

**STRIKING A BALANCE
BETWEEN PRODUCT AVAILABILITY
AND PRODUCT SAFETY:
LESSONS FROM THE VACCINE ACT**

DANIEL A. CANTOR

TABLE OF CONTENTS

Introduction	1854
I. The Vaccine Crisis	1858
A. Instability of the Vaccine Market	1858
B. The Inability of the Civil Tort System to Provide Adequate Compensation for Vaccine-Related Injuries	1859
II. The Vaccine Act	1860
III. Vaccine Act's Ban on Direct Failure to Warn Claims ...	1863
A. The Learned Intermediary Doctrine	1864
B. Exceptions to the Learned Intermediary Doctrine .	1866
C. Problems with Physicians Serving as Learned Intermediaries	1868
1. Customary practice standard of informed consent	1869
2. The weakening of the learned intermediary doctrine in an environment that supports universal vaccination	1870
3. The responsibility of the manufacturer who has knowledge that its warning is not being followed	1871
D. Importance of Informed Consent After Immunization	1873
E. Vaccine Act's Informational and Recording Requirements	1874
1. Vaccine informational materials	1874
2. Health care provider recording requirements ..	1875
IV. The Relationship Between Federal and State Law	1876

A.	The Preemption Doctrine	1877
B.	FDA Regulation of the Vaccine Industry	1879
C.	Preemption Case Law	1881
	1. The courts' rejection of preemption claims brought by vaccine manufacturers	1881
	2. Preemption and the physical conflict dilemma	1884
D.	The Vaccine Act's Presumption of Warning Adequacy as an Attempt to Resolve the Physical Conflict Dilemma	1886
V.	Vaccine Act and <i>Restatement</i> 402A Comment k	1886
	A. The Vaccine Act's Blanket Application of Comment k to All Vaccines Covered by the Act	1887
	B. A Criticism of the Vaccine Act's Blanket Application of Comment k	1889
	1. Textual challenge	1889
	2. Policy challenge	1892
VI.	Recommendations	1896
	A. Direct Warnings	1896
	B. Relationship Between Federal and State Law	1898
	C. Comment k	1899
	Conclusion	1902

INTRODUCTION

During the twentieth century, America has developed a childhood immunization program that many praise as the most spectacular public health success in history.¹ Over a period of fifty years, the United States has dramatically reduced the annual occurrence of polio, whooping cough, and measles.² Diseases that once threatened to end prematurely the life of every American infant are now prevented with a routine series of early childhood vaccinations.³

With such a record of success, it is perhaps surprising to discover that American vaccine policy remains in a state of flux. At the heart of the controversy lies a legal debate that extends beyond the

1. See H.R. REP. NO. 908, 99th Cong., 2d Sess. 4 (1986) [hereinafter 1986 HOUSE REPORT] (stating that childhood vaccination has saved thousands of lives and billions of health care dollars), reprinted in 1986 U.S.C.C.A.N. 6344, 6345.

2. Randall B. Keiser, *Deja Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986*, 47 FOOD DRUG COSM. L.J. 25, 25 (1982) (citing reduction of American polio incidence from 57,000 cases in 1952 to 4 in 1984, whooping cough incidence from 265,000 cases in 1934 to 2000 in 1982, and measles incidence from 2250 deaths in 1941 to 2 deaths in 1983).

3. See 1986 HOUSE REPORT, *supra* note 1, at 4, reprinted in 1986 U.S.C.C.A.N. at 6345 (stating that vaccines have prevented thousands of deaths every year).

relatively narrow field of childhood immunization. This debate focuses on the recurring product liability dilemma of how to properly establish a balance between product safety and product availability. Due to the social costs at stake, the debate over this issue is particularly intense in the context of children's vaccines. On the one hand, vaccine manufacturers insist that increased regulation and liability will make vaccine producers uninsurable and stymie research and development.⁴ Given the indisputable social utility of children's vaccines, this argument carries significant merit. On the other hand, plaintiffs' coalitions and certain scientists insist that vaccine manufacturers currently market unsafe vaccines to American children.⁵ As evidence, these groups cite the recurring incidence of brain damage and even death in young vaccine recipients.⁶

Recent legislative and executive proposals have once again brought the vaccine debate to the political forefront. In 1993, the Clinton administration introduced and successfully passed a bill providing free vaccines to eligible children.⁷ Commenting on the legislation, President Clinton stated, "Our nation is the only industrialized nation in the world that does not guarantee childhood vaccination for all children. It ought to be like clean water and clean air. It ought to be part of the fabric of our life."⁸

Shortly after passing this initiative, Republican candidates for the House of Representatives published the "Contract with America."⁹ Item nine of the Contract advocates the curtailment of state strict liability laws and the passage of uniform federal product liability legislation.¹⁰

4. *National Childhood Vaccine-Injury Compensation Act of 1985: Hearing on S. 827 Before the Senate Comm. on Labor and Human Resources, 99th Cong., 1st Sess. 240 (1985)* (statement of Robert Johnson, President, Lederle Lab.) (stating that number of carriers willing to insure Lederle in 1985 dropped from 26 to 8).

5. *See id.* at 42 (statement of Jeffrey H. Schwartz, President, Dissatisfied Parents Together) (announcing Dissatisfied Parents Together's goal of enacting more stringent testing procedures for children's vaccines).

6. *See Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 2d Sess. 73 (1984)* [hereinafter *1984 Vaccine Hearing*] (statement of Dr. Edward Brandt, Jr., Assistant Secretary of Health) (explaining that risk of permanent neurologic damage from DTP vaccine is one in 310,000).

7. *See* 42 U.S.C. § 1396s(a)(1)(A) (Supp. V 1993) (providing vaccinations at no charge for statutorily eligible children).

8. Paul Richter, *Child Vaccination Program Is Pushed Health*, L.A. TIMES, Feb. 13, 1993, at A1 (internal quotation marks omitted).

9. *See* Tony Mauro, *Contract with America: The Common Sense Legal Reform Act*, USA TODAY, Nov. 17, 1994, at A10 (stating that more than 300 Republican congressional candidates signed Contract with America on September 27, 1994).

10. *See The Republican 'Contract with America'*, PHILA. INQUIRER, Dec. 18, 1994, at C8.

Although neither of these proposals directly affects vaccine-related injury litigation, both demonstrate the continuing difficulties our nation faces in its attempt to establish a workable balance between product availability and product safety. In the interest of increasing dialogue on this crucial issue, this Comment reexamines a recent legislative attempt to reform vaccine product liability litigation, the National Childhood Injury Compensation Act of 1986 (Vaccine Act).¹¹ This important legislation removed the common law element of negligence from vaccine product liability litigation by creating a no-fault compensation program funded by an excise tax on vaccines.¹² The Vaccine Act requires plaintiffs to file a claim against the Secretary of the Department of Health and Human Services (the Secretary) rather than against the vaccine manufacturer.¹³ A valid claim includes an affidavit and documentation proving that the injuries received were caused by a vaccine.¹⁴ If the petitioner is dissatisfied with the result of the no-fault litigation, she may reject the judgment and pursue a civil tort action against the vaccine manufacturer.¹⁵

Although the Vaccine Act permits vaccine-injury victims to sue manufacturers under state product liability laws, Congress limits the legal theories available to those who forego the Vaccine Act's compensation system.¹⁶ The Vaccine Act affords protection consistent with *Restatement (Second) of Torts* section 402A comment k¹⁷ (comment k) to vaccines covered by the Act, thereby shielding manufacturers from strict design defect liability.¹⁸ The Vaccine Act also adopts the learned intermediary doctrine, allowing manufacturers

11. See 42 U.S.C. §§ 300aa-1 to -34 (1988 & Supp. V 1993).

12. *Id.* § 300aa-15(i)(2) (1988) (providing for payments for vaccine-related injury or death through Vaccine Injury Compensation Trust Fund); see also 26 U.S.C. § 9510(a) (1988 & Supp. V 1993) (mandating that revenues from taxes on vaccines provide monies for fund).

13. 42 U.S.C. § 300aa-12(b)(1) (1988 & Supp. V 1993).

14. *Id.* § 300aa-11(c).

15. *Id.* § 300aa-21(a)(1)-(2) (1988) (requiring that petitioner must file with Court of Federal Claims decision whether to accept compensation or pursue civil action within 90 days of court's final judgment). The Court of Federal Claims has jurisdiction over claims concerning compensation under the Vaccine Act. *Id.* § 300aa-12(a) (Supp. V 1993).

16. See *infra* notes 51-57 and accompanying text (discussing limitations on causes of action available under Vaccine Act).

17. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) (explaining that manufacturers of items that are unavoidably unsafe, such as prescription drugs, shall not be held strictly liable for injuries relating to their product, as long as product is manufactured properly and contains adequate warnings). The justification for the absence of strict liability lies in the fact that while these products can never become totally safe, they constitute a desirable and helpful product, furthering the health and well-being of society. *Id.*

18. 42 U.S.C. § 300aa-22(b)(1) (1988) (stating that manufacturer of vaccine shall not be liable for any vaccine-related injury or death caused by unavoidable side effects so long as manufacturer properly prepared and labeled vaccine with proper warnings).

to fulfill their duty to warn by transmitting information to the treating physician rather than to the vaccinee directly.¹⁹ Finally, the Vaccine Act creates a presumption that manufacturer warnings that comply with the Food and Drug Administration (FDA) standards are adequate, thereby preventing state courts from performing an independent assessment of these warnings' sufficiency.²⁰

The Vaccine Act is important legislation because it represents an effort by both vaccine consumers and vaccine manufacturers to strike a middle ground between the seemingly incongruous goals of vaccine safety and vaccine availability. Instead of focusing on the statutory no-fault compensation program of the Vaccine Act, this Comment examines the role that the civil tort system plays in balancing product safety and product availability. As a device for framing this often amorphous topic, this Comment reviews and comments on the Vaccine Act's three fundamental alterations to state tort law for those plaintiffs, who, after rejecting the results of the statutory no-fault compensation program, proceed with a civil law suit against a vaccine manufacturer. Admittedly, the Vaccine Act's alterations of state tort law will not have a large impact on vaccine litigation because most vaccine injury claims are resolved within the statutory framework. The hope is, however, that an examination of the alterations to the civil tort system, codified by Congress in the Vaccine Act, will provide guidance for future legislative reforms in the area of product liability.

Part I explores the vaccine crisis that inspired Congress to reform vaccine litigation. Part II describes the Vaccine Act. Part III considers the Vaccine Act's adoption of the learned intermediary doctrine. Part IV analyzes the Vaccine Act's presumption that warnings complying with FDA standards are adequate and confronts the larger question of the proper relationship between federal regulations and state common law. Part V discusses the Vaccine Act's blanket application of comment k to all vaccines.

Following the evaluation of Congress' alteration of state tort law, Part VI offers a series of conclusions and recommendations for future legislative action. First, the Vaccine Act's elimination of a plaintiff's cause of action under a failure-to-warn tort theory represents a prudent compromise between the dual interests of reducing manufacturer liability and maintaining vaccine safety. Second, the presumption of warning adequacy in the Vaccine Act allows manufacturers to

19. *Id.* § 300aa-22(c) (providing that no manufacturer shall be liable in civil actions for failing to directly warn injured recipient).

20. *Id.* § 300aa-22(b)(2). *But see id.* § 300aa-23(d)(2) (allowing plaintiff to rebut presumption by showing that manufacturer engaged in fraud or failed to exercise due care).

disregard knowledge of vaccine inadequacies so long as the vaccine warning complies with FDA standards. To remedy this deficiency, Congress should require manufacturers with knowledge of warning deficiencies to seek FDA permission to modify their warnings even though existing warnings meet FDA standards. Third, Congress' blanket application of comment k immunity to all vaccines ignores research indicating that manufacturers may currently possess the scientific knowledge to produce safer, alternative vaccines. Congress therefore should amend the Vaccine Act by incorporating a risk-benefit analysis prior to awarding "unavoidably unsafe" status to a vaccine.

I. THE VACCINE CRISIS

In response to fears that the civil tort system had destabilized the vaccine market, Congress reexamined vaccine liability issues in the early 1980s.²¹ In addition to concerns about the availability of vaccines, Congress received pressure from pro-plaintiff groups complaining about the civil tort system's inequities.²² These dual concerns led Congress to the conclusion that American vaccine policy was in a state of crisis and required a systemic overhaul.²³

A. *Instability of the Vaccine Market*

Several related incidents brought to light the instability of the American vaccine market. Fearful that the \$3.5 billion in damages sought by vaccine injury victims between 1980 and 1984 presaged major financial exposure,²⁴ six manufacturers ceased production of vaccines.²⁵ Whereas at one time eight private pharmaceutical companies produced the diphtheria-tetanus-pertussis (DTP) vaccine, only two, Lederle and Connaught, continued to manufacture the DTP vaccine in 1986.²⁶ Similarly, by 1986, Lederle and Connaught were

21. See 1986 HOUSE REPORT, *supra* note 1, at 7, reprinted in 1986 U.S.C.C.A.N. at 6348 (stating that concerns of vaccine market instability led to creation of Vaccine Act); SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., 2D SESS., CHILDHOOD IMMUNIZATIONS 72 (Comm. Print 1986) [hereinafter CHILDHOOD IMMUNIZATIONS] (stating that manufacturers began fleeing from vaccine market in 1966).

22. See 1986 HOUSE REPORT, *supra* note 1, at 7, reprinted in 1986 U.S.C.C.A.N. at 6348 (discussing dissatisfaction with current compensation system); 1984 Vaccine Hearing, *supra* note 6, at 111 (statement of Donna Gray, Dissatisfied Parents Together) (asking Congress for compensation program).

23. See 1986 HOUSE REPORT, *supra* note 1, at 7, reprinted in 1986 U.S.C.C.A.N. at 6348.

24. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 86 (presenting results of vaccine manufacturer survey).

25. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 68.

26. CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 68.

the only manufacturers of polio vaccines.²⁷ The majority of vaccine manufacturers left the market citing the unavailability of product liability insurance.²⁸

The decrease in the number of vaccine manufacturers resulted in a concomitant decline in the national vaccine stockpile.²⁹ In 1986, the vaccine stockpile had fallen below the Center for Disease Control's recommended six-month reserve supply.³⁰ Those manufacturers remaining in the vaccine market greatly increased their prices.³¹ For example, a dose of the measles, mumps, and rubella (MMR) vaccine increased in cost from \$2.71 in 1980 to \$8.47 in 1986.³² Congress therefore feared an actual vaccine shortage and the possible reemergence of formerly contained deadly diseases.³³

B. The Inability of the Civil Tort System to Provide Adequate Compensation for Vaccine-Related Injuries

In addition to concerns regarding the effects of liability on the vaccine market, Congress also voiced doubts about the sufficiency of the civil tort system as a compensation mechanism.³⁴ Certain components of state tort law present substantial barriers to compensation for victims of vaccine-related injuries. For example, many courts have bestowed "unavoidably unsafe" status upon vaccines, thereby foreclosing strict liability design defect claims.³⁵ Furthermore, the fact that vaccination is often made compulsory by law, makes it

27. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 67.

28. See 1984 Vaccine Hearing, *supra* note 6, at 266 (statement of Dr. James Mason, Director, Center for Disease Control) (explaining that Connaught's inability to obtain insurance was reason for its withdrawal from market).

29. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 70-71.

30. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 71 (reporting that as of 1986, Center for Disease Control had four-month stockpile of oral polio vaccine and was attempting to establish 10-week stockpile of DTP vaccine).

31. See 1986 HOUSE REPORT, *supra* note 1, at 4, *reprinted in* 1986 U.S.C.C.A.N. at 6345 (stating that price of vaccines has increased greatly due in part to increased litigation surrounding vaccine-related injuries or deaths).

32. CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 63.

33. See 1986 HOUSE REPORT, *supra* note 1, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 6348 (discussing fear that withdrawal of one vaccine manufacturer could trigger outbreak of preventable disease).

34. See 1986 HOUSE REPORT, *supra* note 1, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347 (noting that very few individuals injured by vaccines ever receive compensation, and stating that "[b]ut for the relatively few who are injured by vaccine—through no fault of their own—the opportunities for redress and restitution are limited, time consuming, expensive, and often unanswered").

