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Note

The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?

Jaclyn Shoshana Levine

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The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology? †

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I. INTRODUCTION

1. Occupying a firm place in the scientific and technologic realm cannot, and does not, insulate vaccines from the law. With powerful social and scientific forces vehemently advocating¹ and forcefully opposing² vaccines, the law, not surprisingly, plays an active role in vaccine development³ and use.⁴ Manufacturer liability for

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¹ An extensive list of organizations that support vaccine research, development, and use, ranging from the American Academy of Family Physicians to the National Institutes of Health. See *Vaccine Page Organizations-General* (visited June 1, 1998) <<http://www.vaccines.com/organizations.htm>>.

² See *Informed Parents Vaccination Home Page* (visited Feb. 28, 1998) <<http://www.unc.edu/~aphillip/www/vaccine/informed.htm>> (“Why are a growing number of parents and health care professionals around the world questioning vaccination? The controversy stems from the thousands of deaths and permanent disabilities attributed to vaccination annually, as well as the many published medical studies, government statistics, congressional testimonies, and other credible sources that directly contradict commonly held assumptions about vaccine safety and effectiveness. Take no one else's word for it: Make your own informed vaccination decisions!”); see also *Welcome to the Concerned Parents for Vaccine Safety Home Page* (visited Feb. 27, 1998) <<http://home.sprynet.com:80/sprynet/Gyrene/Home.htm>> (a multi-level web site with downloadable documents and links to other philosophically-aligned sources of information).

³ The Food and Drug Agency (“FDA”), the National Institutes of Health (“NIH”), and Centers for Disease Control and Prevention (“CDC”) have the primary legal mandates to further and approve vaccine development and use. See Food Drug & Cosmetic Act, 21 U.S.C. § 355 (1994) (requiring FDA to grant approval before a drug can enter interstate commerce); see also Children’s Vaccine Initiative, 42 U.S.C. § 283d (1994) (mandate to National Institute of Allergies and Infectious Diseases and National Institute of Child Health and Human Development to develop childhood vaccines to be used in United States and abroad).

vaccine injuries arguably illustrates the most visible and contentious relationship between the law and vaccines.

2. Starting in the 1970s, and peaking in the 1980s with a national insurance crisis⁵ as a significant part of the background, some vaccine manufacturers were forced to pay large awards or settlements to vaccine-injury victims and their families.⁶ Consequently, vaccine manufacturers seriously threatened to cease producing vaccines, using the important role vaccines play in American public health as political leverage.⁷ What makes this law-science standoff particularly interesting is that rather than forcing vaccine technology to bend to the law's demands, as has historically been the case for other inherently dangerous medical products,⁸ Congress decided to reshape the law.⁹

⁴ Vaccine cases have provided the context for some of the Supreme Court's most serious examinations of due process and compelled technology use. *See Jacobson v. Massachusetts*, 197 U.S. 11, 24-27, 38-39 (1905) (landmark case upholding constitutionality of compulsory vaccination laws); *see also United States v. Anderson*, 328 U.S. 699, 700 (1946) (involving criminal prosecution of U.S. military inductee for refusing vaccination).

⁵ In the years prior to congressional reform of vaccine manufacturer tort liability, insurance premiums rose steeply, and benefits, including maximum policy payouts to manufacturers, declined rapidly. *See Mitchell F. Dolin, Excess Defense Coverage and Long-Tail Liabilities*, 32 TORT & INS. L.J. 875, 875, 883-87, 891-98 (1997) (discussing the role of third party insurance in defending product liability suits and the 1984-85 liability crisis, including the stop gap measure of overlapping multiple policies). *See generally* Kyle D. Logue, *Toward a Tax-Based Explanation of the Liability Insurance Crisis*, 82 VA. L. REV. 895 (1996) (describing the 1980s liability crisis and arguing that it was related to the tax reform efforts occurring at the same time).

⁶ *See Morris v. Parke, Davis & Co.*, 573 F. Supp. 1324, 1325 (C.D. Cal. 1983) (permitting plaintiff to pursue *punitive damages* under a market share theory, established in *Sindell v. Abbott Laboratories*, 607 P.2d 924 (Cal. 1980), from DPT manufacturers if plaintiff could prove they had conscious disregard for safety).

⁷ Some manufacturers, such as Connaught and Wyeth, actually ceased making the DPT vaccine. *See* 131 Cong. Rec. S3843-04 (daily ed. Apr. 2, 1985) (statement of Sen. Hawkins). After the Compensation Program, which absolved manufacturers of liability, was implemented, some manufacturers resumed production. *Cf.* NATIONAL VACCINE ADVISORY COMMITTEE, NATIONAL VACCINE PROGRAM, ADULT IMMUNIZATION, Appendix VII (1994) [hereinafter ADULT IMMUNIZATION] (listing Wyeth and Connaught as producing DPT vaccine).

⁸ For instance, although breast implants are often used safely in post-radical mastectomy reconstructive surgery, and the data showing their dangerousness are equivocal at best, recent litigation against the manufacturer has severely affected the silicon breast implant market. *See* MARCIA ANGELL, SCIENCE ON TRIAL 19, 21-23, 111-32 (1996).

⁹ Neither technological determinism, which posits that science and technology are independent forces that the law cannot drive, nor technological neutrality, which credits human choice for scientific and technological advances, adequately explain Congress' choice to reshape the law to

3. Congress enacted the 1986 National Childhood Vaccine Injury Act ("Vaccine Act")¹⁰ to solve this vaccine crisis. The Vaccine Act outlined a comprehensive national initiative to coordinate and encourage vaccine use.¹¹ Congress included the National Vaccine Injury Compensation Program ("VICP" or "Compensation Program") within the larger piece of legislation to address specifically vaccine manufacturer liability.¹² The legislation mandated that victims first seek a remedy in a federally administered no-fault process before pursuing a civil court remedy against manufacturers.¹³

4. This legislative solution to the vaccine crisis and its legal roots was both reasonable and revolutionary. Congress acted reasonably by making public health a priority.¹⁴ By passing the Vaccine Act the national legislature acknowledged that legal change was not an alternative, it was an imperative. Congress created a legal revolution by not only conceiving and implementing a creative no-fault solution to

benefit vaccine technology. Only the theory of technological realism, which asserts that law and science have a dynamic relationship, each one shaping the direction of the other, explains this incident. *See* PRISCILLA M. REGAN, *LEGISLATING PRIVACY: TECHNOLOGY, SOCIAL VALUES, AND PUBLIC POLICY* 10-15 (1995).

¹⁰ 42 U.S.C. §§ 300aa-1 to -34 (1994).

¹¹ *See id.* § 300aa-2(a)(1)-(9) (describing the role the Director of the National Vaccine Program has in research, development, testing, licensing, production, procurement, distribution, use, evaluation, coordination, and funding of vaccines).

¹² *See id.* §§ 300aa-10 to -34.

¹³ *See id.* § 300aa-11.

¹⁴ Representative Madigan introduced the first draft of the Vaccine Act on March 27, 1985. *See* 131 Cong. Rec. H1587 (daily ed. Mar. 27, 1985) (Statement of Rep. Madigan). Though later modified to create a no-fault program, Representative Madigan's proposed legislation clearly voiced the House's first priority as preserving vaccines as a part of the American public health system. *See id.* ("This legislation is based on three major principles: First, the childhood immunization program in this country is one of our most important health efforts; second, the future availability of some vaccines is in severe jeopardy; and third, those children injured by vaccines deserve fast and equitable compensation.").

the liability crisis, but by explicitly basing it on the aspirational Restatement¹⁵ (Second) of Torts (“Second Restatement”).¹⁶

5. The Compensation Program portion of the Vaccine Act was controversial when Congress adopted it.¹⁷ Nevertheless, even the VICP’s original detractors would have to admit that it has met its central goal¹⁸ of preserving the American vaccine market without bankrupting the federal government.¹⁹ The Compensation Program’s success is evident in the contemporary vaccine market; although only a

¹⁵ Promulgated by the American Law Institute (“ALI”), a Restatement furthers the ALI’s purpose “to promote the clarification and simplification of the law and its better adaptation to social needs” by expressing the majority view of the law, and in some cases acting correctively by proposing what the law should be. *American Law Institute Bylaws*, § 1.01 (eff. May 17, 1994) (visited May 5, 1997) <<http://www.ali.org/ali/bylaws2.htm>> [hereinafter *ALI Bylaws*]. A Restatement is not law unless a legislature takes the unusual step of incorporating it into legislation, or a court takes notice of its standards and applies them.

¹⁶ See generally RESTATEMENT (SECOND) OF TORTS (1963-64 Main Vol. & Supp.) [hereinafter SECOND RESTATEMENT].

¹⁷ Representatives Dannmeyer, Fields, Nielson, and Schaefer jointly filed a dissenting view to H.R. 5546, The National Childhood Vaccine Injury Act. See National Childhood Vaccine Injury Act of 1986, H.R. REP. NO. 99-908, at 78, reprinted in 1986 U.S.C.C.A.N. 6344, 6382-3. Although agreeing that federal action was necessary, they objected to the financing mechanism, an excise tax, and believed that the bill “further erodes the concept of compensating victims of negligent acts, and provides authority for the establishment of several unnecessary and duplicative [sic] advisory councils and commissions.” *Id.* at 6382. Of course, these House members also supported their own bill, H.R. 1780, which would have used liability capitation, damages not to exceed \$1,000,000, and paid awards out of private insurance. *Id.* at 6382-83; see also WENDY K. MARINER, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, INNOVATION AND CHALLENGE: THE FIRST YEAR OF THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 6-8 (1991) [hereinafter FIRST YEAR] (describing the opposition of the Department of Justice to a new entitlement, and the opposition of the Department of Health and Human Services to “nearly automatic compensation” focusing on injuries when the agency was attempting to fulfill a concurrent mandate to promote vaccination (citation omitted)).

¹⁸ See 131 Cong. Rec. S3843-04 (daily ed. Apr. 2, 1985) (statement of Sen. Hawkins) (“It is obvious that a legislative solution is needed to stabilize the supply of childhood vaccines and restore public confidence in the childhood immunization program.”); see also *Amendola v. Secretary Dep’t Health & Human Servs.*, 23 Cl. Ct. 621, 626 (1991) (discussing the policy goals of the Vaccine Act); *Stotts v. Secretary Dep’t Health & Human Servs.*, 23 Cl. Ct. 352, 358 (1991) (stating that compensating vaccine injury victims was also a central goal of the VICP).

¹⁹ See National Childhood Vaccine Injury Act of 1986, H.R. REP. NO. 99-908, at 78 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6382 (dissenting Representatives’ views suggesting that the Compensation Program would put the federal government at risk financially).

small number of manufacturers produce vaccines, vaccines are still available and widely used today.²⁰

6. 1998 marks the tenth anniversary of the Compensation Program's implementation. Given the Compensation Program's basic success, this anniversary presents a natural time for reflection. Rather than allowing this examination to be self-congratulatory, this Note argues that Congress should vigorously scrutinize the VICP and the scientific and legal contexts in which it exists. Congress should first identify potential challenges to the efficient process the VICP uses and the vaccine market equilibrium it encourages. After considering the likelihood and strength of these challenges, Congress should contemplate making appropriate changes in the Vaccine Act to maintain vaccine availability, market equilibrium, and encourage increasing vaccine safety.

