to a large number of injured); Viscusi et al., *supra* note 23, at 1480 (noting the "perverse incentives" and social harm which occurred in the Bendectin and DPT vaccine litigation); Jackson, *supra* note 9, at 237 (claiming "regulation" imposed by the common law is an inadequate compensatory mechanism and "risk deterrent").

141. See *A Question of Competence*, *supra* note 12, at 773 (describing dual

pharmaceutical manufacturers fully comply with all agency requirements for testing, reporting and surveillance.¹⁴² However, this affirmative defense would not be available where a manufacturer is guilty of fraud or misrepresentation with respect to its compliance with FDA regulations, or where the FDA itself was “errant” in its judgment.¹⁴³ In these circumstances compensation for an individual’s drug related injuries would not be precluded.¹⁴⁴

To respond to those legitimate concerns regarding the ability of the FDA to assume a heightened protector role, adoption of preemptive legislation should also include provisions for increased agency funding and staffing resources.¹⁴⁵ These will ensure adequate resources for effective oversight following new drug application approval and post-clinical trial period when many safety issues are first identified.¹⁴⁶ To mitigate perceptions of agency capture, Congress should avoid further expansion of pharmaceutical industry funding of FDA operations to ensure autonomy of the agency in its regulatory role.¹⁴⁷

The choice of an FDA defense over the expansion of no-fault compensation programs modeled after the NCVIA is predicated on the broader application that tort protection preemption legislation

regulation as the confrontation of tort liability and FDA compliance giving rise to higher costs, adverse impact on drug research and development and interference with the objectives of the FDA).

142. Viscusi et al., *supra* note 23, at 1478; Viscusi, *supra* note 6, at 588; Brown, *supra* note 4, at 40. Some advocates of an FDA defense limit preemptive effect to the award of punitive damages only as exemplified by a handful of states (Arizona, New Jersey, Ohio, Oregon and Utah) passing legislation to that effect. *Id.*

143. *A Question of Competence*, *supra* note 12, at 791-93. The courts have historically considered failure to abide by the regulations of the FDA as negligence per se. *Id.* at 791. Additionally, improper decision made by the FDA must be included as a basis to circumvent preemption, allowing a private action to proceed. *Id.*

144. *Id.* at 793.

145. Gilhooley, *supra* note 74, at 1488. *See also* Green, *supra* note 55, at 476 (quoting an FDA study that the agency cannot “execute all of its statutory responsibilities within the limitations of existing resources”).

146. *Id.* at 498-99. Legal requirements to do so aside, there is evidence of under-reporting of adverse drug reactions. *Id.* at 499. The FDA currently lacks sufficient resources to monitor compliance and assess the reported information and its implications on a drug’s use and labeling. *Id.*

147. Alison R. McCabe, *A Precarious Balancing Act—The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 SUFFOLK U. L. REV. 787, 792-93 (2003). To respond to public criticism regarding the time required for FDA approval of a drug, Congress enacted the Prescription Drug User Fee Act which assesses a user fee on pharmaceutical companies submitting new drug applications. *Id.* The money received from the drug industry is used to expand FDA resources. *Id.* The FDA’s dependency on these funds has generated concern that the FDA’s role as an independent regulator may be compromised. *Id.* at 818-19; Milne, *supra* note 121, at 512.

affords.¹⁴⁸ While successful in addressing the vaccine crisis, no-fault compensation programs are less attractive where there are no public health mandates justifying direct government involvement in the tort scheme.¹⁴⁹ No-fault compensation programs continue to wrestle with issues of scientific versus legal causation even in programs like the NCVIA, where there is a common basis for identifying and categorizing immunization injuries.¹⁵⁰

These issues—the lack of public policy favoring government assumed liability and the difficulty of issues of proof that remain in no-fault schemes—limit the application of no-fault compensation alternatives as a remedy for tort liability.¹⁵¹ The enactment of a federal standard with respect to drug product liability through adoption of an FDA defense will create the needed uniformity missing from fragmented, state-based tort reform.¹⁵²

B. *Adjunct Therapy: Incentive Alternatives*

It is recommended that in order to augment the benefits derived from the implementation of an FDA defense, it should include selective incentive programs modeled after those developed for pediatric drugs. The greater degree of certainty resulting from elimination of dual regulation is insufficient to stimulate research and development among certain categories of drugs and biologicals without additional incentives.¹⁵³

Incentive programs should be offered where the pharmaceutical industry abandoned or avoided investment due to risk and its negative impact on profit.¹⁵⁴ A balance must be struck in crafting incentives to provide sufficient rewards in order to generate a reasonable return on investment without creating the

148. See Noah, *supra* note 12, at 392-94 (citing liability concerns of vaccine manufacturers for those products not covered under the NCVIA).