35. See, e.g., *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-31 (4th Cir. 1984) (finding comment k applicable to drugs and medical devices); *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (holding that comment k applies to all prescription drugs); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1323 (Kan. 1986) (holding that sabin polio vaccine is unavoidably unsafe as matter of law).

extremely difficult, if not impossible, to prove proximate cause.³⁶ Specifically, manufacturers argue that better warnings about a vaccine's potential dangers would not persuade potential plaintiffs to forego receiving a vaccine because all children must receive vaccinations before beginning school and all children must attend school.³⁷ Vaccine-injury litigation is also extremely lengthy. Given the fact-intensive discovery needed to establish manufacturer liability, a victim of a vaccine-related injury must often wait years from the date of injury to receive compensation.³⁸

II. THE VACCINE ACT

The Vaccine Act created a no-fault compensation system for victims of certain vaccine-related injuries.³⁹ For injuries occurring after passage of the Act, all petitioners alleging injury are required to participate in the Act's adjudication process.⁴⁰ If petitioners are not satisfied with the outcome of the statutory no-fault adjudication process, they may pursue traditional tort actions.⁴¹

The Vaccine Act restructures many aspects of civil torts litigation.⁴² The Secretary, rather than the vaccine manufacturer, serves as the defendant.⁴³ The Office of Special Masters of the United States Court of Federal Claims acts as the trier of law and fact.⁴⁴ Rules of

36. See Peggy J. Naile, *Tort Liability for DTP Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 682 (1989) (stating that state-mandated vaccination removes choice element); Fay F. Spence, *Alternatives to Manufacturers Liability for Injuries Caused By the Sabin-Type Oral Polio Vaccines*, 28 WM. & MARY L. REV. 711, 734 (1986) (arguing that inadequate warning cannot constitute proximate cause of vaccine injury).

37. See Spence, *supra* note 36, at 732 (arguing that mandatory vaccination makes adequacy of warning irrelevant).

38. See 1986 HOUSE REPORT, *supra* note 1, at 6, reprinted in 1986 U.S.C.C.A.N. at 6347 (stating that lawsuits can take years to complete); CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 87 (reporting results of manufacturer survey showing that of 299 claims filed between 1980 and 1985, 72% were still pending in 1985).

39. See 42 U.S.C. § 300aa-13(a)(1)(A)-(B) (1988) (directing that petitioner shall receive compensation if petitioner proves causation and Secretary of Health and Human Services fails to prove that unrelated factors caused injury); see also 1986 HOUSE REPORT, *supra* note 1, at 3, reprinted in 1986 U.S.C.C.A.N. at 6344 (referring to Vaccine Act as "no-fault" compensation system).

40. See 42 U.S.C. § 300aa-11(a)(2)(A) (1988 & Supp. V 1993) (explaining that petitioners may not bring civil action in state or federal court if seeking more than \$1000 in damages unless petitioner has filed petition pursuant to Vaccine Act).

41. See *id.* § 300aa-21(a)(1)-(2) (1988) (stating that following entry of judgment, petitioner shall file election within 90 days either accepting or rejecting judgment).

42. Cf. CL. R. App. J., Rule 7 ("There shall be no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice.").

43. 42 U.S.C. § 300aa-12(b)(1) (1988 & Supp. V 1993).

44. See *id.* § 300aa-12(d)(3)(A) (Supp. V 1993) (instructing special master to issue decision as to whether petitioner is entitled to compensation).

procedure under the Vaccine Act are less formal than traditional rules.⁴⁵

Petitioners in the no-fault compensation system may prove entitlement to compensation in two different ways. The Vaccine Act contains a Vaccine Injury Table listing certain injuries, symptoms of such injuries, and time limits for the onset of such injuries.⁴⁶ A petitioner able to demonstrate both that she suffered an injury listed in the vaccine table and that the first manifestation of the injury occurred within the time limit prescribed by the table creates a presumption of causation.⁴⁷ A petitioner who is unable to prove the existence of a table injury is still entitled to compensation if she can prove causation-in-fact.⁴⁸ Petitioners may satisfy the burden of proof by demonstrating causation-in-fact by a preponderance of the evidence.⁴⁹ Once a petitioner has established either a table injury or causation-in-fact by a preponderance of the evidence, the burden shifts to the respondent to prove that a factor unrelated to the administration of the vaccine caused the injury.⁵⁰

As previously noted, after adjudication of their claims under the Vaccine Act's no-fault compensation system, petitioners may elect to reject the finding of the special master or judge and proceed to file a tort action in state or federal court.⁵¹ The Vaccine Act does, however, place certain limitations on such civil causes of action.⁵² The Act states that vaccine manufacturers are not liable for unavoidable side effects caused by vaccines that are properly prepared and accompanied by adequate warnings.⁵³ The Act also directs that manufacturer compliance with FDA warning standards creates a

45. See *id.* § 300aa-12(d)(2)(A)-(E) (recommending that Court of Federal Claims provide for less rigid rules). The Vaccine Act specifically directs the Court of Federal Claims to promulgate rules that "provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions." *Id.* § 300aa-12(d)(2)(A).

46. See *id.* § 300aa-14 (1988 & Supp. V 1993) (providing table of presumed causation for DTP, polio, and MMR vaccines).

47. *Id.* § 300aa-13(a)(1)(A) (1988).

48. *Id.* § 300aa-11(c)(1)(C)(ii)(I).

49. *Id.* § 300aa-13(a)(1)(A); see *McClendon v. Secretary of Dep't of Health & Human Servs.*, 23 Cl. Ct. 191, 195-96 (1991) (holding that burden of proof required is preponderance of evidence rather than scientific certainty).

50. See 42 U.S.C. § 300aa-13(a)(1)(B). The Code states that illnesses or injuries not previously known to have a relation to the vaccine that are nonetheless proven to arise out of the administration of the vaccine do not fall into the category of "factors unrelated to the administration of the vaccine." *Id.* § 300aa-13(a)(2)(A)-(B).

51. See *id.* § 300aa-21(a)(1)-(2).

52. See *id.* § 300aa-22(b)-(c) (granting comment k immunity to all vaccines, creating presumption of adequacy in all warnings that comply with FDA standards, and banning liability for direct failure to warn).

53. See *id.* § 300aa-22(b)(1).

presumption of adequate warnings.⁵⁴ Petitioners may rebut this presumption by demonstrating with clear and convincing evidence that the manufacturer did not exercise due care or that the manufacturer engaged in fraud or intentional withholding of information.⁵⁵ Additionally, the Act prohibits claims based on the direct failure to warn, when failure to provide a direct warning constitutes the sole claim.⁵⁶ Finally, although the Vaccine Act places limitations on certain tort claims, it expressly prohibits States from banning civil actions not proscribed by the Act itself.⁵⁷

The Vaccine Act also creates certain information distribution and recording requirements for health care providers and vaccine manufacturers.⁵⁸ Pursuant to the Act, health care providers must report to the Secretary all injuries that are listed in the Vaccine Injury Table and occur within seven days of vaccine administration.⁵⁹ Health care providers must also inform the Secretary of all incidents of contraindicating reactions listed in the manufacturer's vaccine package insert.⁶⁰

The Vaccine Act also instructs the Secretary to develop and distribute vaccine information materials to health care providers.⁶¹ The vaccine information materials must include explanations of: (1) the vaccine's benefits; (2) the vaccine's risks; (3) the existence of the National Vaccine Injury Compensation Program; and (4) other relevant information.⁶² The Act then requires all health care providers administering vaccines to distribute the information to the legal representative of a child receiving the vaccine.⁶³

Manufacturers must keep detailed records of their manufacturing process.⁶⁴ The Vaccine Act mandates recording the "manufacturing, process, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine including any significant problems encoun-

54. *See id.* § 300aa-22(b)(2) (declaring that compliance with requirement of Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1988 & Supp. V 1993), and Public Health Service Act, 42 U.S.C. § 262 (1988), creates presumption of adequate warning).

55. *See id.* §§ 300aa-22(b)(2)(A), -23(d)(2)(A)-(C).

56. *See id.* § 300aa-22(c).

57. *See id.* § 300aa-22(e).

58. *See id.* §§ 300aa-25 to -28 (1988 & Supp. V 1993) (requiring physicians to record information related to administration of vaccine; requiring Secretary to write vaccine information materials for distribution by physicians; and requiring manufacturers to keep detailed records of manufacturing process).

59. *See id.* § 300aa-25(b)(1)(A)-(C) (1988).

60. *Id.*

61. *See id.* § 300aa-26(a) (1988 & Supp. V 1993) (giving Secretary one year from promulgation of Act to develop and distribute materials).

62. *Id.* § 300aa-26(c) (Supp. V 1993).

63. *See id.* § 300aa-26(d) (1988 & Supp. V 1993).

64. *See id.* § 300aa-28(a)(1)-(4) (1988).

tered in the production, testing, or handling of such batch, lot, or other quantity.⁶⁵ Upon discovery of a potential safety hazard involving a vaccine, a manufacturer must report the findings to the Secretary within twenty-four hours.⁶⁶ The Vaccine Act imposes both civil and criminal penalties on manufacturers for destroying, altering, falsifying, or concealing required records.⁶⁷

III. VACCINE ACT'S BAN ON DIRECT FAILURE TO WARN CLAIMS

As discussed in the preceding section, the Vaccine Act prohibits claims against manufacturers for failing to provide an adequate warning to the ultimate recipient of the vaccine.⁶⁸ This legislative decision directly conflicts with judicial decisions that required direct warnings at mass vaccine clinics where the vaccine is not administered by a private physician.⁶⁹ Thus, the legislation raises questions as to whether the Vaccine Act has sacrificed too many patient safety mechanisms.⁷⁰ After reviewing the learned intermediary doctrine and its exceptions, and the Vaccine Act's informational and reporting requirements, this Comment concludes that the Vaccine Act's informational and reporting requirements partially compensate for

65. *Id.* § 300aa-28(a)(1).

66. *See id.* § 300aa-28(a)(2) (requiring report of any suspicious test results that might indicate potential safety hazard).

67. *See id.* § 300aa-28(b)(1)-(2) (stating that manufacturer would be subject to civil penalty of \$100,000, criminal fine of \$50,000, or one year imprisonment).

68. *See supra* note 56 and accompanying text (stating that vaccine manufacturer shall not be liable for claims arising solely out of manufacturer's lack of direct warning to injured vaccine recipient).

69. *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977). The court in *Givens* held that the learned intermediary doctrine did not apply when a private physician administered a vaccine in a private setting because the setting resembled a clinic situation similar to that in *Reyes*. *See also Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1277 (5th Cir.) (following "mass vaccine" clinic exception to learned intermediary doctrine enunciated in *Davis*, *cert. denied*, 419 U.S. 1096 (1974)); *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that manufacturer must provide direct warning where vaccine is administered at mass clinic). *But see Walker v. Merck & Co.*, 648 F. Supp. 931, 934 (M.D. Ga. 1986), *aff'd*, 831 F.2d 1069 (11th Cir. 1987) (limiting Fifth and Ninth Circuits' mass vaccine exceptions to polio cases); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986) (applying learned intermediary doctrine solely because physician administered vaccine). Some commentators have argued that, given the courts' narrow reading of *Davis* and its progeny, the Vaccine Act's elimination of direct warning duty does not significantly alter products liability landscape. *See Okianer C. Dark, Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 857 (1988) (arguing that plaintiffs may still have cause of action against manufacturer through such claims as negligent preparation, improper design, or failure to warn physician under strict liability standard).

70. *See Susan A. Casey, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 957 (1993) (asserting that learned intermediary doctrine overestimates physicians' willingness to serve as conduit between manufacturers and patients); Alan R. Styles, *Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts*, 39 CLEV. ST. L. REV. 111, 123 (1991) (arguing that under learned intermediary doctrine, doctors are not always willing to perform individualized risk assessments).

many of the advantages lost by barring direct warning claims, namely informed consent and patient safety.⁷¹ Given that Congress passed the Vaccine Act in response to concerns about vaccine availability and safety,⁷² the decision to abolish direct warnings was a prudent compromise.⁷³ As the term "compromise" suggests, however, the Vaccine Act is not the ultimate protector of vaccinee safety, and future amendments should respond to this problem.⁷⁴

A. *The Learned Intermediary Doctrine*

The Act's rejection of manufacturer liability for failure to provide a direct warning to the ultimate consumer amounts to a statutory adoption of the "learned intermediary doctrine."⁷⁵ First coined in 1967,⁷⁶ the learned intermediary doctrine holds that, in the case of prescription pharmaceuticals, manufacturers satisfy their duty to warn by providing an adequate warning to the treating physician.⁷⁷ The learned intermediary doctrine, therefore, serves as an important

71. See *infra* notes 152-57 and accompanying text (arguing that informational and reporting requirements both permit vaccinee to actively participate in risk-benefit analysis and reduce physician discretion in decision to utilize vaccine).

72. See 1986 HOUSE REPORT, *supra* note 1, at 7, reprinted in 1986 U.S.C.C.A.N. at 6345 (stating that concerns propelling legislation are inadequacy of civil tort system as compensation mechanism and instability of vaccine market).

73. See *infra* notes 334-35 and accompanying text (asserting that Act seeks to insulate manufacturer from liability as well as establish pro-plaintiff compensation system).

74. See *infra* notes 331-32 and accompanying text (proposing combining federal reporting regulations with state common law-based direct warning rule).

75. See Dark, *supra* note 69, at 848-49 (stating that Vaccine Act removes mass vaccine exception to learned intermediary doctrine); Theodore H. Davis & Catherine B. Bowman, *No-Fault Compensation for Unavoidable Injuries: Evaluating the National Childhood Vaccine Injury Compensation Program*, 16 U. DAYTON L. REV. 277, 304 (1991) (arguing that Act abrogates direct warning causes of action previously permitted under *Davis* and its progeny); Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 158 (1988) (stating that Act removes manufacturers' duty to warn ultimate users directly).

76. See *Sterling Drug v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (labelling consumer's doctor as "learned intermediary" between manufacturer and consumer).

77. See *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir.) (stating that manufacturers of prescription drugs must only warn prescribing physicians), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Lab.*, 399 F.2d 121, 129 (9th Cir. 1968) (describing customary rule that manufacturer has duty only to warn physician prescribing drug); *Dunkin v. Syntex Lab.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (stating that Tennessee law only requires prescription drug manufacturer to warn prescribing physician adequately); *Buckner v. Allergan Pharmaceuticals*, 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981) (holding that manufacturer's duty to warn of drug's potential dangers is fulfilled by adequate warning to prescribing doctor); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 839 (Ohio 1981) (arguing that position of physician as learned intermediary removes manufacturers' duty to warn ultimate consumers of prescription drugs directly).

exception to the common law rule that manufacturers must adequately warn the ultimate recipients of their products.⁷⁸

Several policy considerations justify Congress' decision to insulate vaccine manufacturers from direct failure-to-warn liability.⁷⁹ First, the prescribing physician is in the best position to make an informed decision about the relative benefits and risks of using the drug.⁸⁰ The physician possesses knowledge of both the drug in question and the patient's medical history.⁸¹ The physician can, taking into account the specific nature of the patient's medical history, perform an individualized balancing of the vaccine's benefits and the dangers of its use.⁸²

Second, patients are not likely to possess the medical knowledge necessary to understand manufacturers' warnings.⁸³ Consumers with inadequate medical knowledge may ignore or misinterpret important warnings.⁸⁴ Third, direct warnings to consumers often take the form

78. See RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 388 (requiring manufacturers of potentially dangerous products to warn foreseeable ultimate users).

79. See Spence, *supra* note 36, at 728 (identifying manufacturers' difficulty in providing direct warnings to users and insufficient patient knowledge as policy considerations supporting learned intermediary doctrine). Circuit Judge Wisdom, in *Reyes v. Wyeth Laboratories*, provided a persuasive justification for the learned intermediary doctrine:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between the manufacturer and consumer.

Reyes, 498 F.2d at 1276.

80. See *Reyes*, 498 F.2d at 1276.

81. *Id.*; see also Barbara Pope Flannagan, *Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs*, 20 U. RICH. L. REV. 405, 413 (1986) (arguing that physician is only individual possessing knowledge of both patient and drug).

82. *Reyes*, 498 F.2d at 1276; see Flannagan, *supra* note 81, at 413 ("The physician's knowledge of the patient and the drug are taken into account when the physician makes a medical judgment as to the appropriate course of treatment for a particular patient.").

83. See *Davis v. Wyeth Lab.*, 399 F.2d 121, 129 (9th Cir. 1968) (arguing that due to medical nature of warning, it is difficult to adequately warn lay consumer); Flannagan, *supra* note 81, at 413 (arguing that direct manufacturer warnings might mislead patient).