7. This Note has three main sections. Part II identifies factors that could challenge the VICP's operations and stabilizing effects on the vaccine market. Though identifying a number of potential external threats, this portion of the Note focuses particularly on the American Law Institute's ("ALI") newly authored²¹ Restatement (Third) of Torts ("Third Restatement").²² Part II also looks at the recent simplification of the VICP's funding tax and other internal changes to the Compensation Program. If Congress actively reexamines the Compensation Program and determines that good cause exists to make changes, Part III suggests a course of action to minimize the negative effects of the threats and challenges discussed in Part II. This proposal centers around fully preempting all remedies for vaccine injuries outside the VICP, funding the VICP with a flat tax, and motivating manufacturer concern for safety with a risk-based rebate. Part IV concludes the Note.

II. CONGRESS SHOULD CRITICALLY REEXAMINE THE VICP

8. Before the 1986 National Childhood Vaccine Injury Act, vaccine-injured individuals could seek compensation from vaccine manufacturers in state courts. Under diversity jurisdiction, federal courts provided an alternative forum, yet the

²⁰ See ADULT IMMUNIZATION, *supra*note 7, at Appendix VII (listing all currently produced vaccines and their manufacturers).

²¹ See *Heavy Substantive Agenda for ALI's 1997 Annual Meeting in Washington, D.C.* (visited May 5, 1997) <<http://www.ali.org/ali/annupdate.htm>>.

²² RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(a) (Proposed Final Draft 1997) [hereinafter THIRD RESTATEMENT].

tort claims of defective vaccine manufacturing, defective vaccine design, or inadequate warnings were the same in both court systems.²³

9. After Congress passed the Vaccine Act, vaccine-injured individuals retained an election to sue manufacturers in these courts,²⁴ but only after going through a no-fault process. In this no-fault process, the petitioners sued the Compensation Program, with the Secretary of Health and Human Services, instead of the manufacturer, as the respondent.²⁵ Congress designed the no-fault Compensation Program to be more than a mere preliminary step to suing manufacturers directly. By creating a petitioner-friendly process with liberal compensation guidelines, Congress hoped to make the VICP so attractive that vaccine-injured individuals would not exercise their election option at all.

10. The sections of the Vaccine Act that created the Compensation Program spells out comprehensively the no-fault process.²⁶ The statute describes how a person petitions the Federal Claims Court for compensation,²⁷ serves notice on the Secretary of Health and Human Services,²⁸ and establishes the existence of a qualifying injury.²⁹ The legislation carves out special rules of discovery, and excludes the possibility of using the no-fault process findings in the civil courts.³⁰ The Vaccine Act also clearly defines the role of the Special Masters who hear claims and make final decisions,³¹ including the preponderance standards of proof and scientific

²³ See generally Wendy K. Mariner, *Compensation Program for Vaccine Related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U. L.J. 599 (1987) (describing the history of American settlement of vaccine injury disputes and comparing it to international approaches).

²⁴ National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-21(a) (1994).

²⁵ See *id.* § 300aa-12(b) (parties involved in petitions).

²⁶ See *id.* §§ 300aa-1 to -34; see also FIRST YEAR, *supra* note 17, at 11-20 (describing and evaluating the Compensation Program's implementation).

²⁷ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-11 (1994) (describing form, content, and limitation of petitions).

²⁸ See *id.* § 300aa-11(a)(1) (notice).

²⁹ See *id.* § 300aa-11(c) (evidence of injury in petition).

³⁰ See *id.* § 300aa-12(d)(3)(B) ("There may be no discovery in a proceeding on a petition other than the discovery required by the special master."); § 300aa-12(d)(4)(A) (no information required by a Special Master may be disclosed without the express written permission of submitting party).

³¹ See *id.* § 300aa-12(d) (duties of Special Masters).

presumptions that operate to make it easy for a petitioner to succeed.³² The legislation lists the multiple categories of compensation a Special Master can award, ranging from past and future medical care to special housing and educational costs.³³ The Vaccine Act establishes how a Special Master makes a final recommendation to the Claims Court,³⁴ and how a petitioner can appeal that decision to the Court of Appeals for the Federal Circuit.³⁵ The Vaccine Act also determines the exact process for a petitioner to reject a Claims Court judgment and seek redress in the civil court system.³⁶

11. During its first years, the Compensation Program encountered difficulty in implementing efficiently the Vaccine Act's legislative scheme, despite the clear process created by Congress. In 1991 Wendy Mariner, a professor of Health Law at the Boston University School of Public Health, evaluated for the Administrative Conference of the United States the Compensation Program's first working year.³⁷ In that report she suggested that the Compensation Program was capable of working through its early problems hearing claims and would settle into a regular working pattern if it did not run out of funding.³⁸ The three most important questions today are: Has the Compensation Program worked out its old problems? Has it met its objectives of reducing manufacturer liability and providing easy compensation to victims? Are new threats emerging to challenge the Compensation Program in the future?

12. The weight of the evidence suggests that the Compensation Program has settled into an effective routine and is meeting Congress' policy goals; no single issue or factor appears ready to destroy the VICP at this time. The Vaccine Trust Fund,³⁹

³² See *id.* § 300aa-13(b) (matters to be considered).

³³ See *id.* § 300aa-15 (long list of factors to be considered for determining compensation).

³⁴ See *id.* § 300aa-12(e)(3) (Special Master's decision is final unless petitioner files an objecting motion).

³⁵ See *id.* § 300aa-12(f) (appeals).

³⁶ See *id.* § 300aa-21(a) (elections); see also § 300aa-22 (standards to be applied in a mandatory three-phase civil action after a petitioner elects to reject the Compensation Program award or judgment of no award).

³⁷ See FIRST YEAR, *supra* note 17; see also Administrative Conference Act of 1964, 5 U.S.C. §§ 591-96 (1994) (establishing the Administrative Conference as an independent federal agency dedicated to evaluating how other federal agencies carry out their duties).

³⁸ See FIRST YEAR, *supra* note 17, at 3, 66-69.

³⁹ See Vaccine Trust Fund, I.R.C. § 9510 (1994).

which pays for compensation to victims in the VICP, is running a surplus.⁴⁰ Both the Senate and the House recommended 1998 funding for the administrative aspects of the VICP at or above previous levels.⁴¹ Finally, after nine years, the VICP has adjudicated the majority of its backlogged cases.⁴² Only a relatively small number of petitioners to the Compensation Program elect to preserve their rights to civil remedies by rejecting VICP awards, and not all of them choose to seek redress in other courts.⁴³ Manufacturers continue to produce vaccines.⁴⁴ Vaccine research is continuing to progress, providing new hope for eliminating diseases.⁴⁵ Despite the good news that no one issue or event is imminently poised to ruin the VICP, Congress should remain vigilant, looking for problems before they occur. The VICP's current conditions demonstrate that it is functioning to meet the needs of 1986 America. These factors neither indicate how well the VICP is handling today's vaccine issues, nor if the Compensation Program is capable of addressing upcoming vaccine problems.

13. A cautious Congress must acknowledge that the world is changing. What works to maintain a vaccine liability equilibrium, satisfying consumers, victims, manufacturers, and public health officials now may not work in the future. Congress should not wait for a dramatic event, such as a sudden decrease in manufacturer concern for vaccine safety or improvement, to signal that it is time to reconsider the VICP. If Congress does wait for another disaster it will be ignoring one of the most

⁴⁰ See National Vaccine Injury Compensation Program, *Summary of Current Issues, Report to the National Institutes of Health Pertussis Conference August, 1996* (visited June 11, 1997) <<http://www.hrsa.dhhs.gov:80/bhpr/vicp/sumcur.htm#3>> [hereinafter *Current VICP Issues*].

⁴¹ See generally H.R. CONF. REP. 105-405 (1997) (Senate and House recommendations for 1998 fiscal year disbursements from the Vaccine Trust Fund to pay for Department of Justice and Federal Claims Court expenses related to the VICP); see also H.R. CONF. REP. 105-390 (1997) (Senate and House recommendations for 1998 fiscal year disbursements from the Vaccine Trust Fund to pay for Department of Health and Human Services expenses related to the VICP).

⁴² See National Vaccine Injury Compensation Program, *Monthly Statistics Report Through April 30, 1997* (visited June 11, 1997) <<http://www.hrsa.dhhs.gov/bhpr/vicp/sumcur.htm>> [hereinafter *VICP Statistics*].

⁴³ See National Vaccine Injury Compensation Program, *Background Information on VICP*, (visited June 11, 1997) <<http://www.hrsa.dhhs.gov/bhpr/vicp/abdvic.htm>> [hereinafter *VICP Background*].

⁴⁴ See ADULT IMMUNIZATION, *supra* note 7, at Appendix VII.

⁴⁵ See, e.g., *Lyme Disease Vaccine Proven To Work in Clinical Trial*, HEALTH LETTER CDC (Sept. 29, 1997), available in 1997 WL 7716620 (describing that a recent study concluded that a new Lyme disease vaccine by Connaught is effective in preventing a disease that afflicts more than 16,000 American children and adults each year).

important lessons of the last vaccine liability crisis: there may not be one single event to indicate that Congress needs to take action.⁴⁶ In general, the law that applies to vaccine injuries⁴⁷ tends to evolve slowly.⁴⁸ Therefore, Congress should be sensitive to the fact that though the Vaccine Act helped redirect the natural evolution of the vaccine-law interaction, it did not halt the evolution.

14. Key to this analytical viewpoint is understanding that one challenge to the compensation program or the vaccine market alone may not necessarily make any difference. However, when changes occur in rapid succession, or concurrently, they may have unintended effects. For example, if manufacturers only experienced liability in some high profile vaccine injury cases *or* lacked liability insurance in the 1970s and 1980s, vaccine prices may have gone up, but the problems would not have

⁴⁶ One of the least understood aspects of product liability law is the role of perception in shaping legal change. A study of the trends in product liability law suits occurring in the federal courts during the same time frame as the vaccine liability “crisis” (1973 - 1986) indicates that vaccine manufacturers were not necessarily under extraordinary attack. TERENCE DUNGWORTH, *PRODUCT LIABILITY AND THE BUSINESS SECTOR* iii-v (1988). In fact, pharmaceutical manufacturers represented only 2.2% of all federal product liability defendants, and more than 60% of those cases related to the Dalkon Shield intrauterine device produced by A.H. Robins and the anti-nausea drug Bendectin produced by Merrill Dow—not vaccines or their manufacturers. *See id.* 19, 39-43, 51.

Despite suffering from selection bias (the study did not include data on lawsuits in state courts) and confounding (asbestos litigation was unusually high in this time period, minimizing the real magnitude of health and pharmaceutical product cases) the study illustrates two important points. First, even if vaccines are particularly vulnerable to liability, the liability may be justified, not signaling a crisis. Second, Congress cannot project when public and industry perception will combine with real legal and scientific developments to signal a new “crisis” requiring attention and action. This Note argues that one rational response to uncertainty is to examine the issues that could combine with perception to create a new sense of crisis.

⁴⁷ For author’s comparison of liability for vaccine injuries under different standards, see Appendix A.