149. See generally Denis J. Hauptly & Mary Mason, *The National Childhood Vaccine Injury Act*, 37 FED. B. NEWS & J. 452 (1990).

150. *Id.* (suggesting no-fault programs work only where formulas can be applied, such as the “table” used to establish presumptive causation of vaccine injury); Ridgway, *supra* note 100, at 71, 73. Even with the injury table, Ridgway notes that determination of causation remains a problem for the NCVIA. *Id.* Elimination of “case-by-case scientific determinations of eligibility” is necessary for an effective no-fault compensation model. *Id.* at 87.

151. Ridgway, *supra* note 100, at 80, 83.

152. Viscusi et al., *supra* note 23, at 1477.

153. Noah, *supra* note 12, at 402-03; Brown, *supra* note 4, at 46 (noting the provision of financial incentives without protection for tort liability will leave the problem only partially resolved).

154. See Brown, *supra* note 4, at 32, 38 (describing the abandonment of research and development in the field of contraception and recommending, among other remedies, inclusion of the drug product line in an incentive-type program).

windfall profits that fuel legitimate criticism of such programs.¹⁵⁵

Incentives must be structured to stimulate investment in those specific drugs and drug product lines where there is a true need for attention.¹⁵⁶ A criticism of the earlier pediatric exclusivity legislation was the ability of the manufacturer to complete studies and receive patent protections for drugs with minimal benefit for the pediatric population.¹⁵⁷ Where patent protections form the basis of incentives, expertise within the FDA on patent law can assist in controlling potential abuse.¹⁵⁸

Limitations on incentives must also be built into a program's design.¹⁵⁹ Options include caps on profits realized through participation (including guarantees on market exclusivity), reimbursement linked to any favorable economic impact on healthcare spending generated by the studies and labeling changes, and incentive compensation based on a multiplier of a manufacturer's research and development costs.¹⁶⁰

Committed collaboration must occur among pharmaceutical manufacturers, the FDA and the medical community. As with the BPCA, time limits should be established to formally assess any incentive program's effectiveness to insure it yields results justifying the financial rewards it provides.¹⁶¹ Pharmaceutical companies must behave responsibly to avoid the conclusion that incentive programs are merely political favors granted to an

155. See Breslow, *supra* note 9, at 189 (discussing the extraordinary costs born by consumers under the BPCA).

156. McCabe, *supra* note 147, at 813; John D. Pinzone, Note, *The Affordable Prescription Drug Act: A Solution for Today's High Prescription Drug Prices*, 16 J.L. & HEALTH 145, 167 (2001). An NIHC study recently confirmed that direct-to-consumer advertising accounts for a majority of spending from new drug profits. The funds generated from patent protection are now diverted from research and development to marketing of pharmaceutical products. *Id.*

157. Breslow, *supra* note 9, at 171-72. Under the FDAMA, pharmaceutical manufacturers were eligible for six-month patent extensions on the completion of pediatric studies without a requirement for label changes. *Id.* at 171. Consequently, the FDA encountered resistance to requested label changes with "unfavorable pediatric research results." *Id.* In just two studies where no labeling changes resulted, manufacturers garnered \$2.3 billion in patent extension benefits. *Id.* at 172. With enactment of the BPCA, stronger measures have been instituted to allow the FDA to declare a drug misbranded if the manufacturer refuses to make recommended labeling changes. *Id.* at 175.

158. McCabe, *supra* note 147, at 818.

159. See Breslow, *supra* note 9, at 183-84 (discussing the House debate on the BPCA and its disproportionate cost to consumers for pediatric pharmaceutical research).

160. *Id.* at 184, 189.

161. *Id.* at 181. The BPCA contains a sunset clause and a mandate to HHS and the Comptroller General to prepare a comprehensive report on the effectiveness of the legislation including the benefits realized and the cost to taxpayers. *Id.*

industry whose primary goal is “intellectual property protection and profit.”¹⁶²

V. CONCLUSION

In a country that spends more per capita on healthcare than any other nation in the world,¹⁶³ it is ironic that we are confronted with a serious and growing shortage of drugs and vaccines. Beholden to stockholders, pharmaceutical companies will simply not make choices in support of research, manufacture and marketing of low-margin, high-liability risk drugs.

Successfully addressing access and innovation concerns in the industry will require creative, and on some level controversial, approaches to the complex problem. As a starting point within the realm of tort liability, the provision of a narrowly defined, long-advocated FDA defense should be reconsidered and implemented at the federal level. Supplementing this tort protection with selective incentive programs should be done where research into and access to classes of drugs have been abandoned and where evidence demonstrates a favorable risk-benefit analysis.

162. See McCabe, *supra* note 147, at 817 (discussing the political influence of the pharmaceutical industry and the potential for “agency capture” of the FDA).

163. *U.S. Health Care Gets Checkup from ABC*, CHI. TRIB., Oct. 16, 2003, § A, at 16.