84. See *Dunkin v. Syntex Lab.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (stating that direct manufacturer warning may interfere with doctor-patient relationship); *McKee v. American Home Prods. Corp.*, 782 P.2d 1045, 1055 (Wash. 1989) (en banc) (arguing that package inserts may confuse and frighten patients); Casey, *supra* note 70, at 948 (arguing that patient may fear discussing package insert with physician and decide to avoid medical treatment); Walter J. Curran, *Package Inserts for Patients: Informed Consent in the 1980s*, 305 NEW ENG. J. MED. 1564, 1566 (1981) (suggesting that package inserts may lead patients to question physician's prescription and reject therapy altogether).

of package inserts,⁸⁵ which unlike a doctor who is available for follow-up questions, cannot respond to all of the concerns and questions of individual consumers.⁸⁶ Fourth, prescription drug manufacturers do not always have adequate access to their ultimate consumers.⁸⁷ Because the prescription drug is not always distributed in its original packaging, the manufacturer may have difficulty relaying the warning to the ultimate consumer.⁸⁸ Finally, the learned intermediary doctrine accepts as reality that patients normally rely on their physicians to make medical decisions in the patient's best interest.⁸⁹

B. *Exceptions to the Learned Intermediary Doctrine*

The learned intermediary doctrine is not without exceptions.⁹⁰ Two years after a court first coined the term "learned intermediary," the Court of Appeals for the Ninth Circuit announced the doctrine's first exception in *Davis v. Wyeth Laboratories*.⁹¹ In *Davis*, the plaintiff received a sabin oral polio vaccine at a mass immunization clinic sponsored by Idaho public health officials and a local medical society.⁹² Within thirty days of vaccination, the plaintiff developed paralysis from the waist down.⁹³ Although the manufacturer provided warnings to the medical society,⁹⁴ the purchaser of the vaccines, the plaintiff did not receive a warning.⁹⁵

When considering the scope of the duty to warn, the court in *Davis* began with the proposition that the learned intermediary doctrine

85. Flannagan, *supra* note 81, at 413 (discussing practical difficulties of direct warnings).

86. Flannagan, *supra* note 81, at 413 (suggesting that physician can both answer patient questions and gauge whether patients fully understand nature of treatment).

87. Casey, *supra* note 70, at 948 (stating that direct contact between manufacturer and patient is rare); Spence, *supra* note 36, at 728 (citing fact that patients receive prescription drugs through physician as reason for learned intermediary doctrine).

88. Casey, *supra* note 70, at 948.

89. See *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981) ("[T]he patient is expected to place primary reliance upon the physician's judgment, and to follow his advice and instructions as to use of the drug.").

90. See Casey, *supra* note 70, at 939-45 (citing mass vaccines, oral contraceptives, and intrauterine devices as products to which learned intermediary doctrine does not apply) (citing *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that manufacturer must provide direct warning in mass immunization clinic context); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867, 878 (E.D. Mich. 1985) (requiring oral contraceptive manufacturers to give user direct warning)).

91. 399 F.2d 121, 131 (9th Cir. 1968).

92. See *Davis*, 399 F.2d at 124.

93. See *id.* at 122.

94. See *id.* at 125 (stating that warnings to medical society were in package insert provided in every bottle of 100 doses).

95. See *id.*

ordinarily governs failure to warn cases involving prescription drugs.⁹⁶ Because the decision to vaccinate is a medical determination, the manufacturer best meets its duty to warn by providing the prescribing physician with adequate information.⁹⁷ After discussing the theoretical underpinnings of the learned intermediary doctrine, however, the court in *Davis* distinguished vaccines dispensed by a private physician from vaccines dispensed at mass clinics. When a private physician is involved, the individualized balancing of benefits and dangers envisioned by the authors of the learned intermediary doctrine may be expected.⁹⁸ Unlike private physicians, mass immunization clinics lack a one-on-one doctor-patient relationship, and therefore, an individualized balancing of the benefits and risks of vaccination is less likely.⁹⁹ The court in *Davis* reasoned that the prescriptive nature of the sabin drug is a result of the vaccine's administrative nature rather than some immutable characteristic of the drug itself: "Here, however, although the drug was denominated a prescription drug, it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved."¹⁰⁰

In deciding that the learned intermediary doctrine does not apply in the mass vaccine context, the court in *Davis* drew an analogy to the situation where a manufacturer directly supplies a consumer with an over-the-counter nonprescription drug.¹⁰¹ In such a case, the manufacturer cannot impose its own endorsement of the drug's worth on the consumer.¹⁰² Rather, the manufacturer must provide the consumer with the necessary information to weigh the benefits and risks of the drug.¹⁰³ Moreover, when a manufacturer sells a drug to an intermediate purchaser, the manufacturer must protect the ultimate consumer's autonomy by either providing a warning to the

96. See *id.* at 130 (stating that directly warning physician is only effective means by which warning would benefit patient).

97. *Id.*

98. *Id.*

99. *Id.* at 131; see also *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1277 (5th Cir.) (referring to "assembly line" nature of mass immunization clinics), *cert. denied*, 419 U.S. 1096 (1974).

100. *Davis*, 399 F.2d at 131. Building on the Ninth Circuit's rationale, the Fifth Circuit later expanded the mass vaccine clinic exception to the learned intermediary doctrine. See *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977). Whereas the court in *Davis* imposed a structural distinction between mass clinics and private physicians, the Fifth Circuit in *Givens* evaluated the nature of the private-physician scenario and determined that the dispensation of vaccinations in the private physician scenario is more analogous to a visit to a mass clinic than a visit to a private physician's office, despite the presence of a physician. *Id.* (finding that administration of vaccine, although supervised by physician, resembled county health clinic setting).

101. *Davis*, 399 F.2d at 131.

102. *Id.*

103. *Id.*

ultimate consumer or by contractually obligating the intermediate purchaser to provide such a warning.¹⁰⁴ Wyeth Laboratories, having taken an active role in establishing the mass immunization clinic, knew that the medical society was not providing warnings to the vaccinees.¹⁰⁵ The court therefore concluded that Wyeth had not met its duty to warn the plaintiff of the risks of the sabin vaccine.¹⁰⁶

The decision in *Davis* highlights one potential danger of congressional adoption of the learned intermediary doctrine under the Vaccine Act. A large percentage of American children receive polio and DTP vaccines in mass immunization clinics.¹⁰⁷ When vaccines are dispensed at a mass immunization clinic, the vaccinee is not likely to receive the benefit of a physician's individualized risk assessment,¹⁰⁸ and therefore, the rationale of the learned intermediary doctrine weakens.¹⁰⁹ The Vaccine Act, consequently, may prevent these children and their legal representatives from properly balancing the benefits and risks of vaccination.

C. *Problems with Physicians Serving as Learned Intermediaries*

Mass vaccination exceptions aside, the learned intermediary doctrine poses other dangers for vaccinees in the private physician context. By not requiring direct warnings to vaccinees, the learned intermediary doctrine implicitly assumes that private physicians will undertake an individualized balancing of benefits and risks before administering the vaccine.¹¹⁰ The present state of the law concerning informed consent for prescription drugs, however, does not require full disclosure by the physician.¹¹¹ As a result, physicians

104. *Id.*

105. *Id.*

106. *Id.*

107. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 60 (stating that 50% of vaccines are administered through public sector programs); see also *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1277 (5th Cir.) (discussing public health professor's testimony that majority of sabin polio vaccines are administered in mass vaccination clinics), *cert. denied*, 419 U.S. 1096 (1974).

108. See *supra* notes 91-106 (discussing mass vaccine clinic exception to learned intermediary doctrine).

109. *Reyes*, 498 F.2d at 1276 (validating learned intermediary doctrine on basis that physician can perform informed risk assessment by applying knowledge of both drug and patient's medical history).

110. *Casey*, *supra* note 70, at 957 (questioning willingness and ability of physicians to serve as learned intermediaries); *Styles*, *supra* note 70, at 123 (arguing that physicians are not always willing to inform patients of prescription drug's risks).

111. *Styles*, *supra* note 70, at 128-29 (stating that customary practice standard for informed consent requires physicians to warn patients only when medical community deems disclosure necessary); Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367, 368 (1986) (arguing that informed consent doctrine does not adequately protect patients who receive prescription drugs).

may not involve vaccinees in the decisionmaking process.

1. Customary practice standard of informed consent

The informed consent doctrine imposes minimum warning duties on physicians.¹¹² In the case of prescription drugs, courts have generally held physicians to a "customary practice standard."¹¹³ Under the customary practice standard, a physician is under a duty to warn only if the medical community determines that disclosure is mandated.¹¹⁴ The customary practice standard does not provide an absolute warning requirement because the medical community itself governs the scope of the duty to warn.¹¹⁵

As one scholar has commented, physicians are often unwilling to warn patients of the inherent risks of prescription drug use because the physicians fear that too much informed consent may frighten the patient and cause the patient to reject treatment.¹¹⁶ *Plummer v. Lederle Laboratories*¹¹⁷ provides a good example of this phenomenon. The plaintiff, Harry Plummer, contracted polio shortly after his grand-

112. See *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.) (stating basic premise that "every human being of adult years has a right to determine what shall be done with his own body"), cert. denied, 409 U.S. 1064 (1972); Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 226-27 (1985) (arguing that doctor's responsibility for patient's well-being requires doctor to provide patient with sufficient information to allow patient to make intelligent, informed decision); Styles, *supra* note 70, at 113 (stating that informed consent doctrine obligates doctors to warn of proposed therapy's risks).

113. See, e.g., *Watkins v. United States*, 482 F. Supp. 1006, 1013 (M.D. Tenn. 1980) (holding that physician was not required to warn patient of dermatological drug's side effects when giving such warnings was not common practice of medical community); *Finley v. United States*, 314 F. Supp. 905, 915 (N.D. Ohio 1970) (finding physician was not negligent because of lack of expert opinion that warning should have been given); Styles, *supra* note 70, at 128-29 (explaining that customary practice standard is determined by customs of medical profession itself, and is therefore not absolute); Tietz, *supra* note 111, at 309 (stating that medical customary practice standard is based on medical community customs rather than patients' expectations).

Some jurisdictions, recognizing that the customary practice standard is determined by physicians, have developed a more patient-oriented measure of informed consent. See *Canterbury*, 464 F.2d at 784 (defining scope of duty to warn as "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy"). But see Styles, *supra* note 70, at 129 (stating that although *Canterbury* standard still governs in many jurisdictions, courts have not applied patient-oriented reasonableness test to prescription pharmaceutical cases).

114. *Watkins*, 482 F. Supp. at 1013 (requiring informed consent only where such consent is standard practice in medical community); *Finley*, 314 F. Supp. at 915 (citing lack of evidence of community warning practice as reason for dismissal of failure to warn claim).

115. See Styles, *supra* note 70, at 128-29 (explaining that physician's duty to warn only goes so far as local medical community deems appropriate). For an argument suggesting a stricter informed consent standard, see *Canterbury*, 464 F.2d at 274 (arguing that informed consent requires standard governing physicians rather than standard governed by physicians).

116. Styles, *supra* note 70, at 130; see also *Casey*, *supra* note 70, at 948 (observing that patient may become intimidated by potential consequences or confused by medical terminology and consequently reject treatment).

117. 819 F.2d 349 (2d Cir. 1987).

daughter was injected with the sabin vaccine.¹¹⁸ Lederle Laboratories provided the administering physician with a warning detailing the danger of individuals contracting polio upon contact with the vaccinee.¹¹⁹ In a pre-trial deposition, Dr. Cohen, the administering physician, made the following comments concerning his perceived duty, as a learned intermediary, to warn the vaccinee:

My feeling . . . was that there is an extremely minute percentage of people who will have the complications from the drug. I felt that, again, because I had never experienced [other practicing physicians] giving these warnings, it . . . wasn't necessary for me to do it; and . . . I felt . . . that giving the warning . . . could scare off parents from bringing children in for future vaccinations, which to me were much more important than the warning itself for the few number of people who are going to contract disease . . .¹²⁰

Plummer demonstrates how the learned intermediary doctrine may result in physicians deciding not to perform an individualized balancing of the benefits and risks of vaccination.¹²¹ Given that the manufacturer's duty to warn extends only to the physician, and the physician's informed consent duty is governed by the community practice standard, the vaccinee may receive neither a direct warning nor a physician performed risk assessment.

2. *The weakening of the learned intermediary doctrine in an environment that supports universal vaccination*

The dangers precipitated by the combined effect of the learned intermediary doctrine and the community practice standard are heightened in the vaccine context.¹²² The current politico-medical environment in the United States is exceedingly pro-vaccine.¹²³ For example, the U.S. Government strongly endorses universal childhood immunization,¹²⁴ and all fifty States mandate vaccination prior to

118. See *Plummer v. Lederle Lab.*, 819 F.2d 349, 352 (2d Cir. 1987).

119. See *id.* (relating warning estimating one in six million chance of contracting contact polio).

120. *Id.*

121. See *Casey*, *supra* note 70, at 957 (arguing that physicians are not prepared to serve as learned intermediaries); *Tietz*, *supra* note 111, at 367 (arguing that doctors do not inform patients of important information about risks of serious side effects of prescription drug use) (citing J. KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 83 (1984)).

122. See *Casey*, *supra* note 70, at 957-58 (arguing that medical community's ability and willingness to act as learned intermediary is overstated and that measuring scope of duty to warn by standard of practice of community affords, at best, only limited knowledge of risks associated with treatment).

123. *Id.*

124. See H.R. REP. NO. 1063, 98th Cong., 2d Sess. 2 (1984) (urging creation of permanent system to deliver comprehensive immunization services), *reprinted in* 1984 U.S.C.C.A.N. 4804, 4805.

entry into the public school system.¹²⁵

Such extensive federal and state support for universal vaccination may have an overpersuasive effect on physicians. Physicians, responding to government propaganda and manufacturer advertising, may become irreversibly persuaded by the value of vaccination and abandon patient-by-patient risk assessments.¹²⁶ When such overpromotion occurs, the value of manufacturer warnings to physicians becomes diluted.¹²⁷

3. *The responsibility of the manufacturer who has knowledge that its warning is not being followed*

The foregoing discussion demonstrates how the pro-vaccine environment, in combination with the customary practice standard of informed consent, diminishes physicians' abilities to function as learned intermediaries. Prior to the passage of the Vaccine Act, state common law provided a mechanism for combating a physician's inability or unwillingness to fully appreciate manufacturer warnings.¹²⁸ In *Incollingo v. Ewing*,¹²⁹ the Supreme Court of Pennsylvania addressed a manufacturer's failure to alter its warning in the face of evidence that the drug was being used indiscriminately.¹³⁰ The plaintiffs submitted evidence that the drug, Chloromycetin, should only be used in treating serious illnesses.¹³¹ As the plaintiffs

125. See CHILDHOOD IMMUNIZATIONS, *supra* note 21, at 103.

126. See James M. Burke, *DTP Controversy: An Assessment of the Liabilities of Manufacturers and Administering Physicians Under Several Legal Theories*, 17 SETON HALL L. REV. 541, 591-92 (1987) (advocating that manufacturers respond to doctors' lack of objectivity with "Dear Doctor" letters, pamphlets, and other advertisements); Casey, *supra* note 70, at 957-58 (arguing that initially adequate warnings may become insufficient when physician makes *per se* determination of drug's value). *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1487 (D. Kan. 1987), provides an illustration of the overpromotion phenomena. The plaintiff parents were provided with information prepared by the Missouri Department of Health describing the risks of the whole-cell vaccine, prior to their child receiving the DTP vaccination. Upon being asked questions about the side effects of the vaccine, however, a nurse responded that the warnings were "just statistics" and that the adverse reactions "didn't really happen." *Id.* The plaintiff infant daughter sustained severe and irreversible brain damage. *Id.* at 1485.

127. See Burke, *supra* note 126, at 591-92 (stating that pro-vaccine environment creates false perception of utility of vaccines); Casey, *supra* note 70, at 957-58 (arguing that overpromotion leads to manufacturers' disregard for warnings).

128. See, e.g., *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (holding that manufacturer who knowingly ignores that warning is being disregarded may be liable for failure to warn); *Incollingo v. Ewing*, 282 A.2d 206, 222 (Pa. 1971) (holding that manufacturer with knowledge that learned intermediaries are ignoring otherwise valid warnings may be liable for failure to warn); Burke, *supra* note 126, at 592 (arguing that manufacturers ignoring environment in which their products are distributed may be liable for failure to warn under learned intermediary doctrine).

129. 282 A.2d 206 (Pa. 1971).

130. *Incollingo v. Ewing*, 282 A.2d 206, 222 (Pa. 1971).

131. See *id.*

brought to light, however, physicians were prescribing the drug to treat non-serious illnesses.¹³² In reviewing the trial court's judgment for the plaintiff, the Supreme Court of Pennsylvania affirmed a jury instruction that the manufacturer's knowledge of, and subsequent inattention to, the fact that the drug was being used indiscriminately could result in a finding of negligence: "When a required warning is retained unchanged in the face of being widely disregarded, and the supplier knows or has reason to know of such wide disregard, a jury may be permitted to find the warning insufficient."¹³³

Incollingo attaches liability to a manufacturer that possesses either actual or constructive knowledge that its warning is being ignored.¹³⁴ Applying the *Incollingo* rationale to the vaccine context, a trier of fact might find that the manufacturer failed to take adequate steps to remedy the fact that the pro-vaccine national environment has lessened physicians' ability to serve as effective learned intermediaries.¹³⁵

Unfortunately, Congress did not include in the Vaccine Act a tort mechanism for overcoming physicians inability to serve as learned intermediaries.¹³⁶ Congress could have achieved this end in one of two ways. It could have required physicians to warn vaccinees directly¹³⁷ or, more in keeping with the learned intermediary doctrine, Congress could have required manufacturers to neutralize the pro-vaccine environment by mandating the use of "Dear Doctor" letters, which provide additional warnings to physicians, and other forms of advertising likely to reach the medical profession.¹³⁸ Rather than requiring manufacturers to recognize environmental barriers to physician warnings, the Vaccine Act creates a presumption that warnings that comply with federal regulatory standards are adequate.¹³⁹ This presumption will likely negate the environmental

132. *See id.*

133. *Id.*

134. *See id.*; Burke, *supra* note 126, at 592 (arguing that charging manufacturers with knowledge of environment will help restore objectivity of physician warnings).