⁴⁸ Product liability law, the broader body of law from which vaccine liability draws its own standards, has liberalized from its original fiercely pro-manufacturer stance. *See, e.g.,* MacPherson v. Buick Motor Co., 111 N.E. 1050, 1053 (N.Y. 1916) (eliminated privity of contract requirement in tort, paving the way for remote purchasers to sue manufacturers directly, in this case an auto manufacturer); Escola v. Coca-Cola Bottling Co., 150 P.2d 436, 438-40 (Cal. 1944) (allowing bystander to receive damages for injuries from an exploding bottle).

As plaintiffs became more successful in product liability lawsuits, the ALI’s Second Restatement codified many of the standards related to the three basic causes of action: defective manufacturing, defective design, and inadequate warnings or instructions. *See* SECOND RESTATEMENT, *supra* note 16, § 402A cmts. f, i, k (comments on “Special Liability of Seller of Product for Physical Harm to User or Consumer”). In grappling with unavoidably unsafe, or inherently dangerous products, such as medical technologies, the Second Restatement delicately tries to balance the interests of industry, society, and consumers by adopting what is generally called a “consumer expectation test” under a negligence standard. *See id.*

appeared as severe. By contrast, when manufacturers were losing cases *and* they could not buy sufficient liability insurance, that was perceived as significantly harmful.⁴⁹ This Note identifies separate, rising vaccine liability issues, and projects how they could combine to create a problematic legal and economic atmosphere. By recognizing flaws inherent in the Compensation Program, ("internal challenges"), as well as outside forces that may affect it ("external challenges"), Congress can make any necessary changes smoothly and gradually. The following sections identify five internal and external challenges to the VICP.

A. The Highly Conservative Third Restatement—External Challenge

1. The Third Restatement will be influential

15. Congress should recognize that the Third Restatement of Torts is a highly influential scholarly work.⁵⁰ Moreover, the Third Restatement proposes to use its influence to further fundamentally different and radically conservative standards for product liability.⁵¹ These standards may conflict with the purposes underlying the Compensation Program, thereby causing problems in the way it works.

16. When academic writing proposes new paths for the law, policy makers, judges, and practitioners may not take notice. However, this new Restatement

⁴⁹ The legislative history suggests that lawmakers at the time recognized that a series of events, and not single happenings, were combining to create the crisis. For what appears to be a particularly anxious statement, see 132 Cong. Rec. E2755-02 (Aug. 6, 1986) (statement of Rep. Fred J. Eckert). ("The lawsuits are mounting. Huge settlements are leading insurance companies to review their liability policies. Premiums are increasing. Coverage is being reduced. Policies are being canceled altogether. Some vaccine manufacturers have already ceased producing their products because they concluded the liability risk is too great.").

⁵⁰ Less than two months after the proposed final draft of the Third Restatement was adopted by the ALI membership, it was submitted to the U.S. District Court for the Northern District of Alabama as legal authority. See *Citing Third Restatement, Union Carbide Also Wants Judgment in MDL*, 5MEALEY'SLITIG.REP.:BREASTIMPLANTS15 (July 24, 1997) (reporting progress of a pending case, *In re Silicone Gel Breast Implant Products Liability Litigation*, MDL 926, CV-92-P-10000-S (N.D. Ala. filed Apr. 1, 1994)).

⁵¹ Professors Henderson and Twerski, the Reporters for the Third Restatement, characterized their job as restating *existing* law. See James A. Henderson, Jr. & Aaron D. Twerski, *Arriving at Reasonable Alternative Design: The Reporters' Travelogue*, 30 U. MICH. J.L. REFORM 563, 564, 585 (1997). They acknowledge, however, that the Third Restatement sometimes takes principles from mere legal dicta to the creation of more modern standards, such as the highly controversial defective design standard. See *id.* at 563. Based on their articulated philosophy that the time has come for a new Restatement, these not-so-clearly existing standards must be intended to influence the law toward what are really new standards described in the Third Restatement.

stands to be more than academic, it is likely to affect state and federal law.⁵² Although the Restatement cannot change law without judicial or legislative adoption, the ALI's membership is comprised of the same people active in legal reform who will make persuasive arguments for implementing the Third Restatement's standards in legislatures and courts.⁵³ While a transition from thoughts to application may not be the purpose of other writings that explore legal theory, it is consistent with the ALI's goal to affect the law.⁵⁴ Therefore, the heated debate in Washington, D.C. at the ALI's annual meeting in May, 1997 can be seen as a preview of the debate and legislative action to come.⁵⁵

17. Considering that the Second Restatement's position on product liability dominated American legal thought for over thirty years, the Third Restatement can rely on precedent to suggest that eventually it too will be widely applied.⁵⁶ Although change will likely take time,⁵⁷ there is no reason to believe that because the Third Restatement is also non-binding it will be any less acceptable to the institutions that create and administer the law than was the Second Restatement.

18. Furthermore, the national tort reform movement, which typically argues for more manufacturer protection and greater restraint on individual freedom to sue

⁵² See *supra* note 50 and accompanying text.

⁵³ Judge Guido Calabresi and Jeffrey O. Cooper recount an anecdote about Judge Cardozo who, while sitting on the New York Court of Appeals, attended an ALI meeting to discuss the Restatement (First) of Torts. Guido Calabresi & Jeffrey O. Cooper, *New Directions in Tort Law*, 30 VAL. U. L. REV. 859, 866-67 (1996). Judge Cardozo, reportedly considering *Palsgraf v. Long Island R.R.*, 162 N.E. 99 (N.Y. 1928) at the time, helped persuade the ALI membership that negligence should be relational, that is, directed toward the plaintiff, to be actionable. See *id.* After the ALI meeting, Judge Cardozo returned to work and convinced a majority of the New York Court of Appeals that they should reverse the lower court's decision for the plaintiff in *Palsgraf* because the Restatement would resolve the problem that way. See *id.*

⁵⁴ Though the Reporters of the Third Restatement may characterize their roles as passive, the same is not necessarily true for the ALI. See *ALI Bylaws*, *supra* note 15, at § 1.01 ("The Institute's purposes are as stated in its Certificate of Incorporation: The particular business and objects of the society are educational, and are to *promote the clarification and simplification* of the law and its better *adaptation* to social needs, . . . and to *encourage and carry on* scholarly and scientific legal work.") (emphasis added).

⁵⁵ See American Law Institute, *Products Liability Restatement Gets Final Approval from Membership* (visited Mar. 26, 1998) <<http://www.ali.org/ali/AMDRAFTS.HTM>>.

⁵⁶ See RICHARD A. EPSTEIN, *CASES AND MATERIALS ON TORTS* 759 (6th ed. 1995).

⁵⁷ See Terry Carter, *Subtle Tort Reform New Restatement Injects Fault Issue in Design Defect Cases*, 83 A.B.A. J. 18 (Aug. 1997).

for injuries, has widespread advocates.⁵⁸ The new Restatement will almost certainly be used in future public debate as "evidence" of what is right or proper about liability, due to its highly visibility since its tentative drafts.⁵⁹

19. The ALI's vote last spring to adopt the Third Restatement should also attract Congress' attention because the Second Restatement was the explicit foundation for the Compensation Program.⁶⁰ Congress may take the Third Restatement as a sign that relying on the Second Restatement's philosophies is no longer advisable. Further, because Congress chose not to fully preempt state remedies,⁶¹ Congress implicitly relied on the Second Restatement to shape the majority of the remedies available outside the Compensation Program.⁶² If the law currently applied to post-election⁶³ vaccine cases in the state and federal courts no longer provides a realistic opportunity for adequate remedies for vaccine injuries based on the Third Restatement's standards, Congress may pay close attention.

⁵⁸ For example, James A. Henderson, Jr., who went from being a professor at the Boston University School of Law and a consultant to a manufacturer association, the National Product Liability Council, to a Reporter for the Third Restatement, testified before Congress in 1982 to support a national product liability standard limiting liability for manufacturers. *See To Regulate Interstate Commerce by Providing For a Uniform Product Liability Law, and For Other Purposes, Hearings on S. 2631 Before the Subcomm. for Consumers of the Comm. on Commerce, Science, and Transportation, 97th Cong. 20* (Mar. 9, 1982). Tort reform also finds support from individuals at the state level. *See generally* RICHARD NEELY, *THE PRODUCT LIABILITY MESS: HOW BUSINESS CAN BE RESCUED FROM THE POLITICS OF STATE COURTS* (1988) (state judge and politician supporting federal judicial activism to reform tort-based civil actions).

⁵⁹ The Third Restatement, even in its tentative drafts, served as the focus of numerous law review articles. *See, e.g.,* Jeffrey D. Winchester, Note, *Section 8(C) of the Proposed Restatement (Third) of Torts: Is it Really What the Doctor Ordered?*, 82 *CORNELL L. REV.* 644, 664-688 (1997) (discussing defective design standards in the Third Restatement's second tentative draft).

⁶⁰ *See* H.R. REP. NO. 99-908, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367 ("Given the existence of the compensation system in this bill, the Committee strongly believes that Comment k [to section 402A of the Second Restatement] is appropriate and necessary as the policy for civil actions seeking damages in tort.").

⁶¹ In the years following the Vaccine Act, courts interpreted congressional intent to allow the coexistence of federal and state remedies for vaccine injuries. *See, e.g.,* *Mazur v. Merck & Co., Inc.*, 742 F.Supp. 239, 246-8 (E.D. Pa. 1990). In fact, Congress mandated that states maintain a remedy for vaccine injuries. *See* National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(e) (1994) ("No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.").

⁶² *See* H.R. REP. NO. 99-908, at 25-26, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6366-67.

⁶³ "Post-election" refers to lawsuits permitted after a Court of Federal Claims judgment. *See* National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-21 (1994).

2. What the Third Restatement Changes

20. One of the most contentious issues the ALI membership debated last spring centered around the decision to change the liability standards for medical products such as vaccines.⁶⁴ The disproportionately lengthy discussion about medical products and prescription drugs indicates just how strikingly different the Third Restatement is from the Second Restatement and majority law. In general, the Third Restatement makes it more difficult for a court that follows its position to impose liability on a vaccine manufacturer because the text moves toward a higher threshold for liability.⁶⁵ To make this turn toward the conservative, the Third Restatement uses two drafting devices.

21. First, the Third Restatement creates a dual liability standard by creating one standard for general product liability and another for medical products and prescription drugs. General liability, described in section 2, retains the more consumer-sympathetic standards the Second Restatement proposed.⁶⁶ In comparison, section 6, which narrowly applies to medical devices and prescription drugs such as vaccines, acknowledges the inherent social utility in medical products and adopts a manufacturer-sympathetic approach.⁶⁷ This special medical product standard makes it difficult for a plaintiff to recover against a manufacturer under most circumstances. In contrast, the Second Restatement treated legal liability for all *types* of products as a single issue. The Second Restatement only proposed different standards of liability if products posed different levels of dangerousness.⁶⁸ By isolating medical device and prescription drug liability, the Third Restatement minimizes opposition to higher liability thresholds. Consumer protection advocates focusing on automobile safety, for example, have no reason to object to the Third

⁶⁴ See Henderson & Twerski, *supra* note 51, at 564 (“Some contend that we have been political brokers. We are told, often by the same critics, that we have been ideologically rigid. It is hard to see how we could be both savvy political brokers and rigid ideologues. We plead not guilty on both counts of the indictment. We have heard from a multitude of voices. Arguments have been presented with both passion and intellectual rigor.”).

⁶⁵ See Angela C. Rushton, Note, *Design Defects Under the Restatement (Third) of Torts: A Reassessment of Strict Liability and the Goals of a Functional Approach*, 45 EMORY L.J. 389, 400-8 (1996).

⁶⁶ See THIRD RESTATEMENT, *supra* note 22, § 2 (strict liability still applies to defectively manufactured products and simple negligence for design and warning cases)

⁶⁷ See *id.* § 6 and comments.

⁶⁸ See SECOND RESTATEMENT, *supra* note 16, § 402A cmt. k.

Restatement because car buyers retain a higher level of protection against manufacturer negligence.

22. The second drafting device the Reporters of the Third Restatement use to make the Third Restatement more conservative is the conservative language of the text itself. Though still arranging liability around the three basic causes of action, the Reporters use extensive comments, illustrations, and rationales to clarify the Third Restatement's intended impact.⁶⁹ The substance of this approach is outlined immediately below.

a. Defective manufacture of vaccines—strict liability

23. The general rule for liability remains that "[a] manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect."⁷⁰ A product is not considered defective unless "at the time of sale or other distribution" it "contains a manufacturing defect as defined in section 2(a)" of the general product liability standards.⁷¹ That broader portion of the Third Restatement states that a product "contains a defect when [it] departs from its intended design even though all possible care was exercised in the preparation and marketing of the product."⁷² Other than updating the language of this section to apply specifically to medical products, this strict liability standard remains consistent with Judge Cardozo's opinion in the benchmark product liability case *MacPherson v. Buick Motor Co.*⁷³

b. Defective design—no liability unless absolutely no benefit

24. Defective design was the most contentious standard in the Third Restatement debated by the ALI membership.⁷⁴ Unlike the liability standard for defective vaccine production, in which the Third Restatement retains the traditional

⁶⁹ See THIRD RESTATEMENT, *supra* note 22, § 6.

⁷⁰ See *id.*

⁷¹ See *id.* § 6(b).

⁷² See *id.* § 2(a).

⁷³ See *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (1916).

⁷⁴ See *Products Liability Restatement Gets Final Approval from Membership*, *supra* note 56.

approach,⁷⁵ the Third Restatement reverses the liberal pro-consumer approach in defective design actions. Contrary to the Second Restatement, the Third Restatement does not find relevant the reasonable consumer's expectation of a design's safety.⁷⁶ Plaintiffs can no longer allege that a manufacturer was negligent if it failed to consider consumer toleration or preferences for risks when it designed a vaccine.

25. Instead of looking at reasonable consumer views, the Third Restatement standard asks whether a learned intermediary, having weighed the foreseeable risks of a vaccine against its therapeutic benefits, would have found it so dangerous that she or he would not have prescribed it for “*any* class of patients.”⁷⁷ Comment f frames the issue by saying that a vaccine design is unreasonable only when objectively viewed, reasonable providers, possessing the knowledge that a reasonable drug manufacturer had or should have had about the risks and benefits attendant to the use of the drug or medical device, would [not] prescribe it for any class of patients. Given this very demanding objective standard, *liability is likely to be imposed only under unusual circumstances*. The court has the responsibility to determine when the plaintiff has met the burden of production for this demanding standard.⁷⁸

26. Although the plaintiff-victims and defendant-manufacturers will present expert testimony supporting their positions at trial, the Third Restatement lowers the threshold for reasonableness to the extent that a jury only has a minimal fact finding role and the testifying experts possess significant power to determine a case's outcome. Rather than requiring an affirmative decision that a vaccine design was or was not reasonable, the Third Restatement limits the jury's decision to believing or not believing in the existence of a class of users for whom the vaccine *may* be useful.

27. Note that the standard never specifically asks whether the testifying learned intermediary would find the vaccine design reasonable. The Third

⁷⁵ See THIRD RESTATEMENT, *supra* note 22, § 6 cmt. a.

⁷⁶ Compare SECOND RESTATEMENT, *supra* note 16, § 402A cmt. c (a consumer has the right to expect reasonably safe goods and is “entitled to the maximum of protection . . . [from] those who market the products”) with THIRD RESTATEMENT, *supra* note 22, §§ 6(c)-(d) and comments (lacking explicit consumer protection language).

⁷⁷ THIRD RESTATEMENT, *supra* note 22, § 6(c) (emphasis added).

⁷⁸ *Id.* § 6(c) cmt. f (emphasis added).

Restatement asks a learned intermediary, who is most likely a doctor,⁷⁹ to determine whether the vaccine has *any use at all*. Nor does the standard ask a learned intermediary to decide whether the manufacturer should suggest the vaccine is safe to use for people with the plaintiff's health background, even if that was implied or stated on the vaccine's label. The Third Restatement elevates the role of learned intermediaries beyond acting as conduits for warnings to the point where they are also vaccine design judges.⁸⁰ This, perhaps, forms a new learned intermediary standard. By pre-selecting physicians as the preferred scientific experts on vaccines, though virologists, biochemists, or other health professionals may have equally good or superior insight into the vaccine design and injury at issue, the Third Restatement expands the importance of health care providers.

28. By pinning liability to a health care provider's perspective, the Third Restatement ensures that lawsuits minimize outsider comparisons of the industry⁸¹ and eliminates the plaintiff's viewpoint from affecting the proceedings. The Third Restatement reinforces this new learned intermediary standard by requiring a plaintiff to establish that a reasonable alternative design was *possible and available* when the vaccine was designed.⁸² Potentially, the Third Restatement allows manufacturers that are the sole producers of a specific type of a vaccine to control their liability risks by exploring one vaccine design during development, thus effectively eliminating defective design as a cause of action.

⁷⁹ See *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1357-8 (3d Cir. 1992) (applying the Second Restatement's learned intermediary rule, and concluding that neither nurses nor pharmacists are learned intermediaries under the Pennsylvania construction of the doctrine).

⁸⁰ The classic Second Restatement learned intermediary standard allows a manufacturer to provide warnings and instructions to health care professionals instead of consumers when that health care professional has an evaluative role. See SECOND RESTATEMENT, *supra* note 16, § 402A cmt. k. This doctrine is based on the unique capabilities health care professionals have in assessing risks and benefits of medical interventions. The Second Restatement's expectation is that these learned intermediaries will pass the manufacturer's warnings and instructions to consumers in a form most likely to facilitate informed consent.

⁸¹ The new standard demands that a better/safer vaccine design be available at the time the vaccine in question was administered. See *Carter*, *supra* note 58, at 18. This prohibits evidence of the development of a safer vaccine design between the time of administration/injury and the law suit to suggest that the original design was negligent, especially when the newer design was produced by a competitor. See *id.* ("As a practical matter, admits Habush, plaintiffs lawyers regularly offer reasonable alternative designs in making their cases. 'But this means it's no longer a strategic decision. . . . Now it's a threshold barrier to getting to a jury.'") (quoting Richard Habush, adviser to the Reporters for the Third Restatement, and a critic of the alternative design requirement).

⁸² See THIRD RESTATEMENT, *supra* note 22, § 6 cmt. f .

29. This Third Restatement standard also highlights a growing deference to the regulatory systems that approve vaccine designs.⁸³ In a sophisticated argument, the Reporters suggest that if an appropriate government agency has already approved a vaccine design, courts should strongly consider not imposing what amounts to their additional, but unstated, regulation.⁸⁴ The Third Restatement weights its arguments in favor of the manufacturer and against judicial regulation of vaccine design by making it extremely difficult for a plaintiff to prevail in this type of suit.⁸⁵ Although taking the idea to an extreme, the Third Restatement parallels the VICP's rebuttable presumption that vaccine designs complying with federal regulatory requirements are *per se* reasonable and not negligent.⁸⁶

c. Defective warning—new learned intermediary standard

30. The Third Restatement attempts to balance a lenient attitude toward manufacturer design choices by mandating warnings.⁸⁷ Hopefully, given the right information, a consumer can decide not to take the vaccine if his or her health background suggests that doing so is dangerous.⁸⁸ On a larger scale, the theory behind warnings attempts to reduce the exposed group for whom a vaccine poses little benefit, but significant risks.⁸⁹

⁸³ See *id.* § 6 cmt. b and corresponding Reporter's Note.

⁸⁴ See *id.*

⁸⁵ See *id.*; see also *id.* § 4(b) (rules governing compliance with regulations).

⁸⁶ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(b)(2)(1994) ("For purposes of [civil vaccine warning liability], a vaccine shall be presumed to be accompanied by proper directions and warning if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act."). One issue that this Note does not attempt to solve is how Congress can substantively improve the way regulations ensure that manufacturers design safe vaccines and effective warnings to limit the number of injuries and deaths from inherent dangers. This should be a large concern for Congress if federal and state regulations become the benchmark for reasonableness in the absence of negligence-based civil liability, which currently provides an external motivation to make vaccines safe and warnings effective. See *Mazur v. Merck & Co., Inc.*, 742 F.Supp. 239, 247 (E.D. Pa. 1990) (federal regulation and tort law serve different purposes). There is no objective evidence that these regulations actually demonstrate how reasonable designs and warnings should look.

⁸⁷ See THIRD RESTATEMENT, *supra* note 22, § 6(d).

⁸⁸ See *id.* § 6 cmt. d.

⁸⁹ See Richard C. Ausness, *Product Category Liability: A Critical Analysis*, 24 N. KY. L. REV. 423, 432-35 (1997) (general discussion of the risk utility test and its applications).

31. The Third Restatement states that a manufacturer will be held liable for injuries when the warning of foreseeable risks are not supplied to the "prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings."⁹⁰ And if the manufacturer does not warn "the patient when [it] knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings" the manufacturer can also be held liable for injuries.⁹¹

32. This requirement that manufacturers be excused from liability if they adequately warn learned intermediaries in an evaluative role is not innovative in itself. The Second Restatement proposed a similar standard,⁹² and the VICP went one step further by eliminating manufacturer responsibility for direct consumer warnings.⁹³ The Third Restatement does, however, suggest a more substantive standard for negligence when plaintiffs question warning and instruction adequacy. Although the Third Restatement does not go so far as to suggest a standardized warning for vaccines, it does explicitly state that, when a warning meets regulatory standards, courts should heavily consider that as adequate and reasonable.⁹⁴ Much in the same way that the new defective design standards hold reasonable consumer expectations of safety irrelevant, the Third Restatement suggests that courts not be overly concerned with the actual impact of a warning.⁹⁵

33. On one level this standard proposes an efficient system, allowing manufacturers to avoid liability based on a particular plaintiff-consumer's ability to comprehend a warning. Nevertheless, this new standard provides no clue as to when a court may legitimately examine the substance of a warning or instruction. Although the Third Restatement uses government regulation as a benchmark for adequacy, it does not suggest the level of accuracy or effectiveness a regulatory standard must demand in order to afford a complying warning or instructing a safe

⁹⁰ See THIRD RESTATEMENT, *supra* note 22, § 6(d)(1).

⁹¹ *Id.* § 6(d)(2).

⁹² See SECOND RESTATEMENT, *supra* note 16, § 402A cmt. k.