135. *See* Burke, *supra* note 126, at 592 (asserting that manufacturers have duty to "neutralize the effect of overpromotion" by using any available means, including advertisements, pamphlets, and even "Dear Doctor" letters).

136. *See* 42 U.S.C. § 300aa-22(a)-(c) (1988) (discussing standards of responsibility with regard to warnings).

137. *See* Casey, *supra* note 70, at 958 (arguing that patients are not as susceptible to overpromotion as physicians are because manufacturers of prescription drugs do not generally market to patients).

138. Burke, *supra* note 126, at 592.

139. 42 U.S.C. § 300aa-22(b)(2).

awareness charged to manufacturers by cases such as *Incollingo*,¹⁴⁰ and as a result, vaccinees may once again suffer from a lack of individualized balancing by a learned intermediary.

D. Importance of Informed Consent After Immunization

Although the duty to warn is an important component of ensuring product safety, one scholar has argued that the necessity of informed consent is nullified by the fact that all fifty States mandate vaccination prior to entry into the public school system.¹⁴¹ According to this argument, Congress' endorsement of the learned intermediary doctrine will not effect the results of individualized balancing because the States have already concluded that the benefits of universal vaccination outweigh the risks.¹⁴² As a result, in theory, Congress' decision to adopt the learned intermediary doctrine simply amounts to the discharging of useless individual risk assessments.¹⁴³

This argument fails to recognize that informed consent plays a role in post-vaccination decisionmaking, as well as in the initial decision whether or not to vaccinate.¹⁴⁴ Although doctors perform a valuable role in communicating complex medical information to patients, the patient nonetheless benefits from a direct warning. After a patient receives a vaccination, a period of time exists, which is sometimes quite large, in which adverse reactions are likely to occur.¹⁴⁵ An informed patient is better able to recognize the signs of an adverse reaction before the reaction becomes debilitating.¹⁴⁶ Because the vaccinee does not reside with the physician, the

140. See *Incollingo v. Ewing*, 282 A.2d 206, 222 (Pa. 1971) (holding drug manufacturer responsible for restricting drug use to "proper situations" where manufacturer knew or should have known of widespread misuse). The adequacy presumption created by the Vaccine Act is not easily rebutted. In order to rebut the presumption, plaintiffs must show that the manufacturer participated in a fraudulent, intentional, or wrongful withholding of information from the Secretary, or prove by clear and convincing evidence that the manufacturer did not exercise due care. *Id.*

141. See Spence, *supra* note 36, at 732 (discussing argument that state vaccination laws, which require vaccinations prior to matriculation, remove choice element and therefore prevent vaccinee from being proximate cause of vaccinee's injury).

142. See Spence, *supra* note 36, at 732-34.

143. Spence, *supra* note 36, at 732-34.

144. See Casey, *supra* note 70, at 959 (explaining that patient plays important role in monitoring signs and symptoms of adverse reactions after use of drug); Tietz, *supra* note 111, at 389 (arguing that patient plays important role in monitoring adverse reactions to prescription drugs).

145. Tietz, *supra* note 111, at 389.

146. See Tietz, *supra* note 111, at 389 (asserting that prescription drug therapy requires continuous monitoring depending on patient's awareness of side effects and their symptoms in order to avoid time lag between ingestion of drug and side effect); see also Casey, *supra* note 70, at 359 (suggesting that doctor's role in detecting signs of adverse reactions ceases once patient leaves doctor's office).

physician's knowledge of the adverse reaction does little good in the post-vaccine scenario unless the physician has communicated the warning to the vaccinee.¹⁴⁷ In the interest of minimizing adverse reactions, a direct-warning rule better ensures that the patient is able to evaluate signs and symptoms than does the learned intermediary doctrine as applied under the community practice standard.¹⁴⁸ Even though patients may not legally reject vaccination, the absence of either a direct warning or a thorough balancing by a learned intermediary still puts the vaccinee's health at risk.

E. Vaccine Act's Informational and Recording Requirements

As the preceding discussion indicates, the Vaccine Act's preemption of direct failure to warn claims may actually increase the net number of vaccinees who do not receive sufficient warnings. The question thus arises whether the recording and informational requirements imposed by the Vaccine Act adequately compensate for the safety features sacrificed by eliminating direct failure to warn causes of action.

1. Vaccine informational materials

Concerning direct warnings for vaccinees, the Act requires that the Secretary furnish health care providers with vaccine information.¹⁴⁹ This information must discuss the benefits of the vaccine, the potential risks of the vaccine, the existence of the National Vaccine Injury Compensation Program, and other relevant information.¹⁵⁰ Health care providers are then required to distribute the information to the legal representative of the vaccinees.¹⁵¹

The vaccine information required by the Vaccine Act has a number of advantages. It allows the vaccinee or the vaccinee's legal representative to take an active role in the decision whether to vaccinate.¹⁵²

147. See Tietz, *supra* note 111, at 389 (highlighting patient awareness of potential side effects as crucial in order for drug therapy monitoring process to be effective, thereby requiring patient to be "coparticipant" in process).

148. See Tietz, *supra* note 111, at 389 (noting that patient compliance with prescription drug therapy improves when patient is informed directly, rather than if physician treats patient as inactive participant).

149. See 42 U.S.C. § 300aa-26(a)-(d) (1988 & Supp. V 1993).

150. *Id.* § 300aa-26(c)(1)-(4).

151. See *id.* § 300aa-26(d)(2) (1988) (requiring physician to provide vaccine information material prior to administration of vaccine).

152. See *id.* § 300aa-26(a) (1988 & Supp. V 1993) (mandating dissemination of vaccine information by health care providers to legal representatives or vaccinees). The very nature of the information that the Secretary must include in the vaccine information—benefits, risks, and compensation for injuries—offers the vaccinee the opportunity to consider for herself the benefits and risks of vaccination.

As discussed earlier, one of the policy considerations underlying the learned intermediary doctrine is that vaccinees often do not have the requisite medical knowledge to understand direct warnings.¹⁵³ Now, however, the vaccine information creates a framework for performing a risk-benefit analysis and thus permits the vaccinee to participate in the ultimate decision. In addition, by requiring physicians to provide vaccinees with written information, the Vaccine Act serves, in part, to objectify the pro-vaccine environment. The written information removes some of the discretion formerly allocated to the physician under the customary practice standard of informed consent.¹⁵⁴

2. Health care provider recording requirements

In addition to the Vaccine Act's mandate that physicians provide vaccinees with reliable information, the Act requires that physicians engage in certain recording practices with respect to the administration of vaccinations.¹⁵⁵ By requiring physicians to report certain recognizable events following vaccination, the Vaccine Act serves to combat the lack of individualized balancing by physicians that has occurred as a result of the excessively pro-vaccine environment.¹⁵⁶

153. See *supra* note 84 and accompanying text.

154. See Styles, *supra* note 70, at 128-29 (discussing customary practice standard of informed consent). Under the community practice standard, a physician, as a learned intermediary, is only required to communicate to the patient information that is deemed necessary by the medical community. *Id.* The Vaccine Act replaces the judgment of the medical community with the judgment of the Secretary of the Department of Health and Human Services (HHS). *Id.*; see also 42 U.S.C. § 300aa-26(a) (1988) (requiring HHS Secretary to develop vaccine information). The Act, however, may still rely on physician discretion to the extent that it requires doctors to supplement the vaccine information with oral explanations in "appropriate cases" without specifying who is to make this determination. *Id.* § 300aa-26(d) (Supp. V 1993). Given the Act's silence as to the meaning of "appropriate cases," *id.*, physicians providing supplementary vaccine information may still be governed by the community practice standard. This result is no different than if Congress had required manufacturers to provide direct warnings to physicians. In both cases, the vaccinee has a finite amount of written information upon which the physician may or may not add his or her medical knowledge. This scenario is at least an improvement over a learned intermediary doctrine without a regulatory imposition of patient warnings.

155. See 42 U.S.C. § 300aa-25(b)(1)(A)-(C) (1988) (detailing recording requirements for health care providers and manufacturers). The recording mandate requires that health care providers and manufacturers report to the Secretary the following information:

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300-14(b) of this title which occur within 7 days of the administration of any vaccines set forth in the Table or within such longer period as is specified in the table or section, (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and (C) such other matters as the Secretary may by regulation require.

Id.

156. Compare *id.* (setting out reporting requirements for health care providers and manufacturers) with *Incollingo v. Ewing*, 282 A.2d 206, 222 (Pa. 1971) (charging manufacturer with knowledge of environment in which drugs are distributed). The Vaccine Act approaches the problem of environmental overpromotion in a different manner than the court in *Incollingo*,

Pursuant to the recording requirements, even if a physician should forego an initial risk-benefit analysis, she is required to report adverse reactions and contraindications.¹⁵⁷

The reporting scheme may play a significant role in reducing DTP-related adverse reactions. Because the DTP vaccine is given in three installments, the reporting requirements may encourage physicians to either eliminate or delay the second and third doses when a potential problem manifests itself. The health care provider recording mandates, therefore, may help reestablish the individualized physician balancing that the authors of the learned intermediary doctrine assumed would take place.

IV. THE RELATIONSHIP BETWEEN FEDERAL AND STATE LAW

The Federal Government, through Congress and through the FDA, has played a key role in the development of American vaccine policy.¹⁵⁸ In designing the Vaccine Act, Congress had the opportunity to assert complete federal control over vaccine regulation by explicitly preempting state tort actions.¹⁵⁹ Congress, however, left petitioners with the option of pursuing civil tort actions,¹⁶⁰ although it created a presumption that manufacturers in compliance with FDA standards satisfy their warning duties¹⁶¹ and prohibited direct warning actions.¹⁶²

The congressional decision not to completely preempt state common law raises important questions about the proper relationship between federal regulatory and state common law regimes. On the one hand, given the Federal Government's predominate role in

which suggested that manufacturers be required to evaluate the state of mind of physicians receiving their warnings. *Incollingo*, 282 A.2d at 222. The Vaccine Act requires physicians to report directly certain contraindicating events. 42 U.S.C. § 300aa-25(b)(1)(A)-(C).

157. 42 U.S.C. § 300aa-25(b)(1)(A)-(B).

158. See, e.g., Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351-392 (1988 & Supp. V 1993) (setting forth various policies regarding, *inter alia*, representation, revocation, certification, and required recording and reporting of information concerning various drugs); Public Health Service Act, 42 U.S.C. §§ 241-289 (1988) (enumerating general powers and duties of Public Health Service, and establishing and specifying role and function of various medical institutions, services, and systems); Jennie Clarke, *Federal Preemption: A Vaccine Manufacturer's Defense*, 56 UMKC L. REV. 515, 525-28 (1988) (documenting growth of federal involvement in vaccine regulation throughout 20th century).

159. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (holding that Congress may preempt state law by explicitly announcing its intention in language of statute); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (concluding that scheme of federal regulation may be so highly pervasive as to allow reasonable inference that Congress intended to leave no room for States to supplement it).

160. 42 U.S.C. § 300aa-22(e) (1988).

161. *Id.* § 300aa-22(b)(2).

162. *Id.* § 300aa-22(c).

twentieth century vaccine regulation, one can argue that the Vaccine Act should have explicitly declared vaccine regulation to be an exclusively federal matter.¹⁶³ On the other hand, one can also argue that the Federal Government has exercised too much influence by passing the Vaccine Act. According to this view, the Vaccine Act's creation of a presumption that warnings are adequate if they comply with FDA standards paralyzes States' common law ability to function as a vehicle for protecting its citizens from the dangers of inadequate warnings.¹⁶⁴ This section examines the inherent tension between federal regulation and state common law as these systems apply to the regulation of vaccine warnings.

A. *The Preemption Doctrine*

Article VI of the U.S. Constitution, in announcing the supremacy of federal law, provides the basis for the preemption doctrine.¹⁶⁵ Federal courts have recognized two types of preemption: statutory and regulatory.¹⁶⁶ Although stemming from different sources of federal law, both types¹⁶⁷ preempt state statutes, regulations, and common law.¹⁶⁸

The U.S. Supreme Court has held that express language indicating a federal intent to preempt state law is a sufficient but not necessary condition for a finding of federal preemption.¹⁶⁹ Preemption may

163. Cf. Naile, *supra* note 36, at 689 (noting that all aspects of vaccine design, manufacturing, and labelling are overseen by FDA).

164. See Richard C. Ausness, *Federal Preemption of State Product Liability Doctrines*, 44 S.C. L. REV. 187, 276-77 (1993) (arguing that FDA only responds to warnings submitted by manufacturers and therefore may not be approving safest possible warnings).

165. See U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land."); see also Ausness, *supra* note 164, at 191 (stating that Supremacy Clause is basis for preemption doctrine); Naile, *supra* note 36, at 683 (stating that Supremacy Clause gives Congress power to override state law).

166. See Clarke, *supra* note 158, at 539; Benjamin W. Heineman, Jr. & Carter G. Phillips, *Federal Preemption: A Comment on Regulatory Preemption After Hillsborough County*, 18 URB. 589, 591 n.10 (1986).

167. See Ausness, *supra* note 164, at 191.

168. See Ausness, *supra* note 164, at 191 (explaining that state common law, as well as state legislation, is preempted by federal law); Clarke, *supra* note 158, at 531 (stating that both statutory and regulatory preemption override laws promulgated by state legislatures and state courts); see also *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (stating that "federal regulations have no less preemptive effect than federal statutes"); Clarke, *supra* note 158, at 530 (noting that courts have used same principles in finding both statutory and regulatory preemption).

169. See, e.g., *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (stating that preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose"); *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 633 (1973) (holding that federal law may expressly or impliedly preempt state law); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (holding that federal law may preempt state law either explicitly or implicitly).

also occur where federal intent to maintain exclusive control is implicit in the "structure and purpose" of the federal law.¹⁷⁰ The test for implied preemption is whether the federal law in question is so comprehensive as to occupy the entire field.¹⁷¹

Additionally, courts must find preemption where a conflict exists between state and federal laws.¹⁷² Conflict preemption has three distinct subcategories:¹⁷³ first, when compliance with both federal and state law is impossible;¹⁷⁴ second, when state law interferes with the objectives of federal law,¹⁷⁵ and third, when state law obstructs the methods used to achieve federal objectives.¹⁷⁶

In understanding preemption analysis, one must consider the limits to the preemption doctrine. The mere possibility of conflict between state and federal law does not lead to preemption.¹⁷⁷ Rather, the conflict must "necessarily exist."¹⁷⁸ Additionally, the concept of federalism carries with it a presumption against preemption.¹⁷⁹ Fearful of interfering with States rights, courts are very reluctant to preempt state law in areas of traditional state regulation.¹⁸⁰ Issues concerning health and safety are primary examples of traditional areas of state regulation.¹⁸¹

170. *Jones*, 430 U.S. at 525.

171. See *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983) (holding that dominant nature of federal interest will create presumption that state enforcement of law on same subject is prohibited); *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153 (finding implied preemption where federal regulation is so pervasive that it gives rise to inference that Congress completely occupied field).

172. See *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153 (holding that conflict results in nullification of state law to extent of conflict with federal law).

173. See *Ausness*, *supra* note 164, at 196-97.

174. See *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153; *Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142-43 (1963).

175. See *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153; *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

176. See *Barbara L. Atwell, Products Liability and Preemption: A Judicial Framework*, 39 *BUFF. L. REV.* 181, 186 (1991); see also *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (finding that dumping claims under state law interfered with federal method of compliance with Clean Water Act).

177. See *Goldstein v. California*, 412 U.S. 546, 554 (1973) (explaining importance of distinguishing between "possible" and "necessary" conflicts); *Atwell*, *supra* note 176, at 186 (arguing that actual conflict must exist to trigger conflict preemption doctrine).

178. *Goldstein*, 412 U.S. at 555 (1973) (holding that only necessary conflict warrants overriding state law).

179. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress" (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))).

180. *Id.* (citing need to achieve balance between federal and state rights); see also *United States v. Bass*, 404 U.S. 336, 349 (1971) (stating that absent clear intent from Congress, Court will be reluctant to impose balance between federal and state rights).