⁹³ The VICP does say that manufacturers will not be excused from directly warning consumers if, when proved by clear and convincing evidence, they abused the lenient standard by willfully hiding risks or failing to use due care when proved by clear and convincing evidence. See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(b)(2)(A)-(B) (1994).

⁹⁴ See THIRD RESTATEMENT, *supra* note 22, § 6 cmt. e ("When the content of the warnings is mandated or approved by a governmental agency regulation and a court finds that compliance with such regulation federally preempts tort liability, then no liability under this Section can attach.").

⁹⁵ See *id.*

harbor from liability. Nor does the Third Restatement demand that these government regulations be concerned with consumer safety. The Reporters and the ALI membership could have kept the courts out of the business of regulating the substance of warnings by allowing compliance to absolve liability, but still require that the regulations demand reasonable warnings.

34. This failure to require reasonably effective warnings is disturbing when combined with the defective design standard. Under the Third Restatement, manufacturers have much more freedom to make vaccine designs suitable for only the smallest group of consumers without fear of liability. Nevertheless, when any medical product is useful for only a particular class of consumers it may be exceedingly dangerous for everyone else. The key to reducing injuries from the medical product, whether it is a prosthetic device or a vaccine, is to identify accurately those who should *and* should not use it. Warnings are one of the most powerful screening mechanisms that manufacturers possess to minimize injuries. An effective warning can also reduce defective design liability by screening out inappropriate users. The potentially dangerous attribute of the Third Restatement is that it relies so heavily, and perhaps naïvely, on executive agencies to protect consumers.

35. If the complex regulations mandating warnings already in force were so effective, and judicial oversight so unnecessary, there would be no vaccine injuries—and yet vaccine injuries persist. By removing substantive judicial examination of warnings without a corresponding increase in concern by another legal entity, the Third Restatement does not adequately seek to protect consumers.

3. The Third Restatement's impact

36. As the Third Restatement's influence grows it will signal a significant shift in the American legal attitude toward injury recovery. The Reporters appear to hope the Third Restatement will do more than correct any overly liberal legal sympathy toward consumer-plaintiffs with a manufacturer-sympathetic legal system. The Reporters create the impression that they want the legal system to reject almost any vaccine injury complaint that does not allege defective manufacturing, fraud, or abuse.

37. The counter argument that these effects, should they materialize, are insignificant because the Compensation Program exists to take care of consumers, is inapposite. The Compensation Program does not cover every vaccine on the market.⁹⁶ Nor does the Compensation Program cover every potential vaccine-related

⁹⁶ See National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-(11), 14(a) (1994) (presumption of causation to vaccines in program, allowing non-Table childhood vaccine injuries to go through VICP, but not suggesting that all vaccines are childhood vaccines).

injury or aggravation.⁹⁷ The potential result of the Third Restatement's growing influence is a group of consumer-plaintiffs who neither receive adequate compensation in the VICP⁹⁸ nor have recourse in the state and federal courts.

38. As for the vaccine market, vaccine prices may fall and availability rise because of the diminished risk of liability. This result is consistent with the Compensation Program's economic goals.⁹⁹ Those goals, however, also looked to build public confidence in vaccination.¹⁰⁰ But with few quality controls built into the Third Restatement's manufacturer liability standards, it is difficult to imagine the legal devices available to encourage safety in a Third Restatement world. One interpretation of this economic effect is to suggest that though vaccine prices will fall, so will vaccine quality. This compromised quality may then affect the general consumer, and not just especially sensitive consumers whose injuries are unpredictable. When liability's deterrent effect slackens, manufacturers will no longer have the motivation to conduct further research and development to improve vaccine safety.

39. The Third Restatement and the VICP have a direct philosophical conflict. Congress designed the Compensation Program to be open ended, with an election for petitioners to seek redress directly from manufacturers in the state and federal civil courts.¹⁰¹ Although the Third Restatement does not explicitly preclude this election option, it does so implicitly by establishing standards under which even a severely injured plaintiff is unlikely to succeed.

40. If Congress agrees with the Third Restatement's conservative effect on state and federal law, the national legislature has two choices for action. Congress can naïvely ignore the conflict, allowing a *de facto* end to the election option within the Compensation Program. Alternatively, Congress can institutionalize this change to the VICP by amending the Vaccine Act to exclude the election option.

41. Regardless of the choice it makes between these two options, Congress ultimately will be held accountable for the legal environment for vaccine injuries because it has already taken an active role in shaping vaccine liability. Congress, therefore, should act carefully in the way it supports or distances itself from the

⁹⁷ See *Carter v. Secretary Dep't Health & Human Servs.*, 21 Cl. Ct. 651, 653-55 (1990) (affirming Special Master's decision that petitioner failed to establish that her non-Table injury, juvenile rheumatoid arthritis, was caused by the covered rubella vaccine).

⁹⁸ More specific results are discussed in section II(E), *infra*.

⁹⁹ See H.R. REP. NO. 99-908, at 5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6346 (priority 4).

¹⁰⁰ See 131 Cong. Rec. S3843-04 (daily ed. Apr. 2, 1985) (statement of Senator Hawkins).

¹⁰¹ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-21 (1994) (election option).

Third Restatement because it may unintentionally affect public perception of the Compensation Program and national vaccine initiatives.

42. The Compensation Program constitutes only one part of a larger Vaccine Act plan for widespread vaccination and disease prevention in the United States. Although Congress has the constitutional authority to pass legislation promoting and requiring vaccination to protect society's health, it still has an obligation to make sure that the pro-vaccination system it puts into place protects the rights of individuals. Congress strengthens the social legitimacy of its other vaccine programs by being able to show that it has created an efficient, just, and comprehensive system of injury compensation. In contrast, Congress undercuts its argument that its motivation is to protect the public from deadly diseases if its motivation appears to focus solely on protecting manufacturer liability interests. If Congress actively or passively allows the manufacturer-focused Third Restatement to affect negatively the way vaccine-injured individuals receive compensation, then it risks undermining public confidence in the Vaccine Act programs. To avoid this negative Third Restatement consequence, Congress will have to balance carefully the business, social, and individual interests in one of the most significant and cost effective health technologies of this century.

43. This philosophical conflict centering around the election option can substantially affect the Compensation Program by increasing the number of awards paid out of the Vaccine Trust Fund. VICP petitioners will elect to receive a Trust Fund award more frequently due to the low probability of winning a civil court judgment against a manufacturer under the Third Restatement's defective design and warning standards. Although Compensation Program statistics suggest that only an extremely small minority of petitioners elect to go to other courts to seek more favorable awards after a VICP judgment,¹⁰² the election option was designed to be an important safety valve. Rather than requiring Compensation Program petitioners to accept lower award levels if the Trust Fund financing becomes insufficient to meet an increasing volume of meritorious claims, Congress created the election provision to force manufacturers back into paying compensation for the injuries they cause. Congress should not sacrifice this important balance between the need to guard business with protecting the consumer's right to be fairly compensated for injuries without explicit deliberation.

B. Emerging Diseases and New Vaccines—External Challenges

¹⁰² See *VICP Background*, *supra* note 43.

44. When Congress created the VICP, it decided to cover a specific class of vaccines, those routinely given to children.¹⁰³ Several factors might have motivated this decision, including the political consideration that focusing on the needs of children is sometimes less controversial than concentrating on adult needs. The provisions of the VICP, however, suggest that the legislature intended the "childhood vaccine" limitation to constrain the volume of injuries going through the no-fault program to avoid overwhelming its administrative and financial capacity.¹⁰⁴ Yet what Congress once considered a constraint on the types of vaccines covered by the Compensation Program may become less meaningful as new vaccines are routinely administered to children for emerging or previously unpreventable diseases.¹⁰⁵

45. The problem does not end with the numbers of children vaccinated for emerging or previously untreatable diseases. The Compensation Program also compensates *adults* who are injured by vaccines routinely given to children.¹⁰⁶ This might be called a catch-up syndrome. Because these vaccines were not available when contemporary adults were children, the initial group of new vaccine recipients

¹⁰³ The enabling legislation's title (the National *Childhood Vaccine Injury Act*) indicates that the Compensation Program was designed to cover vaccines routinely recommended for children. However, this limitation does not exclude adults who take these same vaccines. See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-11 (1994). Indeed, there are no age requirements for recovering under the VICP. See *id.*; *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 5-7 (1st Cir. 1994) (finding that when both parents contracted polio from daughter who had been vaccinated and developed disease, other's acceptance of VICP award did not bar father and daughter from suing under Massachusetts law applied in federal court under diversity jurisdiction).

¹⁰⁴ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-11(b)(1)(B) (limiting pre-1988 injuries to a maximum of 3500 petitions); see also *Charette v. Secretary of Dep't of Health and Human Servs.*, 33 Fed. Cl. 488, 491-93 (1995) (affirming Special Master's decision to dismiss claim by wife of man killed by anaphylactic reaction to typhoid vaccine, which is not included in VICP).

¹⁰⁵ "Routinely administered" is a term of art within the VICP. The Congressional mandate to the Secretary of Health and Human Services is to expand the VICP to cover more vaccines when the CDC determines that they should be "routinely administered" to children. See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-14(e)(1)-(2) (1994) ("When. . . the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for *routine administration* to children, the *Secretary shall*, within the 2 years of such recommendation, amend the Vaccine Injury Table" to include the vaccine in the Compensation Program) (emphasis added). See generally EMERGING VIRUSES (Stephen S. Morse, ed. 1993) (essays discussing the ecological and historical patterns of disease emergence, recession, and reemergence, including the potential for upcoming disease epidemics of new and old diseases).

¹⁰⁶ See discussion *supra* note 103.

are larger than would normally be expected.¹⁰⁷ Therefore, the group of injured consumers may be larger than the Compensation Program can handle. In 1986 there was a certain logic to assuming children would make up the bulk of VICP petitioners; it was reasonable for Congress to assume that most adults are immune to "childhood" diseases because they were either vaccinated or had naturally developed an immunity from exposure to the wild virus. Nevertheless, new data indicates that some vaccines, including the most dangerous pertussis vaccine, do not provide lifelong immunity.¹⁰⁸ Re-vaccination against these diseases, whether in childhood or adulthood, multiplies the potential number of vaccine injuries the VICP will have to handle.

46. Furthermore, the line between adult and childhood vaccines is blurring. Vaccines for diseases such as hepatitis B are now routinely given to both adults and children. There are other diseases and vaccines which are not currently under Compensation Program, but are prime candidates for being included in the future because of their potential for helping children and adults. With vaccines, such as the HPG-30 AIDS vaccine, in the clinical trial phase of development and pushing science further, newer and riskier vaccines are not remote possibilities, they are close to being reality.¹⁰⁹ The risks these vaccines pose become more socially palatable when the diseases they prevent are deadly and the associated costs of caring for injuries and disability are higher. Many public health advocates would love to insulate all Americans against diseases such as AIDS with a vaccine, even if it did pose risks. To prevent these diseases and others from developing later, the most logical course of action is to vaccinate people when they are very young. Yet a vaccine's routine administration to children is almost an automatic qualifying factor for VICP coverage.

¹⁰⁷ Despite the fact that the VICP now covers the hepatitis B vaccine, many contemporary adults were never vaccinated against the disease because the vaccine only became available in the late 1970s. Consequently, adults recently vaccinated against hepatitis B are taking a "childhood" vaccine. See W. Charles Cockburn, *Disease Control and Prevention in the 20th Century: The Role of Immunization*, in PROCEEDINGS OF THE INTERNATIONAL CONFERENCE ON THE ROLE OF THE INDIVIDUAL AND THE COMMUNITY IN THE RESEARCH, DEVELOPMENT, AND USE OF BIOLOGICALS, at 6 (Mar. 2-5, 1976); see also National Vaccine Injury Compensation Program, *Vaccine Injury Table* (eff. Mar. 24, 1997) (visited June 11, 1997) <http://www.hrsa.dhhs.gov/bhpr/vicp/table.htm> (listing the Hepatitis B vaccine) [hereinafter *New Vaccine Injury Table*].

¹⁰⁸ See *The Whooping Cough Afflicts Teens, Adults: Preliminary Data Suggest Pertussis Often Causes Coughs in Grown-Ups*, WALL ST. J., Oct. 2, 1997.

¹⁰⁹ See AIDS WKLY. PLUS (Sept. 29, 1997), available in 1997 WL 11007305 (reporting positive findings from tests of the HPG-30 AIDS vaccine); Brigid Schulte, *Terrifying Risk in AIDS Fight: Volunteers Would Risk Lives to Find Vaccine Against Deadly Disease*, SEATTLE TIMES, Sept. 27, 1997, at A2 (announcing 50 AIDS activists' offer to receive an attenuated AIDS virus to further the pace of vaccine research and clinical trials).

47. The net result of advancing technology confronting and successfully preventing new diseases is a larger group of vaccine-injured consumers. The social benefit of the vaccines may very well justify these injuries. However, social utility presents one of the best arguments for Congress ensuring that the VICP is financially and administratively capable of providing compensation to petitioners. Still, the VICP is not well prepared to handle a sudden or large influx of petitions. Although the Federal Claims Court, assisted by the Special Masters, has adjudicated more than 75% of the initial backlog of pre-1988 cases,¹¹⁰ it has taken almost ten years to do so. A time lag due to an overload of cases may have been justified at the beginning of the Compensation Program because Congress was trying to draw cases specifically out of the civil courts and into the no-fault program. However, adjudication delays today would not serve any noble or useful purpose—they would only highlight administrative weakness.

C. Key Actors and Vaccine Table Amendments—Internal Challenge

48. Congress delegated authority to a number of different people and parties when it created the VICP, including the Secretary of Health and Human Services ("Secretary"), the Advisory Committee on Childhood Vaccines ("Advisory Committee"), the CDC, and the Compensation Program Director.¹¹¹ Over the past ten years these actors have carried out their work and made conservative changes in the VICP's coverage and operations in a generally quiet, unreported manner. The political process, pressures of public accountability, and the developing sciences of virology and immunology tend to limit these actors' choices when it comes to changing what vaccines the VICP covers, and how the Compensation Program operates. The relative lack of controversy and public attention have allowed the VICP to work during the past ten years without any significant legislative or judicial challenges to its original form and functions. However, this quiet environment is not guaranteed, and could quickly change based on leadership or activism by one of the key players in the Compensation Program.

49. Each of these different people and parties charged with administering the VICP have the potential to make rapid or radical changes in it. As they confront more controversial and pressing issues, these key players may seize an opportunity to take action. The recent volatile break between the former Surgeon General Joycelyn Elders¹¹² and the Clinton administration is one example of how a single

¹¹⁰ See *VICP Statistics*, *supra* note 42.

¹¹¹ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 to -34 (1994).

¹¹² The Surgeon General does not have a direct role in the VICP, however, that position has a number of similarities to the roles that key actors in the VICP play. Each individual creates policy,

public health official can bring controversy to a highly respected position or program.¹¹³ Granted, vaccines are not as taboo as the sexuality issues that Dr. Elders boldly confronted, but as long as vaccines predictably injure and kill children they remain controversial. The fact that many people have no realistic opportunity to give or withhold consent to vaccination because it is mandated by law underscores the volatile individual liberty issues that always percolate under the surface of public acceptance of vaccination.¹¹⁴ The balance the uncontroversial VICP strikes between the individual and social concerns about vaccination helps to further public health efforts to control or eliminate diseases by quieting public objections to vaccination. Congress should consider how the roles of these key individuals may affect the future of the Compensation Program.

50. Take, for instance, the Secretary of Health and Human Services, who acts as a powerful gatekeeper for the Compensation Program. When Congress created the VICP it contemplated the development of beneficial new vaccines. Knowing that making injury compensation available reassures the public, manufacturers and the insurance industry, Congress added 42 U.S.C. § 300aa-14(c), empowering the Secretary to amend the Vaccine Injury Table and Aids to Interpretation through notice and comment rulemaking.¹¹⁵ The Secretary holds a significant amount of discretion in making these amendments when the Centers for Disease Control and Prevention recommend that a new vaccine be administered routinely to children. The First Circuit decision in *O'Connell v. Shalala* affirmed this rulemaking authority by clarifying that the power to amend the Vaccine Injury Table is extremely broad, and even includes a power to remove vaccines from the program.¹¹⁶

takes on particular causes by drawing public attention to problems, marshals resources committed to change, and sets scientific standards.

¹¹³ See Sabin Russell, *Not Afraid To Speak Her Mind*, S.F. CHRON., Nov. 9, 1997, at 3Z3 (interview with Dr. Elders in which she expressed that being an activist, even if doing so is controversial, is a part of being a central public health figure).

¹¹⁴ See *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905) (stating that a mandatory vaccination statute was constitutional despite the liberty interest implicated).

¹¹⁵ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-14(c).

¹¹⁶ *O'Connell v. Shalala*, 79 F.3d 170, 179 (1st Cir. 1996) (“The petitioners’ interpretation means that every alteration to the text of a proposed rule—even a minor technical or grammatical alteration—would have to be rerouted through the [Advisory Committee], subject to a fresh notice-and-comment period. This extra step would be necessary even when the Secretary changes a proposed regulation *in accordance with the [Advisory Committee’s] announced wishes* or to correct a syntactical bevue [sic]. Such a construction would create a nearly endless circle and attenuate the rulemaking process without achieving any corresponding benefit. Because it is difficult to believe that the Congress intended to prolong the revisory process by directing the Secretary to engage in a mindless minuet, the prospect of wasted motion cuts against the petitioners’ interpretation.”).

Although the Secretary must respond to a CDC recommendation of including a new vaccine on the Injury Table, the Secretary need not wait for a recommendation. Instead, the Secretary has the authority to act on independent initiative or even public petition.¹¹⁷

51. With less than three years left in Secretary Shalala's tenure as the head of Health and Human Services, she may have more latitude to make significant changes that draw more public attention. For example, the Secretary might use the VICP to encourage manufacturers to develop and distribute riskier vaccines by placing them on the Injury Table before they are widely accepted. This would give manufacturers more liability protection and would be consistent with Secretary Shalala's personal trend of Vaccine Injury Table¹¹⁸ and Aids to Interpretation amendments.¹¹⁹

52. If there is a valid generalization from Secretary Shalala's actions, it is that people in key VICP roles will attempt to make the VICP more widely applicable. In doing so, the Secretary and other key Compensation Program players risk drawing negative scrutiny. This is not to suggest that they refrain from making necessary changes in the VICP simply to avoid controversy. Rather, the Secretary should take into consideration these opposing viewpoints and attempt to address them rationally to preserve the VICP's important work.

53. Congress should not take action to limit VICP key players' activism. That would hinder public health efforts and be nearly impossible to enforce. However, Congress should be aware that Americans have not reached a consensus on vaccine safety, the zone of protection manufacturers deserve, or the appropriate role the VICP should take in balancing future injury issues. If these key actors in the VICP do speak out more frequently and loudly than they have in the past by amending the Vaccine Injury Table, Congress should pay close attention. Whatever action Congress takes to silence or amplify these key players' arguments could affect the vaccine availability-liability balance, the growing effectiveness of public vaccination programs the Vaccine Act encourages, or the VICP's public acceptance and participation levels.

D. Flat Tax—Internal and External Challenge

¹¹⁷ See 42 U.S.C. § 300aa-14(c).

¹¹⁸ Hepatitis B, conjugated and unconjugated Hib, and Varicella (chicken pox) have been added to the list of the vaccines the VICP covers. See *New Vaccine Injury Table*, *supra* note 107. The original Vaccine Injury Table focused on encephalopathy and seizure disorders, and now the VICP covers a wider range of defined injuries such as chronic arthritis, brachial neuritis, and thrombocytopenic purpura. See *id.* at (6)-(11).

¹¹⁹ See *New Vaccine Injury Table*, *supra* note 107 (accompanying scientific exposition).

54. Congress was sensitive to the problems that expansion could pose to the VICP, whether that expansion comes from a greater number of petitioners accepting Trust Fund awards or larger numbers of vaccines and injuries being covered. As a result, the VICP legislation actually ties vaccine and injury inclusion in the VICP to adequate reserves in the Trust Fund.¹²⁰ However, a change in VICP funding, a \$0.75 flat tax on all vaccines,¹²¹ may put the program in jeopardy.

55. Until this recent change, every dose of vaccine that is produced in this country and appears on the Vaccine Injury Table was subject to a risk-based excise tax.¹²² The amount of tax on every dose of vaccine a manufacturer produced was determined by using actuarial principles assessing the risk the vaccine posed for injury. The graduated tax scale made the VICP act like an experience rated insurance program: the more dangerous the vaccine, the higher the tax. Of course, manufacturers had the opportunity to pass on the cost of the tax to bulk buyers, such as state governments, hospitals and clinics. Nevertheless, manufacturers initially paid the tax, and the proceeds were put into the Vaccine Trust Fund, where they accumulated to pay for the VICP's administration and awards.¹²³

56. To understand how the risk-based tax worked, consider the DPT¹²⁴ vaccine "cocktail," which protects against three diseases: diphtheria, pertussis ("whooping cough"), and tetanus. This single vaccine generates almost 75% of all of the injuries that the VICP covers, and primarily from only the pertussis component.¹²⁵ A vaccine that only protects against diphtheria and tetanus had an \$0.06 excise tax per dose because those components are relatively safe.¹²⁶ Yet when the more dangerous pertussis bacteria was added to the vaccine, the excise tax

¹²⁰ See I.R.C. § 9510(c) (1994).

¹²¹ See Pub. L. No. 105-34 § 904, 111 Stat. 788, 873-74 (1997) (codified at I.R.C. § 4131(b)).

¹²² See *Excise Tax Financing of Federal Trust Funds*, available in 1993 WL 739690 (C.R.S.) (January 5, 1993) [hereinafter *Federal Trust Funds*] (explaining federal trust funds).

¹²³ See I.R.C. § 9510 (1994). After the change to a flat tax, the taxes are still placed into the Vaccine Trust Fund. See *id.*

¹²⁴ This is also called the DTP vaccine.

¹²⁵ See *VICP Statistics*, *supra* note 43.