181. *Atwell*, *supra* note 176, at 188; see also *Hillsborough County v. Automated Medical Lab.*, 471 U.S. 707, 716 (1985) (explaining presumption of peaceful coexistence between state and

B. FDA Regulation of the Vaccine Industry

Arguments favoring federal preemption of state tort law remedies for vaccine injuries focus on the comprehensive nature of the FDA's regulation of the vaccine industry.¹⁸² In order to assess such arguments, this Comment initially reviews the history and present state of the FDA's role in federal vaccine policy.¹⁸³

The Federal Government's involvement with vaccine regulation began with the passage of the Virus, Serum, Toxin Act of 1902.¹⁸⁴ Under this federal legislation, the Public Health Service, and later the Department of Treasury, regulated the vaccine industry.¹⁸⁵ Although the names of the various administrative branches have changed over time,¹⁸⁶ the Federal Government has remained active in vaccine regulation throughout the twentieth century.¹⁸⁷ Presently, the FDA's Center for Drug and Biologics bears primary responsibility for vaccine regulation.¹⁸⁸

Pursuant to the Federal Food, Drug, and Cosmetic Act of 1938,¹⁸⁹ the FDA is the primary regulator of vaccines.¹⁹⁰ The FDA meets its obligations in a two-fold manner. The FDA promotes public health by approving the use of new and safe treatments.¹⁹¹ The FDA also protects public health by removing unsafe and ineffective drugs from the market.¹⁹² As the federal guardian of vaccine safety, the FDA

federal health and safety regulations).

182. See, e.g., *Hurley v. Lederle Lab.*, 651 F. Supp. 993, 999 (E.D. Tex. 1986) (stating that comprehensiveness of federal regulation demonstrates implied congressional intent to preempt state tort law), *rev'd on other grounds*, 863 F.2d 1173 (5th Cir. 1988); *Naile*, *supra* note 36, at 689 (arguing that comprehensiveness of federal regulations leaves no room for state tort law).

183. For a comprehensive overview of FDA vaccine regulation, see *Clarke*, *supra* note 158, at 525-29.

184. Pub. L. No. 57-274, 32 Stat. 728 (1902) (codified at 42 U.S.C. §§ 141-143 (1938)); see *Clarke*, *supra* note 158, at 525 (describing allocation of regulatory responses during 20th century).

185. *Clarke*, *supra* note 158, at 525 (noting that Congress passed 1902 Act following deaths of 12 children resulting from tetanus contamination from diphtheria and tetanus vaccine).

186. See *Clarke*, *supra* note 158, at 525. In 1944, Congress passed the Public Health Service Act (PHSA). Pub. L. No. 78-410, 58 Stat. 682, 702 (1994) (codified at 42 U.S.C. § 262 (1938)). The PHSA incorporated the Virus, Serum, Toxin Act and transferred regulatory responsibilities to the Federal Security Agency. *Clarke*, *supra* note 158, at 525. The Division of Biologics Standards (DBS), a subsidiary of the National Institutes of Health, assumed regulatory authority in 1955. *Id.* In 1972, DBS evolved into the FDA's Bureau of Biologics. *Id.* at 525-26.

187. See *supra* notes 163-81 and accompanying text (discussing Federal Government's role in 20th century vaccine regulation).

188. *Clarke*, *supra* note 158, at 526 (explaining that FDA's Office of Biologics Research and Review and the Bureau of Drugs together form the Center for Drugs and Biologics).

189. 21 U.S.C. §§ 301-392 (1988 & Supp. V 1993).

190. 21 U.S.C. § 371 (1988) (granting Secretary regulatory power).

191. 50 Fed. Reg. 7452 (1985) (explaining FDA's attempt to rewrite revision in order to expedite approval process for beneficial drugs).

192. *Id.* (describing protective role played by FDA).

has issued comprehensive regulations for the design and manufacture of vaccines.¹⁹³

The FDA's regulation of vaccines begins prior to the manufacturing stage.¹⁹⁴ Initially, a potential manufacturer must apply to the FDA for a license to manufacture the vaccine.¹⁹⁵ FDA regulations require manufacturers to submit a sample lot of the vaccine and summaries of tests run on the lot.¹⁹⁶ These regulations take into account not only the vaccine itself, but also employee qualifications and responsibilities,¹⁹⁷ as well as the condition of the manufacturer's work area.¹⁹⁸

The FDA has promulgated additional, specific rules for the production of the pertussis component of the DTP vaccine.¹⁹⁹ Manufacturers must test every lot of the pertussis component for potency²⁰⁰ and toxicity.²⁰¹ A written release from the FDA serves as final approval of the DTP lot.²⁰²

In addition to regulating design and manufacture, the FDA carefully evaluates the labelling of vaccines.²⁰³ The FDA requires that labels include the makeup of the vaccine, the administration schedule, and the indications and contraindications for usage.²⁰⁴ Of particular importance to the preemption discussion is the fact that the FDA must approve all language contained in a vaccine label.²⁰⁵ Once certain language is approved, manufacturers may not change label language without first filing a supplemental new drug application with the FDA.²⁰⁶ Manufacturers who alter warning language

193. Clarke, *supra* note 158, at 527.

194. See 21 C.F.R. § 601.1 (1994) (requiring both establishment and product license).

195. *Id.*

196. See *id.* § 601.2 (requiring manufacturer to submit "data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency").

197. See *id.* § 211.25 (requiring that all persons involved in manufacturing process have education, training, and experience necessary to carry out assignment).

198. See *id.* § 600.10 (allowing only designated individuals into vaccine-processing area).

199. See *id.* §§ 620.1 to .6 (providing requirements for propagation of bacteria, bacterial content, detoxification, potency tests, toxicity tests, dosage, and labelling).

200. See *id.* § 620.4 (prescribing laboratory test using mice as samples); see also *TABER'S CYCLOPEDIA MEDICAL DICTIONARY* 1359 (16th ed. 1985) (defining potency as "strength of medicine").

201. See 21 C.F.R. § 620.5 (requiring toxicity test using mice as samples); see also *TABER'S CYCLOPEDIA MEDICAL DICTIONARY*, *supra* note 200, at 1883 (defining toxicity as "the extent, quality, or degree of being poisonous").

202. 21 C.F.R. § 610.2 (stating that "a manufacturer shall not distribute a lot of a product until the lot is released by the Director").

203. See, e.g., *id.* §§ 610.60 to .65 (describing labelling requirements for DTP vaccine).

204. *Id.*

205. *Id.* § 601.12.

206. *Id.*; Clarke, *supra* note 158, at 529.

without FDA approval face criminal prosecution.²⁰⁷

The FDA, in deciding whether to approve or reject certain warning language, promotes a policy of uniform labelling and warnings.²⁰³ While manufacturers must provide adequate warnings, manufacturers cannot insulate themselves from liability by issuing overly broad warnings. All information contained in vaccine labels and warnings must have clinical relevance.²⁰⁹ The FDA only permits warnings about known hazards, not theoretical possibilities.²¹⁰

C. Preemption Case Law

1. *The courts' rejection of preemption claims brought by vaccine manufacturers*

In the vaccine context, courts generally have not found an intent by Congress, or any agency, to preempt a State's failure to warn cause of action.²¹¹ The Fourth Circuit's decision in *Abbot v. American Cyanamid Co.*²¹² provides a well-organized discussion of the issues involved in the warning preemption debate. The plaintiff, after receiving a DTP vaccination manufactured by American Cyanamid, suffered severe neurologic injuries.²¹³ Raising a motion for summary judgment, the manufacturer argued that the plaintiff's failure to warn and design defect theories were preempted.²¹⁴ American Cyanamid offered what the Fourth Circuit described as a "broad" and a "narrow" preemption argument.

American Cyanamid's "broad" argument, essentially an occupation of field claim, insisted that the comprehensive nature of federal

207. Clarke, *supra* note 158, at 529; *see also* 21 C.F.R. § 601.5(b)(3) (stating that FDA will revoke manufacturer's license and hold agency hearing for noncompliance if manufacturer fails to report labelling changes).

208. *See* 50 Fed. Reg. 51,402 (1985) (naming uniformity as goal of regulation).

209. 44 Fed. Reg. 37,442 (1979) (limiting relevant pharmacological information to that which is of significant, normal, and practical clinical applicability).

210. 21 C.F.R. § 201.56(c) (requiring that manufacturers base warnings on "data derived from human experience" and not on claims where there is inadequate evidence). The regulations further mandate that conclusions based on animal data shall be identified as such. *Id.*

211. *See* *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1176 (5th Cir. 1988) (collecting federal and state decisions rejecting preemption claims); *Knudsen v. United States*, 691 F. Supp. 1346 (M.D. Fla. 1987); *Foyle v. Lederle Lab.*, 674 F. Supp. 530 (E.D.N.C. 1987); *Martinkovic v. Wyeth Lab.*, 669 F. Supp. 212 (N.D. Ill. 1987); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332 (C.D. Cal. 1987); *MacGillivray v. Lederle Lab.*, 667 F. Supp. 743 (D.N.M. 1987); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483 (D. Kan. 1987), *cert. denied*, 498 U.S. 981 (1990); *Wack v. Lederle Lab.*, 666 F. Supp. 123 (N.D. Ohio 1987); *Patten v. Lederle Lab.*, 655 F. Supp. 745 (D. Utah 1987).

212. 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988).

213. *See* *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1110 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988).

214. *See id.*

vaccine regulation left no room for state regulation.²¹⁵ American Cyanamid cited the detailed labelling requirements imposed by FDA regulations as evidence that the FDA intended to regulate exclusively all aspects of vaccine labelling.²¹⁶ American Cyanamid argued that because the federal requirements regulated virtually every detail of the label, there should be no room for state action.²¹⁷

The Fourth Circuit, however, refused to find preemption based upon occupation of field, stating that the comprehensiveness of federal regulations does not result in a per se finding of preemption.²¹⁸ The court began with the premise that issues addressed by congressional legislation are matters of national concern.²¹⁹ Every issue addressed by Congress, however, does not preclude concurrent state law.²²⁰ Instead, proponents of federal preemption must overcome several adverse presumptions.²²¹ First, health and safety matters are traditionally areas of state concern and are not easily found to be preempted.²²² Second, given that agencies promulgate

215. See *id.* at 1111-12.

216. See *id.* at 1112; see also *supra* notes 203-07 and accompanying text (discussing labelling requirements).

217. *Abbot*, 844 F.2d at 1112.

218. *Id.* (citing *Hillsborough County v. Automated Medical Lab.*, 471 U.S. 707, 719 (1985)) (stating that although all matters addressed by Congress are of national concern, not all matters of national concern warrant preemption). *But see* Naile, *supra* note 36, at 690. Naile argues that DTP regulations are distinguishable from the blood regulations in *Hillsborough County*. *Id.* First, the local interest in blood collection, the subject addressed by the court in *Hillsborough County*, is stronger than the local interest in vaccine regulation. *Id.* Second, the local regulations did not require the collectors to violate federal regulations, while state tort law may require vaccine manufacturers to violate FDA regulations. *Id.* Third, the FDA blood collection regulations expressly state their intent of nonexclusivity, while FDA vaccine regulations do not make a similar admission of nonexclusivity. *Id.*

Each of Naile's three arguments distinguishing *Hillsborough County* from the vaccine preemption debate misses a crucial point. By arguing that blood collection is a stronger local interest than vaccine regulation, Naile ignores the utilitarian benefits of infectious disease control. Local governments, acting in the best interest of their constituents, have a strong interest in establishing strong preventive vaccination programs. Concerning the argument that state tort verdicts might compel violation of federal vaccine regulations, Naile ignores the fact that the possibility of conflict is not a sufficient ground for preemption. See *Goldstein v. California*, 412 U.S. 546, 554-55 (1973) (distinguishing between possibility of conflict and inevitability of conflict). Finally, the lack of an affirmative statement of nonexclusivity in FDA vaccine regulations does not distinguish *Hillsborough County*. "When preemption by regulation is considered, courts are reluctant to find preemption by federal regulations when the agency does not make very clear an intent of preemption since agencies normally address problems in a detailed manner." *Abbot*, 844 F.2d at 1112.

219. *Abbot*, 844 F.2d at 1112.

220. *Id.* (noting that mere existence of federal legislation does not preempt all related state law).

221. *Id.* The Court noted that preemption is difficult to find when: (1) Congress did not expressly manifest its intention to preempt, *id.* (citing *Maryland v. Louisiana*, 451 U.S. 725, 726 (1981)); (2) the preemption argument is based on the comprehensiveness of federal regulations, *id.* (citing *Hillsborough County*, 471 U.S. at 717); or (3) no federal remedy exists, *id.* (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

222. *Id.*; *Hillsborough County*, 471 U.S. at 715.

very detailed regulations,²²³ regulations lacking a clear intent to preempt presumptively do not occupy the field.²²⁴

American Cyanamid's "narrow" preemption argument took the form of a conflict of policy objectives, claiming that state tort law interfered with the intended effects of the federal vaccine policy.²²⁵ According to the Fourth Circuit, the federal objective of FDA regulations was to promote vaccine safety.²²⁶ The defendant argued that, in addition to safety, federal vaccine policy is committed to protecting the availability and use of the vaccines.²²⁷ The imposition of excessive state tort law liability, the defendant argued, frustrates these policy objectives by driving manufacturers from the market.²²⁸ In considering American Cyanamid's motion for summary judgment based on a policy objectives conflict, the court framed the issue as "whether the federal interest requires that federal regulations be viewed as having struck the balance between safety and quantity or whether the regulations merely establish minimum safety standards and allow state regulation to establish the balance."²²⁹

In an attempt to discern the nature of the federal policy that American Cyanamid claimed was harmed by state regulations, the Fourth Circuit turned to the Vaccine Act.²³⁰ As a preliminary matter, the court rejected the defendant's argument that because the Vaccine Act does not expressly address preemption it is neutral on the matter.²³¹ Rather, the court turned to the Vaccine Act's legislative history²³² and found two assumptions weighing against a finding of

223. See *Abbot*, 844 F.2d at 1113 (citing *Hillsborough County*, 471 U.S. at 718).

224. See *id.* at 1112 (noting that courts are more reluctant to infer preemption from comprehensiveness of regulations than from comprehensiveness of statutes).

225. See *id.* at 1113.

226. See *id.* (stating overall goal of legislation is safety of drugs and biological products).

227. See *id.*; see also *Naile*, *supra* note 36, at 527 (listing objectives of federal vaccine regulation as safety and efficiency).

228. See *Abbot*, 844 F.2d at 1113.

229. *Id.*; see also *Hillsborough County*, 471 U.S. at 721 (holding that federal objective of blood collection regulations was to establish minimum standards, not to strike balance of safety and quality). For other cases viewing federal regulations as minimum standards, see *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975); *Griffin v. United States*, 500 F.2d 1059, 1060-67 (3d Cir. 1974); *MacGillivray v. Lederle Lab.*, 667 F. Supp. 743, 746 (D.N.M. 1987); *Toner v. Lederle Lab.*, 732 P.2d 297, 311 n.12 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988); *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1055 (Kan.), *cert. denied*, 469 U.S. 965 (1984); *Feldman v. Lederle Lab.*, 479 A.2d 374, 390 (N.J. 1984).

230. See *Abbot*, 844 F.2d at 1113-14 (viewing Vaccine Act as most recent statutory expression of federal vaccine policy).

231. *Id.* at 1113.

232. See 1986 HOUSE REPORT, *supra* note 1, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6345 (stating that prior to passage of Vaccine Act, civil tort system was sole compensation mechanism).

preemption.²³³ First, the Vaccine Act recognizes that prior federal vaccine legislation, specifically the Federal Food, Drug, and Cosmetic Act²³⁴ and the Public Health Service Act,²³⁵ does not preempt state tort actions.²³⁶ Second, the Vaccine Act expressly states that state tort actions remain available to aggrieved parties.²³⁷ Finding that the Vaccine Act did not evince a federal intent to strike an immutable balance between vaccine safety and availability, the court refused to adopt the opposite policy determination.²³⁸

2. Preemption and the physical conflict dilemma

In *Hurley v. Lederle Laboratories*,²³⁹ (*Hurley II*) the Fifth Circuit, like the Fourth Circuit in *Abbot*, did not find that FDA regulations completely preempted state warning claims.²⁴⁰ The Fifth Circuit did, however, recognize that specific FDA regulations may result in a

233. *Abbot*, 844 F.2d at 1113.

234. 21 U.S.C. §§ 301-393 (1988 & Supp. V 1993).

235. 42 U.S.C. §§ 200 to 300aaa-13 (1988 & Supp. V 1993).

236. *Abbot*, 844 F.2d at 1113. While the court did not cite the specific language of the Vaccine Act, it noted that the purpose of the two earlier acts was to promote "the safety of drugs and biologic products." *Id.* Moreover, the court noted that the Vaccine Act is "replete" with the assumption that "state tort and contract actions are available without preemption by earlier federal legislation." *Id.*

237. 42 U.S.C. § 300aa-22(a) (1988) (stating that except as otherwise provided, state law applies to vaccine injury civil actions); *Abbot*, 844 F.2d at 1113.

238. *Abbot*, 844 F.2d at 1114. In *Hurley v. Lederle Lab.*, the Fifth Circuit delivered an even stronger admonishment against the federal judiciary determining the objectives of federal vaccine policy. *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1177 (5th Cir. 1988) (*Hurley II*), *rev'd* 651 F. Supp. 993 (E.D. Tex. 1986) (*Hurley I*). The court in *Hurley II* acknowledged the theoretical possibility of removing state tort liability in order to further the policy objective of increasing vaccine supplies. *Id.* The court then proceeded to demonstrate that the wisdom of such a policy decision is uncertain. First, preempting state tort law might promote consumer insecurity concerning the quality of vaccines. *Id.* Second, the price increases caused by state tort damages may be passed on to the Federal Government, thereby eliminating the very need to preempt state tort law. *Id.* Given the potentially adverse consequences that would arise from a finding that state tort law conflicted with the objectives of federal vaccine policy, the Fifth Circuit found that there was no sufficient evidence on which to declare state tort law preempted. *Id.*

Interestingly, the Fifth Circuit's decision in *Hurley II* reversed a decision by the U.S. District Court for the Eastern District of Texas finding preemption based on, *inter alia*, an objectives conflict. *Hurley v. Lederle Lab.*, 651 F. Supp. 993 (E.D. Tex. 1986) (*Hurley I*), *rev'd*, 863 F.2d 1173 (5th Cir. 1988) (*Hurley II*). In *Hurley I*, the district court found that allowing individual States to dictate warnings standards would irreparably harm the federal policy of warning uniformity. *Id.* at 1005-06.

With the Vaccine Act as a guide, the Fifth Circuit in *Hurley II* established a better and more consistent decision than the district court in *Hurley I*. The Vaccine Act's legislative history alleviates the need for courts to choose between indeterminative policy considerations. If Congress did not believe that state law warning actions damaged the Act's policy favoring uniformity, courts no longer have a need to find an objectives conflict.

239. *Hurley II*, 863 F.2d at 1173.

240. See *id.* (recognizing that in limited instances state law may conflict with federal law or regulations but finding that manufacturer's arguments so broadly phrased as to preempt all state product liability law for vaccine). The court noted that there should be a reluctance to find that "federal law implicitly preempts state law." *Id.*

limited preemption of state tort law when a manufacturer cannot satisfy a federal regulation without violating state law and vice versa.²⁴¹ This reasoning represented a compromise between two competing concerns. On the one hand, courts would place manufacturers in an inescapable bind by finding the FDA-approved warning insufficient. In order to meet a state-warning standard, the manufacturer would have to violate federal law.²⁴² On the other hand, the court in *Hurley II* found limits to the value of FDA-approved warnings. Given that the FDA only evaluates warnings based on the information submitted by manufacturers, the FDA's role in the warning evaluation process is somewhat "passive."²⁴³ In approving designs, the FDA only considers the sufficiency of the proposed designs and does not consider alternative designs or regulation schemes.²⁴⁴ The warnings approved by the FDA, therefore, may not represent the safest potential warnings, for the FDA may not have considered the full universe of relevant information.

241. See *id.* at 1179 (finding that specific FDA approval of manufacturer warning preempts state inadequate warning claim, assuming FDA has all relevant information to make approval decision).

242. *Id.* For arguments that physical conflicts, where the manufacturer cannot concurrently satisfy both federal and state law, place vaccine manufacturers in an unfair position, see *Hurley I*, 651 F. Supp. at 1000 (arguing that Texas common law determination of inadequate warnings can create physical conflict with FDA standards). See also Clarke, *supra* note 158, at 536-37 (asserting that state court juries often impose warning duties inconsistent with federal regulations); Naile, *supra* note 36, at 689 (arguing that state tort liability punishes manufacturer for not violating federal law).

Broader policy arguments against allowing state courts to find failure to warn liability are often raised in conjunction with the foregoing physical conflict arguments. Many argue that the FDA is in a better position to establish and judge warning standards than are state judges and juries. See, e.g., Pennington P. Landon, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 116-17 (1988); Alan Schwartz, *Proposals for Products Liability Reform: A Theoretical Synthesis*, 97 YALE L.J. 353, 369 (1988). FDA officials have superior resources and superior technical expertise with which to make complicated safety policy decisions. Ausness, *supra* note 164, at 276. To allow state judges and juries to second-guess FDA standards defeats the safety enforcement structure that Congress established through its creation of the FDA. See Naile, *supra* note 36, at 694 (arguing that jury evaluation of FDA standards frustrates congressional intent in delegating exclusive authority to FDA to approve and license vaccines).

243. See *Hurley II*, 863 F.2d at 1179 (noting that FDA only considers vaccine designs "if and when" manufacturers come forward with proposal).

244. See *id.* (concluding that absence of FDA-approved alternatives to whole-cell vaccine does not indicate FDA disapproval of any such alternatives). There are other reasons for allowing state law to coexist with FDA regulations. Over the past decade, the FDA was forced to limit its budget and cut back on its staff. See Ausness, *supra* note 164, at 276 (stating that FDA has cut staff by 2000 since 1980 (citing Bruce A. Silverglade, *Preemption—The Consumer Viewpoint*, 45 FOOD DRUG COSM. L.J. 143, 144 (1990))). With reduced financial and staff capacities, the FDA has a diminished ability to independently assess vaccine warnings. See *id.*; see also Jones *ex rel.* Jones v. Lederle Lab., 695 F. Supp. 700, 711 (E.D.N.Y. 1988) (finding that limited FDA resources would restrict agency's ability to perform independently).

D. The Vaccine Act's Presumption of Warning Adequacy as an Attempt to Resolve the Physical Conflict Dilemma

The Vaccine Act's presumption of adequate warning when manufacturers comply with FDA standards may represent an attempt to balance the Fifth Circuit's conflicting views toward physical conflict preemption in *Hurley II*.²⁴⁵ In the interest of insulating manufacturers from having to choose between federal criminal liability or state tort liability, the Vaccine Act begins with the assumption that the FDA-approved warning is adequate.²⁴⁶ The Vaccine Act, however, takes into account the passive nature of the FDA's warning-evaluation process and compensates for this deficiency by allowing plaintiffs to rebut the presumption²⁴⁷ with a showing that the manufacturer "engaged in fraud or intentional withholding of information."²⁴⁸ If the manufacturer has not provided the FDA with all relevant information for examining the manufacturer's proposed warning, the Act does not insulate the manufacturer against state inadequate warning claims.²⁴⁹

V. VACCINE ACT AND RESTATEMENT 402A COMMENT K

Section 300aa-22(b)(1) of the Vaccine Act adopts *Restatement (Second) of Torts* section 402A comment k. Comment k represents an

245. See 1986 HOUSE REPORT, *supra* note 1, at 6, reprinted in 1986 U.S.C.C.A.N. at 6345 (outlining inadequacy of civil tort system as compensation mechanism and instability of vaccine market as reasons propelling vaccine legislation).

246. 42 U.S.C. § 300aa-22(b)(2) (1988). The presumption reflects a legislative discomfort with the litany of cases viewing FDA regulations as floors rather than ceilings. For cases finding that FDA regulations are minimum standards, see *supra* note 229.

247. 42 U.S.C. §§ 300aa-22(b)(2), -23(d)(2) (1988 & Supp. V 1993). Pursuant to §§ 300aa-22(b)(2)(A) and -23(d)(2), a plaintiff may vitiate the presumption by showing that the manufacturer engaged in fraud or intentional and wrongful withholding of information from the Secretary of Health either before or after approval of the vaccine, or other criminal or illegal activity relating to the safety and effectiveness of vaccines. *Id.* § 300aa-23(d)(2)(A). Alternatively, the plaintiff may show by "clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with . . . [the] Act." *Id.* § 300aa-22(b)(2)(B).

This congressional approach closely parallels the Fifth Circuit's analysis in *Hurley II*. According to the Fifth Circuit, a finding of physical conflict is warranted where state law imposes standards violative of federal law and where the manufacturer has provided the FDA with all the information necessary to evaluate the proposed warning. *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1179 (5th Cir. 1988) (citing *KVUE, Inc. v. Austin Broadcasting Corp.*, 709 F.2d 922, 931-32 (5th Cir. 1983)). The Fifth Circuit therefore held that the only question presentable to the jury was whether Lederle provided the FDA with all available information. *Id.* at 1179-80. In effect, the Vaccine Act arrives at the same result by allowing rebuttal of the warning presumption only if the manufacturer withheld material information.

248. 42 U.S.C. §§ 300aa-22(b)(2)(A), -23(d)(2)(A)-(C) (1988).

249. *Id.* § 300aa-23(d)(2)(B); see also *supra* note 246 (discussing ways plaintiff may overcome presumption that manufacturer warnings in compliance with FDA standards are adequate).

important exception to the strict liability doctrine.²⁵⁰ This exception recognizes that there exists a certain class of products that is incapable of being made safer,²⁵¹ but nonetheless provides great value to society.²⁵² Acknowledging the utilitarian interest in the availability of such "unavoidably unsafe" products, comment k directs that, so long as the "unavoidably unsafe" product is properly prepared and marketed, strict liability will not apply.²⁵³ Because proper manufacturing and proper warnings are prerequisites to immunity, comment k only provides manufacturers with protection from liability premised on strict liability design defect claims.²⁵⁴

A. The Vaccine Act's Blanket Application of Comment k to All Vaccines Covered by the Act

The Vaccine Act's legislative history clarifies Congress' intention to apply comment k immunity to all vaccines covered by the Act.²⁵⁵ In deciding to apply comment k to vaccines, Congress expressed fear that sympathetic juries would ignore the social utility of vaccines and routinely rule for innocent victims and against "equally 'innocent'" manufacturers.²⁵⁶ Congress, seeking to ensure the continued compensation of victims while removing economic disincentives for manufacturers, applied comment k to all vaccines covered by the Act and created a no-fault compensation system for injured parties

250. See Dark, *supra* note 69, at 820-21 (explaining that where product is unavoidably unsafe, strict liability does not apply if product contains proper warning); Tim Moore, *Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?*, 26 HOUS. L. REV. 707, 708 (1989) (arguing that unavoidably unsafe products, properly manufactured and containing proper warnings, are not subject to strict liability).

251. See RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k ("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.").

252. See RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k (calling marketing and use of unavoidably unsafe products such as Pasteur vaccine "fully justified, notwithstanding the high degree of risk which they involve").

253. RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k.

254. See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) (reading comment k to hold that absence of appropriate warning constitutes unreasonable danger, thus allowing strict liability claim); *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 465 (Ct. App. 1987) (holding that comment k immunity concerns only design defects); *Toner v. Lederle Lab.*, 732 P.2d 297, 305 (Idaho 1987) (holding that express language of comment k only immunizes manufacturers from strict liability for design defects and not for manufacturing or warning defects); *Feldman v. Lederle Lab.*, 479 A.2d 374, 383 (N.J. 1984) (holding that comment k immunity does not insulate manufacturer from strict liability for failure to warn).

255. 1986 HOUSE REPORT, *supra* note 1, at 26, reprinted in 1986 U.S.C.C.A.N. at 6367 ("The committee has set forth comment k in this bill because it intends that the principle in comment k regarding 'unavoidably unsafe products' . . . apply to the vaccines covered in the bill . . .").

256. 1986 HOUSE REPORT, *supra* note 1, at 26, reprinted in 1986 U.S.C.C.A.N. at 6367 (discussing need to create alternative that compensates victim while not unduly penalizing manufacturer).

deprived of strict liability causes of action.²⁵⁷

The Vaccine Act's blanket adoption of comment k represents one of three possible ways of approaching "unavoidably unsafe" products.²⁵⁸ As an alternative to insulating all vaccines from strict design defect liability, Congress could have eliminated comment k and subjected all designs to strict design defect liability.²⁵⁹ Additionally, as a middle ground between blanket insulation and no insulation, Congress could have adopted a threshold test to determine whether a given vaccine warrants special protection.²⁶⁰ This approach was developed by the California Court of Appeals in *Kearl v. Lederle Laboratories*.²⁶¹ The court in *Kearl* did not contest the basic concept of exceptional social utility underlying comment k.²⁶² Instead, the California Court of Appeals expressed concern with the manner of the comment's application.²⁶³ Characterizing the judiciary's application of comment k as "routine" and "mechanical,"²⁶⁴ the court in *Kearl* held that before a jury hears the issue of design defect liability, a judge must make a threshold determination of whether to grant a defendant comment k immunity.²⁶⁵ In making this decision, the judge should consider:

- (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product both was "substantial" and "unavoidable"; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review.²⁶⁶

A third approach to the "unavoidably unsafe" product issue is to subject all products to strict design defect liability.²⁶⁷

257. See 1986 HOUSE REPORT, *supra* note 1, at 26, reprinted in 1986 U.S.C.C.A.N. at 6367 (allowing victim to seek relief even where vaccine is as safe as possible).

258. See *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (explaining that courts could apply strict liability doctrine to all products, apply comment k to all products, or apply threshold test to determine when comment k protection should apply).

259. See *id.*

260. See *id.*

261. 218 Cal. Rptr. 453, 463-64 (Ct. App. 1985) (holding that judge must engage in three-prong test to decide whether to apply comment k).

262. *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 463 (Ct. App. 1985).

263. *Id.* ("The statement that drugs are unavoidably [dangerous], and therefore within the protection of comment k, has become almost tautological." (quoting Comment, *Can a Prescription Drug Be Defectively Designed?—Brochu v. Ortho Pharmaceutical Corp.*, 31 DEPAUL L. REV. 247, 254 (1981))).

264. *Id.*

265. See *id.* at 463-64.

266. *Id.* at 464.

267. See *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988).

B. A Criticism of the Vaccine Act's Blanket Application of Comment k

Given the multitude of divergent judicial interpretations of comment k, Congress had no paradigmatic example to follow when drafting the Vaccine Act.²⁶⁸ Textual and structural arguments exist both supporting and rebutting a blanket application of comment k to all vaccines. A close reading of the text of comment k and analysis of the comment's underlying policy, however, indicates that the concept of "unavoidably unsafe" products, defined by the *Restatement* as incapable of being made safe for their intended and ordinary use,²⁶⁹ cannot support a blanket approach.²⁷⁰

1. Textual challenge

A literal reading of the text of comment k suggests that the "unavoidably unsafe" standard requires some sort of discerning test.²⁷¹ The comment begins with the words, "There are some products"²⁷² The American Law Institute's use of "some" indicates that not all products in a class automatically merit immunity from strict liability design defect claims.²⁷³

The comment continues, "[I]n the present state of human knowledge, these products are quite incapable of being made safe for their intended and ordinary use."²⁷⁴ Measuring from the time of distribution, a plain-language interpretation of these two clauses suggests that only a product that is not subject to improvement using

268. See Davis & Bowman, *supra* note 75, at 289 (explaining that different jurisdictions have employed divergent interpretations of comment k); Moore, *supra* note 250, at 724-25 (citing four separate approaches to comment k treatment). Compare *Toner v. Lederle Lab.*, 732 P.2d 297, 308 (Idaho 1987) (holding that comment k immunity does not apply to all prescription drugs), *cert. denied*, 485 U.S. 942 (1988) with *Brown*, 751 P.2d at 482 n.11 (finding that immunity from strict design defect liability applies to all prescription drugs) and *Grundberg v. UpJohn Co.*, 813 P.2d 89, 90 (Utah 1991) (holding that all drugs approved by FDA are "unavoidably unsafe" as matter of law).

269. RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k.

270. See *Toner*, 732 P.2d at 308 ("It is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives."). An interesting counterargument, however, is that any improvement of a drug changes its chemical nature, thus creating an entirely new drug. According to this argument, the act of improving old drugs results in the creation of a new drug. Because the end result of improvement is a new drug, a manufacturer, by definition, cannot produce a safer version of the same drug. See *Brown*, 751 P.2d at 478 (rejecting argument that improving drug's design will create new drug that cannot be considered definitionally as improved design of old drug).

271. See *Toner*, 732 P.2d at 308 (arguing that comment contemplates risk-benefit analysis); Moore, *supra* note 250, at 722 (stating that language of comment k does not indicate any intent to provide blanket protection to all drugs).

272. RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k.

273. RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k.

274. RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k.

currently held scientific knowledge warrants comment k immunity.²⁷⁵

In order for the Vaccine Act to comport with the language of comment k, Congress would have to perform either a risk-utility analysis before promulgating section 22(b) or allow the judiciary to perform a risk-utility analysis at trial.²⁷⁶ Given that Congress rejected the latter approach,²⁷⁷ we must presume that Congress applied a risk-utility analysis to the vaccines covered by the Act. The language of comment k, however, raises questions as to whether the whole-cell DTP vaccine warrants classification as an "unavoidably unsafe" product.²⁷⁸

In order to reach the conclusion that the whole-cell DTP vaccine is not an "unavoidably unsafe" product, it is first necessary to provide some history concerning vaccine designs. The DTP vaccine currently licensed by the FDA consists of three parts—diphtheria toxoids, tetanus toxoids, and the whole cell pertussis component.²⁷⁹ Adverse reactions to the DTP vaccine have been linked to the pertussis portion of the vaccine.²⁸⁰ While the immunizing factors in the diphtheria and tetanus portion of the vaccine can be identified and purified, the offending elements of the pertussis portion cannot be removed.²⁸¹

Many experts in the medical community, concerned with the reactivity of the pertussis portion of the DTP vaccine, have advocated

275. See *Toner*, 732 P.2d at 306 (stating that "unavoidable risk" requires no feasible alternative design that, at time of product's production, accomplishes same purpose with less risk). On the other hand, textual arguments certainly exist supporting Congress' blanket application of comment k immunity to all vaccines covered by the Vaccine Act. Comment k cites the Pasteur vaccine as an "outstanding example" of an "unavoidably unsafe" product. *Id.* Louis Pasteur, a 19th century French chemist, developed a rabies vaccine and made substantial contributions to the field of immunology. *TABER'S CYCLOPEDIA MEDICAL DICTIONARY*, *supra* note 200, at 1239. Additionally, comment k speaks of "many . . . vaccines" worthy of comment k treatment. *RESTATEMENT (SECOND) OF TORTS*, *supra* note 17, § 402A cmt. k.

276. The language of comment k would permit Congress to provide blanket comment k immunity, if, prior to promulgating the Vaccine Act, Congress performed an "alternative design" analysis for all of the vaccines covered. It is textually unacceptable, however, for Congress to legislate blanket immunity from strict liability under the guise of applying comment k. If Congress decides to insulate manufacturers from strict design defect liability, Congress should announce that it is abandoning comment k and is creating a new standard.

277. See 1986 HOUSE REPORT, *supra* note 1, at 26, *reprinted in* 1986 U.S.S.C.A.N. at 6367 (explaining that comment k applies to all vaccines covered by Act).

278. See *infra* notes 282-99 and accompanying text (stating that existence of equally effective, safer version of DTP supports view that whole-cell DTP is not "unavoidably unsafe").

279. Naile, *supra* note 36, at 661.

280. Naile, *supra* note 36, at 662.

281. Naile, *supra* note 36, at 662; *Toner v. Lederle Lab.*, 732 P.2d 297, 300 (Idaho 1987) (stating that complex nature of pertussis-causing organism is so complex that toxin cannot be deactivated) (citing *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 731 (2d Cir. 1979)), *cert. denied*, 485 U.S. 942 (1988).

the development of an alternative vaccine.²⁸² Currently, two alternatives to the whole-cell pertussis portion exist: acellular and non-cellular vaccines.²⁸³ Although not currently manufactured, a non-cellular vaccine was discovered in the 1950s.²⁸⁴ Testing of the non-cellular vaccine has revealed a product with adequate immunogenicity but lower reactivity than its whole cell pertussis counterpart.²⁸⁵

In 1961, Eli Lilly & Company applied for a patent for a non-cellular pertussis vaccine named Tri-Solgen.²⁸⁶ Upon FDA approval, Tri-Solgen dominated the market until the mid-1960s.²⁸⁷ Of special importance to the comment k issue is an internal clinical evaluation run by Lederle Laboratories and Eli Lilly in 1967.²⁸⁸ The test compared the relative reactivity of Lederle's Tri-Immunol vaccine, a whole-cell DTP vaccine, against Lilly's Tri-Solgen non-cellular vaccine.²⁸⁹ The results of a test on 335 infants showed that the whole-cell vaccine had a much higher reactivity rate than did the non-cellular vaccine.²⁹⁰ Although Lederle had first-hand evidence demonstrating the lower reactivity rate of the non-cellular pertussis vaccine, it continued to market the whole-cell version.²⁹¹

In 1975, Lilly stopped producing Tri-Solgen.²⁹² Wyeth Laboratories secured an option to the rights for the manufacturing technology of Tri-Solgen. Wyeth could not, however, purchase Lilly's license, because FDA regulations require manufacturers of identical vaccines to acquire separate licenses.²⁹³ During the late-1970s, Wyeth devel-

282. See Burke, *supra* note 126, at 547.

283. Naile, *supra* note 36, at 668-69 (discussing acellular vaccine, used for mass immunization in Japan since 1991, and non-cellular vaccines as alternatives to whole-cell vaccine).

284. Toner, 732 P.2d at 300 (noting that clinical testing of non-cellular vaccine occurred in early 1950s); Burke, *supra* note 126, at 568-70 (stating that Eli-Lilly developed non-cellular DTP vaccine in 1950s).

285. Burke, *supra* note 126, at 569-70; see TABER'S CYCLOPEDIA MEDICAL DICTIONARY, *supra* note 200, at 896 (defining immunogenicity as "[t]he capacity to stimulate the formation of antibodies").

286. Burke, *supra* note 126, at 569.

287. See Burke, *supra* note 126, at 569 (citing public relations campaign documenting Tri-Solgen's reduced reactivity rate as reason for non-cellular vaccine's success).

288. See Burke, *supra* note 126, at 569 (discussing internal clinical evaluation comparing reaction rates between Tri-Solgen and whole-cell vaccine). The interoffice memo, released in 1985 by an organization named Dissatisfied Parents Together, was produced in response to a discovery request during DTP litigation. *Id.* at 569 n.163.

289. Burke, *supra* note 126, at 569 (stating that Lederle initiated test to evaluate the purported success of Lilly's vaccine).

290. Burke, *supra* note 126, at 259; see also Toner v. Lederle Lab., 732 P.2d 297, 300 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988).

291. Burke, *supra* note 126, at 569.

292. See Toner, 732 P.2d at 300; Burke, *supra* note 126, at 570.

293. See Naile, *supra* note 36, at 668 (explaining that Wyeth could not meet FDA facility-licensing requirements).

oped its own non-cellular vaccine.²⁹⁴ The FDA, however, refused to license Wyeth's product, citing both a lack of evidence showing that the non-cellular vaccine was superior to the whole-cell version and concerns about possible toxicity.²⁹⁵ Since Lilly's withdrawal from the DTP market, only the whole-cell DTP vaccine has been available in the United States.²⁹⁶

Application of the language of comment k to the above-mentioned DTP history reveals that DTP may not qualify as an "unavoidably unsafe" product.²⁹⁷ The scientific history suggests that manufacturers have possessed the knowledge and the production capabilities to produce a safer version of the DTP vaccine.²⁹⁸ At the same time, however, the FDA does not currently permit the sale of the non-cellular DTP vaccine.²⁹⁹ This analysis demonstrates that a textual interpretation of comment k does not, standing alone, resolve the safety versus availability dilemma in the context of design defect liability. Rather, one must examine the policy considerations underlying the strict liability doctrine and the exception to these considerations contained in comment k.

2. Policy challenge

Although the Vaccine Act's adoption of a blanket approach to comment k partially conflicts with a textual interpretation of the comment, Congress' decision nonetheless finds support in the case law of many jurisdictions.³⁰⁰ Decisions announcing a blanket

294. Naile, *supra* note 36, at 668.

295. Naile, *supra* note 36, at 668.

296. Burke, *supra* note 126, at 570.

297. See Burke, *supra* note 126, at 575 (explaining that strongest argument against awarding whole-cell vaccine "unavoidably unsafe" product status is existence of equally effective and less dangerous alternative product); see also *Toner*, 732 P.2d at 306 (stating that existence of alternative design, posing less risk, would undermine purpose of comment k and would not receive immunity from liability). In *Toner*, the Idaho Supreme Court, in response to questions certified by the Ninth Circuit, did not find it necessary to determine whether the whole-cell DTP vaccine is an unavoidably unsafe product because the question as to the effects of comment k on strict liability was discussed simply to help answer the certified question of comment k's application to negligence claims. *Id.* at 303-04. Nevertheless, the Idaho Supreme Court did offer some hints as to what its answers would be. The court in *Toner* said that "not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives." *Id.* at 308. Given the conceptual framework offered by the court, the ability of DTP manufacturers to produce a non-cellular vaccine could preclude granting the whole-cell vaccine comment k status.

298. See *supra* notes 282-95 and accompanying text (discussing manufacturer knowledge of potentially safer, alternative DTP vaccine).

299. See Naile, *supra* note 36, at 668 (stating that FDA refused to license Wyeth Laboratories to produce Tri-Solgen or its own non-cellular vaccine).

300. See *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 380-81 (D. Md. 1975) (stating that comment k applies to all prescription drugs); *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (holding that comment k applied to all prescription drugs); *Johnson v. American*

approach recognize the analytical dilemmas created by rejecting a balancing test.³⁰¹ For example, in *Brown v. Superior Court*,³⁰² the Supreme Court of California stated:

It seems unjust to grant the same protection from liability to those who gave us thalidomide as to the producers of penicillin. If some method could be devised to confine the benefit of the comment k negligence standard to those drugs that have proved useful to mankind while denying the privilege to those that are clearly harmful, it would deserve serious consideration.³⁰³

These courts nonetheless elevate the consumer interest in the availability of drugs over the safety interest of holding manufacturers strictly liable for their products.³⁰⁴

The Vaccine Act's blanket application of comment k is premised on concerns that strict product liability causes of action destabilized the vaccine market.³⁰⁵ A 1986 Report, written by the House Committee on Energy and Commerce, illustrates congressional concern with the future of the country's universal immunization policy.³⁰⁶ In explaining the need for legislation in this area, the House Report begins with a compelling assessment of the successes of American vaccine policy:

Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease. Billions of medical and health-related dollars have been saved by immunizations.³⁰⁷

Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986) (holding that sabin polio vaccine is unavoidably unsafe as matter of law).

301. See, e.g., *Brown*, 751 P.2d at 479 (admitting that blanket approach may reduce potential for development of safer drugs); Terrie Bialostok Brodie, *Brown v. Superior Court: Drug Manufacturers Get Immunized from Strict Liability for Design Defects*, 19 GOLDEN GATE U. L. REV. 435, 441-42 (1989) (discussing *Brown* court's statement that *Restatement* lacks clarity as to proper application of comment k).

302. 751 P.2d 470 (Cal. 1988).

303. *Brown*, 751 P.2d at 481.

304. See, e.g., *id.* at 479 (stating that both because drugs are very beneficial to society, and because holding drug manufacturers to strict liability standard may reduce drug availability, public policy favors negligence standard for drug manufacturers); Burke, *supra* note 126, at 559 (stating that application of negligence standard, rather than strict liability, for drugs is based on belief that product availability of certain drugs is more important than manufacturer accountability for drug defects).

305. See *supra* note 1 and accompanying text.

306. 1986 HOUSE REPORT, *supra* note 1, at 1-7, reprinted in 1986 U.S.C.C.A.N. at 6344-48 (stating purpose and need of new systems for compensating individuals who have been injured by vaccines routinely administered to children).

307. 1986 HOUSE REPORT, *supra* note 1, at 4, reprinted in 1986 U.S.C.C.A.N. at 6345.

The Report then discusses the small number of vaccinees who suffer permanent and sometimes deadly vaccine-related injuries.³⁰³ The Report goes on to document the recent withdrawal of manufacturers from the vaccine market and the concomitant increase in vaccine prices.³⁰⁹ After considering the benefits of universal vaccination and the recent instability of the market, the Committee on Energy and Commerce concluded that Congress must ensure the continued availability of children's vaccines.³¹⁰

The legislative history demonstrates the utilitarian, policy-based reasoning underlying the Vaccine Act's adoption of comment k. This reasoning closely parallels the California Supreme Court's product-availability-over-product-safety approach in *Brown v. Superior Court*. The court in *Brown* candidly admitted that it was rejecting the increased safety benefits promoted by strict design defect liability in order to promote the rapid availability of highly beneficial drugs.³¹¹ In reaching its decision to grant all prescription drugs comment k immunity, the California Supreme Court cited three policy considerations. First, society has a greater interest in the immediate availability of beneficial drugs than in the increased safety of these drugs.³¹² Second, manufacturers, unsure of the future status of their products under a risk-benefit comment k analysis, will be deterred from developing new drugs.³¹³ Third, manufacturers carrying greater product liability insurance to cover design defect liability will raise the

308. 1986 HOUSE REPORT, *supra* note 1, at 4, reprinted in 1986 U.S.C.C.A.N. at 6347 ("While most of the Nation's children enjoy great benefit from immunization programs, a small but significant number have been gravely injured.")

309. See 1986 HOUSE REPORT, *supra* note 1, at 4, 6-7, reprinted in 1986 U.S.C.C.A.N. at 6345, 6347-48 (describing how increased number of lawsuits against vaccine manufacturers and decreased availability of affordable product liability insurance has resulted in higher vaccine prices and manufacturer's withdrawal from vaccine market).

310. See 1986 HOUSE REPORT, *supra* note 1, at 7, reprinted in 1986 U.S.C.C.A.N. at 6348 ("Thus, the withdrawal of even a single vaccine manufacturer would represent the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.")

311. *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988) ("Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.")

312. *Id.*

313. *Id.* According to this argument, the looming prospect of large damage awards will deter manufacturers from investing in socially valuable research and development. See Moore, *supra* note 250, at 718-19 (stating that manufacturers considering developing new drugs will be deterred because there is no assurance that state court will find drug "unavoidably unsafe" under risk-benefit analysis).

price of vaccines and make vaccines unavailable to the average consumer.³¹⁴

As was the case with the textual interpretation of comment k, the court in *Brown* relied on policy considerations that do not justify the Vaccine Act's application of blanket immunity for all vaccines.³¹⁵ *Brown* recognizes that there are certain socially valuable drugs that cannot be improved using current scientific knowledge.³¹⁶ Given the health benefits rendered by such drugs, *Brown* reads comment k as justifying the immediate marketing of the drugs, regardless of the fact that future scientific advances may allow safety improvements.³¹⁷ The court believed that the public could be harmed if manufacturers delayed distributing prescription drugs, whose safety could not be improved under current scientific knowledge, in order to avoid design defect liability.³¹⁸ As the previous discussion of the history of DTP testing indicates, however, manufacturers may currently possess the knowledge to produce a safer vaccine.³¹⁹ That knowledge may presently allow manufacturers to make safety alterations without significantly inhibiting the distribution of their product.³²⁰

Furthermore, both *Brown* and the Vaccine Act accept the ill-conceived policy notion that strict design defect liability deters investment in research and development.³²¹ Holding vaccine manufacturers strictly liable for design defects promotes, rather than deters, research and development.³²² Under a risk-utility approach to comment k, manufacturers who do not act on current scientific knowledge to produce safer vaccines would be held strictly liable for design defects.³²³ Given that manufacturers are held to the knowl-

314. See *Brown*, 751 P.2d at 479 (arguing that insurance will increase price and lower availability of pharmaceuticals).

315. See *Brodie*, *supra* note 301, at 454-55 (arguing that *Brown* court's belief is without merit because design defect liability neither deters research and development nor destabilizes vaccine market); *Moore*, *supra* note 250, at 732 (arguing that design defect liability actually encourages research and development).

316. See *Brown*, 751 P.2d at 479 (stating that it is not beneficial to withhold some drugs until scientific knowledge advances enough to determine all of drug's effects).

317. See *id.* (stating that interest in availability of socially useful drugs outweighs benefit of postponing distribution until new scientific knowledge evolves).

318. *Id.*

319. See *supra* notes 286-92 and accompanying text (discussing Lederle and Eli Lilly tests of Tri-Immunol and Tri-Solgen in 1960s).

320. See *Moore*, *supra* note 250, at 732-33 (arguing that design defect liability encourages research, but does not inhibit product availability).

321. See *Brown*, 751 P.2d at 479; 1986 HOUSE REPORT, *supra* note 1, at 7, reprinted in 1986 U.S.C.A.N. at 6348 (suggesting that Vaccine Act will lead to more stable vaccine market because manufacturers will have better understanding of potential exposure to litigation).

322. See *Moore*, *supra* note 250, at 732 (stating that design defect liability "fuels" research).

323. See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) (holding that existence of equally effective but safer version of product warranted finding of

edge of experts in their fields,³²⁴ most manufacturers will invest considerable time and resources into research and development in order to avoid design defect liability.³²⁵

Rather than promoting research and development, the Vaccine Act's blanket application of comment k removes incentives for vaccine manufacturers to improve their products.³²⁶ By insulating vaccine manufacturers from strict design defect liability, the Vaccine Act implicitly announces that the Federal Government is satisfied with the current state of vaccine safety, and that the Government will not use the tort system to encourage manufacturers to improve their vaccines.³²⁷

VI. RECOMMENDATIONS

A. Direct Warnings

Evaluating the Vaccine Act's treatment of consumer warnings is a difficult task. On the one hand, the legislation banning direct failure to warn liability removes an important vehicle for promoting an informed patient population.³²⁸ On the other hand, by requiring health care providers to distribute standard warnings written by the Secretary, the Act attempts to achieve, by way of regulation, the same result that *Davis v. Wyeth*³²⁹ and its progeny achieved through the civil tort system.³³⁰

While this Comment applauds the design of the Vaccine Act's informational and recording requirements, it also recognizes that state law direct warning causes of action and federal reporting require-

design defect); *Toner v. Lederle Lab.*, 732 P.2d 297, 306 (Idaho 1987) (holding that drug must be as safe as possible in order to trigger comment k immunity), *cert. denied*, 485 U.S. 942 (1988).