¹²⁶ See I.R.C. § 4131(b) (1994) (amended by Pub. L. 105-34 § 904, 111 Stat. 788, 873-74 (1997)).

jumped to \$4.46 to pay for the injuries it would cause and to signify that the pertussis component of the vaccine is much more risky.¹²⁷

57. Other vaccines listed on the Vaccine Injury Table demonstrated this same pattern, with higher taxes identifying vaccines that pose higher risks. Under this insurance-like philosophy, the next highest vaccine tax was for oral (“live”) polio vaccines.¹²⁸ This relatively high tax on the oral polio vaccine existed because its injuries create the second largest group of claims in the VICP.¹²⁹

58. Congress originally appropriated money to pay for injuries that occurred before the Compensation Program started in 1988.¹³⁰ By doing this, the initial vaccine tax levels were lower, paying only for prospective injuries.¹³¹ Today, the VICP is financially independent of Congressional appropriations because the risk-based vaccine tax took into account the dangerousness of a vaccine, and accordingly determined a tax rate.¹³²

59. The Vaccine Trust Fund has a unique problem—it has more money than it currently needs.¹³³ The VICP web site reports that the increasing combination of vaccines makes differentiating risk difficult for specific vaccines, accounting for the misfit between the tax revenue and Compensation Program costs.¹³⁴ Yet that does not fully explain why there is a misfit between the tax and program costs. The VICP works under a presumption that the individual risks of a vaccine can be measured, predicted, and incorporated into a tax formula in order to gather adequate financial reserves to pay compensation. Accurate scientific proof of the individual injuries each protective agent in a vaccine causes is crucial to the way the excise tax incorporates risk. When vaccines combine different protective agents in the same medium, the tax formula simply adds their individually established risk-based taxes.

60. The assumptions, that the tax will adequately estimate the risk of injury and accurately finance the Trust Fund by aggregating the individual vaccine risks,

¹²⁷ See *id.*

¹²⁸ See *id.*

¹²⁹ See *VICP Statistics*, *supra* note 43.

¹³⁰ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-15j (1994).

¹³¹ See *Federal Trust Funds*, *supra* note 122, at *11.

¹³² See *id.*

¹³³ See *Current VICP Issues*, *supra* note 41.

¹³⁴ See *id.*

become less realistic as scientists begin to make more vaccines with higher numbers of components. This cumulative tax approach ignores the positive, negative, or unknown synergy of protecting against multiple diseases with one vaccine.¹³⁵ Consequently, new combinations of protective agents in a single medium makes it difficult to quantify how many people will eventually draw on the Trust Fund. This uncertainty is incompatible with the way the excise tax operates.¹³⁶ Without publicly examining the issue further, the Compensation Program administrators argue that the vaccine tax must eliminate the element of risk to eliminate the funding uncertainty.

61. The attack on the risk-based tax assumes that the risk component, and not the cumulative method of calculating, causes the over-funding problem. Under the current flat-tax system, which became effective last year, the tax will be a flat \$0.75 per component of a vaccine but will continue to aggregate based on the number of components.¹³⁷ A trivalent vaccine, whether it protects against diphtheria, pertussis, and tetanus, or measles, mumps, and rubella, would have a \$2.25 tax—three times the \$0.75 tax. Even if risk was what rendered the vaccine tax inaccurate, it does not eliminate the possibility that combining protective agents while only using simple addition to calculate the tax also constitutes part of the problem.

62. Without an explanation of why the winning \$0.75 proposal is more accurate at determining injuries, and therefore Compensation Program costs, than the alternate proposal of a \$0.84 tax, it is difficult to say how this will be any improvement over the current system. This really only proves that the previous risk model, which is up to ten years old for some of the vaccines, is not in touch with current vaccine injuries; this change to a flat tax does not prove that risk is an unmanageable or undesirable part of the tax.

63. Nor does the mere change to a flat tax necessarily solve the over funding situation. The flat tax forecloses serious considerations of alternative explanations of why the VICP revenue and participation are mismatched. Rather than simply jumping to a "solution" for over funding, Congress should consider other reasons why there might be over funding, and if that reason indicates an inherent and worsening flaw in the Compensation Program's overall design. If Congress understands why

¹³⁵ This simple tax mechanism does not even come close to confronting the issues of separating risk when multiple vaccines are administered at the same time, or whether administering multiple vaccinations is ethical if scientists cannot estimate their combined risks.

¹³⁶ See *Current VICP Issues*, *supra* note 41.

¹³⁷ The compromise also rejected the Senate's proposal of limiting the flat tax to a two-year experiment with an evaluation of its permanent feasibility based on a study by the Secretary of the Treasury. See I.R.C. § 4131(b)(2) (Supp. 1997).

the VICP has more money than it needs, it can make a better decision about the VICP's future format and what funding philosophy is best suited to maintaining the VICP's self-sufficiency.¹³⁸

64. The problem with adjusting the vaccine tax to eliminate the Trust Fund surplus with a flat tax of \$0.75 per vaccine dose¹³⁹ produced is that the flat tax is a one-time solution. Lowering the Trust Fund reserves without identifying why it is over funded does not solve the underlying problem. Moreover, by lowering the Trust Fund reserves the Compensation Program no longer has the option of handling an unexpected vaccine crisis.¹⁴⁰ Without any financial flexibility, Congress would end up inefficiently duplicating a process it already has available to meet the "predictable unpredictability" of disease epidemics.¹⁴¹

¹³⁸ There are numerous reasons why the Trust Fund might be overfunded. At the most simple level, the risk-based vaccine tax might be miscalculated, thereby "misdiagnosing" the need for compensation. Private insurance might be paying for injuries in lieu of public monies from the Trust Fund, which only pays for unreimbursable costs. Still, successful vaccination campaigns in socio-economically disadvantaged areas rely heavily on mass clinics where there may be inadequate screening for risk factors, and when injuries do occur, few attorneys are willing to take injury cases to the Compensation Program on a contingency fee basis. Each one of these explanations merits a different remedy, from changing the tax formula, to amending the Vaccine Act to cover different types of costs, to providing free legal assistance. Overfunding alone does not clearly suggest that the problem is related to a risk component in the tax.

¹³⁹ See *Current VICP Issues*, *supra* note 41 (flat tax level initially proposed in President Clinton's 1995 budget).

¹⁴⁰ See generally ARTHUR M. SILVERSTEIN, *PURE POLITICS AND IMPURE SCIENCE* (1981) (discussing the unexpected emergence of the "swine flu" in 1976, and the emergency legislative action Congress enacted to make the appropriate vaccine available).

¹⁴¹ The recent tension between the United States and Iraq involved using anthrax as a biological weapon. See Fouad Ajami, *Saddam and a Sack of Sugar*, U.S. NEWS & WORLD REP., Dec. 1, 1997, at 46. Anthrax is a vaccine preventable disease, and the Michigan Biologic Products Institute ("MBPI") is the sole American anthrax vaccine producer. See ADULT IMMUNIZATION, *supra* note 7, at Appendix VII. Currently, Department of Defense contracts account for \$20 million in annual sales by the MBPI, with virtually no private use (or liability) of the vaccine. See *Former Workers Question State Assessment of MBPI Value*, MICH. INFO. & RES. SERV., July 17, 1997, at 1-2. If the military and CDC decide that it is wise to vaccinate a wider number of Americans against anthrax, the State of Michigan would, understandably, be wary of liability. To allay Michigan's liability fears, and ensure that the vaccine would be available, the anthrax vaccine could be included in the VICP. Yet without a surplus, the Trust Fund might not be able to pay all of its meritorious claims for injuries from other vaccines in addition to anthrax injuries because the anthrax vaccine has never been taxed, nor is it included in any financial planning for the VICP.

A much more likely emergency scenario for a vaccine would revolve around a vaccine for the H5N1 "Hong Kong" or "Avian" influenza. See Brian Palmer, *A Bird-to-Human Flu*, U.S. NEWS & WORLD REP., Jan. 12, 1998, at 30;. Although influenza is normally treated as a routine illness, even in benign years it kills up to 20,000 Americans. See Laura Tanglely, *Detecting Secrets of a*

65. If VICP participation increases for any reason, a flat tax may quickly end the Compensation Program. A flat tax does not consider risk at all. By ignoring the relationship between the dangerousness of a vaccine and petitions filed in the Federal Claims Court, Congress makes the VICP vulnerable to one bad batch of vaccine bankrupting the entire no-fault program. Section 9510(d)(1) of the Internal Revenue Code, which governs the Vaccine Trust Fund, limits the liability of the federal government to the amount in the Trust Fund.¹⁴² As an independent program, the federal government provides no backup funding after claims exhaust the Trust Fund.

66. If this flat tax coincides with the Third Restatement, the combination might incidentally eliminate a secondary warning system about vaccine dangerousness.¹⁴³ In reality, few vaccine users probably know about the risk-based vaccine tax, or that a higher tax implies a higher level of danger. Insurance, free programs, and lack of understanding and concern insulate many consumers from this sort of economic warning. However, cost conscious health care professionals who must purchase vaccines may be extremely sensitive to this type of information. To those intermediaries accustomed to seeing a risk-based tax incorporated into a vaccine's price, a flat tax might falsely indicate that a particular vaccine has become safer, or that all vaccines are equally safe. The Third Restatement requires that the learned intermediary play a larger role in weeding out inappropriate vaccination candidates, yet a flat tax may remove an important and easily understood vaccine warning.

E. Complementary Initiatives—Internal and External Challenges

Potential Killer: Scientists Home In on Why Bird Flu May Spawn the Next Deadly Pandemic, U.S. NEWS & WORLD REP., Jan. 26, 1998, at 60. The possibility that this new flu strain may be as devastating as the 1918 worldwide Spanish influenza pandemic, which killed more than 20 million people, is particularly frightening for public health planners and virologists who see an inherent problem in finding a H5N1 vaccine culture medium. *See id.* at 61. Given the recent failure of several lots of Parke-Davis' Fluogen vaccine for a less virulent strain of influenza, the pressure is mounting on manufacturers to provide a safe and *effective* vaccine for this new killer disease. *See Flu Shot Advisory* (visited Oct. 5, 1997) <<http://www.alaw.org/pr.121896.html>> (warning about the Parke-Davis recall). Immunity from tort liability through the VICP would help encourage manufacturer efforts to address the potential epidemic, but it would also expose the VICP to a significant financial drain if even a small percentage of injuries result.

¹⁴² *See* I.R.C. § 9510(d)(1) (1994).

¹⁴³ The primary warning about which courts are concerned comes directly from vaccine manufacturers in written disclosures of costs and benefits of specific vaccines. *See, e.g.,* Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1293 (5th Cir. 1974) (case brought for injuries infant sustained from Sabin oral polio vaccine, negligent warning claimed because only nurse saw vaccine package insert listing the vaccine's risks).

67. Other initiatives related to vaccines may interact with the Third Restatement or offset its effects on the vaccine market. Although universal health care is an unpopular subject, adopting more comprehensive health care coverage would significantly lessen the amounts awarded under the VICP.¹⁴⁴ As section 300aa-15(g) says, the VICP will not provide compensation for any item or service which could be paid for "under any State compensation program, under an insurance policy, or under any Federal or State health benefits program . . . or an entity which provides health services on a prepaid basis."¹⁴⁵ If Congress or state legislatures are inclined to subsidize health care costs, childhood vaccines will almost certainly be included. Not only are vaccines relatively low cost,¹⁴⁶ their opponents are less credible.¹⁴⁷

68. In addition, the new national vaccination tracking system may help epidemiologists refine risk assessments by making it easier to determine actual injuries and the rate of lawsuits those injuries spawn.¹⁴⁸ As a result of more descriptive and accurate data, Congress may be in a better position to assess other aspects of the VICP, such as the link between the Trust Fund surplus and the risk-based tax.