324. See John P. Reilly, *The Erosion of Comment K*, 14 U. DAYTON L. REV. 255, 260 (1989).

325. See Moore, *supra* note 250, at 732.

326. See Finn v. G.D. Searle & Co., 677 P.2d 1147, 1165 (Cal. 1984) (Bird, C.J., dissenting) (arguing that design defect liability encourages manufacturers to correct safety flaws); Christopher J. Albee & Dawn Kilgallen, Comment, *Providing Blanket Comment K Immunity to All FDA Approved Ethical Drugs: The Defect in Grundberg v. Upjohn Co.*, 7 ST. JOHN'S J. LEGAL COMMENT. 475, 493-94 (1991) (arguing that blanket application benefits manufacturers at expense of public safety).

327. Comment k speaks of justified marketing. Blanket application of comment k to all vaccines implies that Congress considers the interest in vaccine availability strong enough to deflate safety concerns. *But see* 42 U.S.C. § 300aa-27(a)-(b) (1988 & Supp. V 1993) (stating that Secretary of Health and Human Services shall promote development of safer vaccines and create task force).

328. See Styles, *supra* note 70, at 113 (stating that adequate patient information satisfies informed consent doctrine).

329. 399 F.2d 121 (9th Cir. 1968).

330. See *supra* notes 91-109 and accompanying text (discussing holding in *Davis*).

ments are not mutually exclusive.³³¹ If the ultimate goal of a universal vaccination policy is safety, federal legislation could maintain both a state common law-based direct duty to warn as well as federal reporting regulations. The combination of a state duty to warn and federal reporting requirements would combat lax community practices and the excessively pro-vaccine environment in two distinct ways. The federal regulations would compensate for inconsistent community practices by requiring physicians to distribute standardized vaccine information and to report contraindications.³³² At the same time, a common law direct warning rule would diminish the current universal vaccination policy's weakening of physician warnings by ensuring that individual vaccinees possess adequate information both to make an informed decision prior to vaccination and to protect against adverse reactions subsequent to vaccination.³³³

The Vaccine Act, however, clearly acknowledges its compromising purpose.³³⁴ The Act seeks both to reduce manufacturer liability and to create a more pro-plaintiff compensation system.³³⁵ Given its goal of insulating manufacturers from excessive liability, the Vaccine Act skillfully removes direct failure to warn liability while continuing to encourage an informed patient base through its vaccine information and reporting requirements.³³⁶

331. See *Cipollone v. Liggett Group*, 112 S. Ct. 2608, 2628-29 (1992) (Blackmun, J., dissenting) (arguing that FDA regulations and state tort law can operate concurrently); Ausness, *supra* note 164, at 278 (arguing that federal regulation and state law can concurrently promote drug safety).

332. See 42 U.S.C. § 300aa-25(b)(1)(A)-(C) (1988) (setting forth vaccine reporting procedures for health care providers and vaccine manufacturers). The regulations can reduce the lack of physician-patient communication that results from the customary practice standard of informed consent. Furthermore, by providing physicians with several scenarios in which they must report to the Secretary, the regulations require doctors to consider seriously the risks of vaccination.

333. See *Incollingo v. Ewing*, 282 A.2d 206, 222 (Pa. 1971) (arguing that manufacturer could be negligent for medical community's disregard of warnings). By charging manufacturers with knowledge of the medical community's ability to comprehend and implement manufacturer warnings, state tort law, in addition to federal regulations, ensures that physicians will become aware of the risks of vaccination. See *Burke*, *supra* note 126, at 592 (endorsing state law requirement that manufacturers use "Dear Doctor" letters and other advertising methods to present objective view of product and combat pro-vaccine environment).

334. See 1986 HOUSE REPORT, *supra* note 1, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 6348 (stating that rationales behind Vaccine Act were dissatisfaction with civil tort system as compensation mechanism and instability of vaccine market).

335. See 1986 HOUSE REPORT, *supra* note 1, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 6348.

336. See 1986 HOUSE REPORT, *supra* note 1, at 29-30, *reprinted in* 1986 U.S.C.C.A.N. at 6370-71.

B. *Relationship Between Federal and State Law*

Prior to the passage of the Vaccine Act, manufacturers were often caught between inconsistent state and federal warning standards.³³⁷ Given that manufacturers may not alter the content of their warnings without FDA approval,³³⁸ compliance with state law warning standards sometimes required manufacturers to violate federal law or regulations. Conversely, compliance with federal regulatory warning standards often exposed manufacturers to liability under state law.³³⁹

The Vaccine Act responded to this dilemma by creating a presumption that warnings complying with FDA standards are adequate.³⁴⁰ This Comment credits the Vaccine Act for taking an affirmative step toward resolving the vaccine warning dilemma. The Vaccine Act's presumption initially tips the scales towards manufacturers while also giving plaintiffs a vehicle for overcoming the presumption. The Act, however, has imprudently moved from one extreme to the other. The legislation removes too much of the impetus for manufacturers to act on their actual or constructive knowledge concerning the adequacy of warnings. The presumption of warning adequacy allows manufacturers to disregard knowledge of actual deficiencies in their warnings so long as the warning complies with FDA standards.³⁴¹

In lieu of the Vaccine Act's presumption of adequate warnings, this Comment proposes the following framework. If under state law a judge or jury finds that a manufacturer knew or should have known of an inadequacy in warning,³⁴² the court should determine whether

337. See Naile, *supra* note 36, at 695 (stating that manufacturers cannot meet state common law standards until FDA authorizes change in warning or design).

338. See *supra* notes 203-10 and accompanying text (discussing role of FDA in approval of warning labels).

339. See Naile, *supra* note 36 and accompanying text.

340. 42 U.S.C. § 300aa-22(b)(2) (1988).

341. FDA labelling requirements for vaccine potency illustrate the potential dangers of presuming the adequacy of a warning when it meets FDA standards. See 21 C.F.R. § 620.6(d) (1994) (requiring that labels on DTP bottles state that vaccine has potency of 12 mouse protective units per dose); Burke, *supra* note 126, at 577-78 (stating that not all bottles contain 12 mouse protective units per dose as suggested on FDA mandated labels). *But see* 21 C.F.R. § 620.4(g) (stating that despite label information, FDA will approve vaccine lot containing between 8 and 36 mouse protective units per dose). A "lot" is "that quantity of uniform material identified by the manufacturer as having been thoroughly mixed in a single vessel." *Id.* § 600.3(y).

The FDA informs manufacturers of the actual mouse protection unit level upon approval of the vaccine. See Burke, *supra* note 126, at 577. If compliance with FDA warning standards is presumptively adequate, the Vaccine Act allows manufacturers to knowingly run the risk of a child receiving a triple dose of the vaccine. *Id.* at 578.

342. The proposal imputes to manufacturers the same standard applied in other warning cases. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 99, at 697 (5th ed. 1984 & Supp. 1988) (explaining that standard used in warning cases is that manufacturer

the manufacturer petitioned the FDA for a change in the warning language in order to resolve the inadequacy.³⁴³ Manufacturers who fail to act on their knowledge or constructive knowledge of an inadequate warning should be held liable.³⁴⁴ If the manufacturer has petitioned the FDA for a change in warning language and the FDA had rejected the petition, however, the manufacturer should not be found liable.³⁴⁵

This proposed framework seeks to force manufacturers to exercise all safety options within their capacity. The law should not allow manufacturers who do not address known or knowable warning inadequacies to seek shelter under a deferential presumption. FDA standards are designed to ensure safety, not to insulate manufacturers from confronting difficult safety issues. If Congress amends the Vaccine Act to reflect this framework, the deterrence function of warning liability would remain intact. At the same time, the amendment would recognize that deterrence has limits, and that state deterrence theories should not force manufacturers to choose between violating federal or state law.

C. Comment k

Congress' decision to grant blanket comment k immunity to all vaccines covered by the Vaccine Act conflicts with both the text and policy of comment k.³⁴⁶ The fact that vaccines as a class have effectively reduced the risk of many formerly deadly diseases does not warrant a per se application of comment k immunity to all vac-

must know or have reason to know of danger of product for liability to attach); Naile, *supra* note 36, at 679 (same).

343. Manufacturers are not completely prohibited from changing warnings after initial FDA approval. See Clarke, *supra* note 158, at 529 (stating that FDA allows manufacturers to propose new language by filing supplemental new drug application).

344. This Comment's endorsement of holding manufacturers liable, when they do not petition the FDA when they have knowledge of warning inadequacy, is premised on the theory that tort law encourages product safety. See Ausness, *supra* note 164, at 277.

This theory does not raise the problem, addressed in *Hurley v. Lederle Lab.*, of placing manufacturers in an inescapable bind between federal and state mandates. *Hurley v. Lederle Lab.*, 651 F. Supp. 993, 999 (E.D. Tex. 1986), *rev'd*, 863 F.2d 1173 (5th Cir. 1988). Manufacturers may attempt to meet state common law requirements through the FDA mechanism of new supplemental applications.

345. Once the FDA has rejected a manufacturer's request to improve a warning, the physical conflict preemption dilemma, where the manufacturer cannot concurrently satisfy both federal and state laws, arises. See *supra* notes 239-49 and accompanying text. At this point, the function of tort law as a safety promoter ceases, and there is little reason to hold manufacturers to a standard not attainable without violating federal law.

346. See *supra* notes 255-67 and accompanying text (discussing Congress' decision to apply blanket comment k immunity to vaccines covered by Vaccine Act).

cines.³⁴⁷ According to the language of comment k, a vaccine only merits special protection when the danger posed by the vaccine is unavoidable and when the utility of the vaccine outweighs the risks.³⁴⁸ As previously discussed, the Vaccine Act's blanket application of comment k is most suspect with regard to the DPT vaccine because numerous studies have indicated that manufacturers are currently capable of producing a safer vaccine.³⁴⁹ This Comment does not question the utility of the DPT vaccine; it questions the wisdom of permanently justifying the dangers of the whole-cell DPT vaccine by applying to the vaccine the label "unavoidably unsafe." As discussed earlier, evidence exists indicating that DPT manufacturers may currently possess the ability to produce a safer vaccine.³⁵⁰ At the present time, however, the FDA only permits the sale of the whole-cell vaccine.³⁵¹ The question must therefore be asked, what degree of design defect liability will best promote manufacturer investment of time and resources into the development of a new DPT vaccine that reduces adverse reactions?

This Comment recommends that Congress repeal the Vaccine Act's blanket application of comment k immunity. In place of a blanket application approach, Congress should adopt the three-part balancing test developed by the California Court of Appeals in *Kearl*.³⁵² The *Kearl* test provides a dual advantage. The three-part threshold test avoids the establishment of a federally endorsed status quo in which vaccine research and development has reached an acceptable endpoint. Under *Kearl*, manufacturers will recognize the possibility that the FDA will approve an alternative DPT vaccine.³⁵³ In order to avoid potential design defect liability, manufacturers will invest in

347. See George H. King, Note, *A Prescription for Applying Strict Liability: Not All Drugs Deserve Comment K Immunization*, 21 ARIZ. ST. L.J. 809, 824-25 (1989) (arguing that only unavoidably unsafe drugs providing exceptional benefits warrant comment k protection).

348. RESTATEMENT (SECOND) OF TORTS, *supra* note 17, § 402A cmt. k.

349. See *supra* notes 285-99 and accompanying text.

350. See *supra* notes 286-96 and accompanying text.

351. See Burke, *supra* note 126, at 570 (stating that since production of Tri-Solgen stopped in 1970s, only whole-cell DTP vaccines have been available).

352. *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 463-64 (Ct. App. 1985) (rejecting blanket approach to application of comment k immunity). *Kearl* establishes a three-part test for determining whether a product is "unavoidably dangerous." The *Kearl* test requires determining: (1) whether the product was intended to confer a high benefit; (2) whether the then-existing risk of the product was "substantial" and "unavoidable"; and (3) whether the interest in availability at the time of distribution outweighs the interest in enhanced accountability. *Id.* at 464.

353. See King, *supra* note 347, at 826 (stating that upon discovery of existence of safer drug, manufacturers would discontinue marketing less safe drug); Moore, *supra* note 250, at 732 (suggesting that imposition of strict design defect liability will encourage research and development).

research efforts to improve the whole-cell DTP vaccine and will petition the FDA for approval of their new designs.³⁵⁴

The *Kearl* test, while promoting manufacturer investment in improved safety, also accommodates the underlying theme of *Brown v. Superior Court*, namely that some drugs possess exceptional social utility and therefore warrant more lenient liability standards.³⁵⁵ Two of the three-prongs of the *Kearl* test consider society's immediate need for beneficial drugs. The first prong considers the nature of the benefits of the drug in question, and the third prong considers the public's interest in the drug's availability.³⁵⁶ The *Kearl* test, therefore, effectively provides DTP manufacturers with temporary immunity from strict design defect liability³⁵⁷ while continuing to encourage manufacturers to search for a safer product.

This lack of permanent protection from strict design defect liability led the Supreme Court of California to overrule *Kearl* in *Brown*:

[Under the *Kearl* test, a] manufacturer's incentive to develop what it might consider a superior product would be diminished if it might be held strictly liable for harmful side effects because a trial court could decide, perhaps many years later, that in fact another product which was available on the market would have accomplished the same result.³⁵⁸

The impact of the court's criticism is not applicable because the FDA only allows manufacturers to market the whole-cell DTP vaccine. The possibility that the FDA may approve a new DTP vaccine will encourage, rather than discourage, individual manufacturers to improve their own products.³⁵⁹ The court in *Brown* envisioned manufacturers halting all research efforts for fear that their future product would one day be found to be defective in design.³⁶⁰ The codification of the *Kearl* test would not lead to this result. Under *Kearl*, the complacent DTP manufacturer, who continues to market an unsafe vaccine, will face liability for a defect in design.³⁶¹

354. See Moore, *supra* note 250, at 732 (arguing that threat of financial liability will promote increased safety efforts by manufacturers).

355. See *Kearl*, 218 Cal. Rptr. at 464 (incorporating weighing benefits of drug and public's interest in availability of drug into threshold test).

356. *Id.*

357. See Moore, *supra* note 250, at 729 (stating that beneficial drugs will continue to receive comment k protection under *Kearl*-like balancing test). Because the FDA currently approves only the whole-cell DTP vaccine, the DTP vaccine will qualify for "unavoidably unsafe" status.

358. *Brown v. Superior Court*, 751 P.2d 470, 482 (Cal. 1988).

359. See *supra* note 315 (discussing argument that strict design defect liability promotes manufacturer investment in research and development).

360. See *Brown*, 751 P.2d at 482.

361. See *Kearl*, 218 Cal. Rptr. at 464 (instructing that trial judge, when considering unavoidability of danger in product, should take into account "availability . . . of any alternative

No given formula for balancing society's need for vaccine availability with society's need for vaccine safety will satisfy all the parties involved. At present, the *Kearl* threshold test offers a viable compromise that both respects the social utility of the DTP vaccine and encourages the development of an even safer product. For these reasons, Congress should repeal the blanket application of comment k to all vaccines and instead codify the *Kearl* three-prong test.

CONCLUSION

The National Childhood Vaccine Injury Compensation Act of 1986 represents a much needed legislative response to the civil tort system's inability to achieve a proper balance between vaccine safety and vaccine availability. To a large degree, the Vaccine Act achieves its goals. Plaintiffs may seek compensation in a no-fault compensation system, and manufacturers are relieved of the burden and expense of defending vaccine injury law suits. The Vaccine Act's modification of state common law for plaintiffs who reject judgment under the statutory no-fault compensation program, however, places too much emphasis on vaccine availability and not enough emphasis on vaccine safety. In order to strike a more equitable balance, this Comment recommends that Congress take the following steps: (1) require manufacturers with knowledge of warning inadequacies to petition the FDA for a warning alteration before giving manufacturers the benefit of the presumption that warnings in compliance with FDA standards are adequate; and (2) adopt the three-factor *Kearl* test for determining "unavoidably unsafe" product status. Both recommendations respect the social utility of vaccines and will therefore promote a workable balancing of safety and availability interests.

If the majority of vaccine injury plaintiffs continue to accept judgment under the statutory no-fault compensation program, these changes will not have a large scale impact on vaccine injury litigation. As Congress begins to consider legislation in other areas of product liability law, however, it should take note of the shortcomings of the Vaccine Act's alteration of state tort law. Congress should also ensure that future statutory modifications of the civil tort system establish a workable balance between product availability and product safety.

product that would have as effectively accomplished the full intended purpose of the subject product"). *Kearl* announces to manufacturers that it is in their best interest to develop the equally effective alternative product rather than be presented with evidence that they are marketing an inferior and dangerous product. *Id.*