¹⁴⁴ See *Hill v. American Cyanamid Co.*, No. 03A01-9108-CV-267, 1992 WL 9466 at * 2 (Tenn. Ct. App. Jan. 24, 1992) (holding that state Medicaid reimbursement of illness costs were not unreimbursable expenses under the VICP and that a special master's finding of insufficient jurisdictional amount should be considered a final judgment, allowing the pursuit of state remedy).

¹⁴⁵ National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-15(g) (1994).

¹⁴⁶ See *VaCCINe: The Virginia Computerized Children's Immunization Network* (visited Oct. 5, 1997) <<http://vmednet.gen.va.us/clinical/vaccine.html>>.

¹⁴⁷ Opponents to mainstream medicine, whether they resist mandatory vaccination or fluoridation of community water sources, tend to be labeled as illegitimate and unreliable. See *Exner v. American Medical Association*, 529 P.2d 863, 866-7 (Wash. Ct. App. 1974) (affirming dismissal of water fluoridation opponent's defamation lawsuit claiming that American Medical Association had personally attacked him in an article attempting to portray the activists in his cause as "charlatans" or "quacks"); *Yiamouyiannis v. Consumers Union, Inc.*, 619 F.2d 932, 942 (2d Cir. 1980) (affirming dismissal of water fluoridation opponent's defamation lawsuit).

¹⁴⁸ See *VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)* (visited Oct. 5, 1997) <<http://www.fda.gov/cber/vaerstxt.html#info>>; see also SUSAN S. ELLENBERG & ROBERT T. CHEN, THE COMPLICATED TASK OF MONITORING VACCINE SAFETY, PUB. HEALTH REP. 10, 11 (Jan. 11, 1997) ("Vaccines, like all other pharmaceutical products, are not entirely risk-free; while most known side effects are minor and self-limited, some vaccines have been associated with very rare but serious adverse effects. Because such rare effects are often not evident until vaccines come into widespread use, the Federal government maintains ongoing surveillance programs to monitor vaccine safety. The interpretation of data from such programs is complex and is associated with substantial uncertainty. A continual effort to monitor these data effectively and to develop more precise ways of assessing risks of vaccines is necessary to ensure public confidence in immunization programs.").

69. Alternatively, the vaccine reporting system can track more than mere adverse events. Already, some states or counties have achieved appreciable results by using a tracking system to send reminders to parents to make sure their children receive a full vaccination schedule.¹⁴⁹ However, these local tracking systems are imperfect. Moving from an area, even within the same state, puts individuals outside of the reach of the reminder program. A national system can increase the likelihood that all children will receive their vaccinations. Of course, more vaccinations will result in a higher number of actual injuries, necessitating VICP coverage and making it especially important for Congress to ensure that the VICP is ready to handle the claims.

F. Assessment of Challenges and Recommendation

70. Congress has legitimate reasons to investigate the VICP. Following further study of these issues, Congress should adopt a clear plan of action to ensure the VICP's future, vaccine availability and safety, and manufacturer accountability based on what W. Kip Viscusi calls a strategy of principled products liability reform.¹⁵⁰ This plan of action can range from full preemption of non-VICP remedies to a simple amendment of the Vaccine Act's language. It might also include a new financing mechanism for the Trust Fund. Nevertheless, the changes must be purposeful, with "efficient incentives for controlling risks and efficient levels of insurance for the injured."¹⁵¹

III. CONGRESS SHOULD MAKE SPECIFIC CHANGES TO THE COMPENSATION PROGRAM BY AMENDING THE VACCINE ACT

71. Whatever changes take place in the Compensation Program, whether or not tied to the Third Restatement, must take into consideration the VICP's initial concerns for moderation. This concern for balance must translate into both form and

¹⁴⁹ See Jon S. Abramson, et al., *Development of a Vaccine Tracking System to Improve the Rate of Age-Appropriate Primary Immunization in Children of Lower Socioeconomic Status*, 126 J. PEDIATRICS 583, 585-86 (1995) (study conducted in Forsyth County, North Carolina, determined that tracking children from birth, combined with discussion of the importance of vaccination, telephone and mail reminders, resulted in a statistically significant increase in age-appropriate vaccination); Raja Mishra, *Immunization Score Rises*, DET. FREE PRESS, July 24, 1997, at B1 (state health officials attribute a new Michigan immunization database with partial credit for the 15% improvement in state immunization rates).

¹⁵⁰ See W. KIP VISCUSI, *REFORMING PRODUCTS LIABILITY* 209-215 (1991).

¹⁵¹ *Id.* at 211 (using the word "insurance" broadly, meaning compensation for injuries as well as a level of confidence for individuals' future if they are injured).

function, providing a simple process accessible to the widest variety of petitioners with varying degrees of resources, while fostering the underlying philosophy that encourages safety and compensation.

A. Full Preemption of State Law

72. A new era for the VICP should start with less confusion than when the program began. One of the largest sources of confusion relates to whether the Compensation Program preempts state law. To resolve this problem, Congress should amend § 300aa-21 of the National Childhood Vaccine Injury Act to eliminate the petitioner's right to elect to reject the VICP award. Allowing the coexistence of federal and state regulation is fundamentally inconsistent in an area, such as vaccine liability, where Congress intends to use a heavy hand in shaping the complex legal balance between society, manufacturers and consumers. By eliminating the election option and fully preempting state law Congress will not only avoid confusion, it will have the control over vaccine liability necessary to institute more comprehensive reforms.

73. Full preemption of state law will also allow Congress to acknowledge the Third Restatement without fully adopting its standards. Whether or not supporting preemption in the abstract, the Third Restatement already anticipates increasing federal preemption of state law for medical product-related liability. In comment b to section 6, the Reporters state clearly that in the case of federal preemption, the Third Restatement's standards for liability cannot apply.¹⁵² Though clearly federal supremacy would achieve this result without acknowledgment from the Reporters, the Third Restatement's discussion of preemption attempts to advertise it as a viable option.

74. Though not the best option, if Congress felt compelled to leave a state remedy in place, it should consider only allowing civil suits for defective manufacturing cases. Injuries from an imperfectly manufactured vaccine have received the most consistent legal treatment in this century. Allowing fault-based (negligence) lawsuits for defective manufacturing would minimize interjurisdictional inconsistencies for manufacturers in comparison to the inevitably varying standards for defective design and improper warning cases. Still, full preemption would provide the most organizational and procedural benefits, completely streamlining compensation for vaccine injuries.

75. If the Third Restatement makes state law less sympathetic to injured users, forcing more and more petitioners to elect to receive a VICP award, eliminating the state remedy would free the creative legal energy dealing with product liability complications to deal with the pressures on a larger VICP. Instead

¹⁵² See THIRD RESTATEMENT, *supra* note 22, § 6 cmt. b.

of marshaling political support for separate controls on state liability for manufacturers, Congress could work on substantive changes in the no-fault portion of the program.

B. Raise VICP Compensation Levels

76. Manufacturers of all products would like to see an end to liability, however, this sort of protection comes at consumers' expense. Consequently, a program that works to share equitably the costs and risks of injury must consider the consumer perspective. Though arguably fair now, the Compensation Program should increase its award levels. Of course, award levels should not exceed the actual money the program takes in through the vaccine tax. Running a deficit would jeopardize the VICP's independence and threaten Congress' current favor. Rather than retaining the financial surplus, the VICP could use the excess funds constructively.¹⁵³

77. One option is for the Compensation Program to increase awards. The first award increase should go to petitioners who allege a vaccine-related death. This initial increase has nothing to do with the permanence of losing a family member, because there is no valid way to measure and compare that grief with the pain families feel from living with a permanently injured child. The rationale behind this increase is equity; the Compensation Program already allows a variable award for injuries not resulting in death. These injury awards can increase or decrease on a case-by-case basis to justly compensate an individual and pay for comprehensive care. In contrast, the death award in the VICP has not changed in the past ten years. Instead of a flat \$250,000 award, the VICP could allow a petitioner's estate to seek additional compensation for costs related to the vaccine injury and illness that led up to death, as well as the costs for preparing the petition to the VICP. Alternatively, Congress could simply raise the lump sum award.

78. Dedicating the surplus bounty toward expanding the VICP's administrative capacity or leaving it for a "rainy day" would be a more conservative approach. This could translate into a focus on quickly adjudicating the remaining backlogged cases by hiring an additional Special Master or sponsoring a study to assess the Compensation Program's current processes. Re-investing the surplus in the VICP will help meet unpredicted needs by making the no-fault program more resilient, which will become increasingly important in light of the upcoming changes to the VICP's financing mechanism. Arguably, the no-fault process can be considered as part of compensation under the VICP because it provides value to petitioners as an alternative to the awkward and slow moving civil courts. So, though petitioners would not necessarily receive higher awards from the

¹⁵³ See *Current VICP Issues*, *supra* note 41.

Compensation Program under this more conservative approach, the process for awarding compensation would be strengthened and raised to a higher level.

79. Congress will have a separate concern for injury compensation if it fully preempts the election option for petitioners. The national legislature must ensure that petitioners will receive adequate compensation under whatever changes are implemented. One of the incentives for granting adequate compensation under the current system is the election option. Special Masters and others involved in the Compensation Program understand that a primary concern is to keep petitioners from ultimately going to the civil courts, which is why VICP awards must be competitive with state and federal court awards. Without an election option, the Compensation Program administrators have no competition from outside sources, and therefore they might let compensation levels drop. "They ought to be grateful for what they get" attitudes that can accompany entitlement programs such as the VICP might combine with the diminished incentive to make generous payments, all to consumers' detriment.

80. Determining how the legislation itself could mandate an increase in compensation to living petitioners is difficult because their awards are variable and independently determined. One option would be to add a flat monetary bonus to every successful petition in addition to the costs and future needs already incorporated in the award. Without knowing the exact scope of the current surplus, it is unlikely that the Compensation Program would be able to sustain this sort of award without a purposeful increase in the funding. Regardless, raising compensation levels deserves further consideration.

C. Flat Tax and Risk-Based Rebate

81. Compensation Program administrators cite difficulty in estimating the *future* risk of vaccines as one reason why a flat tax is preferable to the current risk-based tax. Given the potential for new vaccines and new vaccine combinations without well-defined risks, there are strong reasons to support a flat tax. However, the risk-based tax has worked well for the VICP. To lessen the problem of accurately determining and generating Compensation Program financing based on projected data without eliminating risk, Congress could impose a flat tax on every dose of vaccine produced and couple it with a risk-based rebate. By incorporating risk into the rebate, the VICP can use retrospective "hard" data based on actual injuries attributable to specific manufacturers.¹⁵⁴ By imposing a risk criteria at the end of petition adjudication, rather than at the time of the initial excise tax levy,

¹⁵⁴ For author's example of how to plan for a flat tax and risk-based rebate see Appendix C, *infra*.

Congress can maintain the VICP's sensitivity to real vaccine safety issues while still improving Compensation Program administration.

82. The combination flat tax and risk-based rebate would help Congress maintain and even increase an incentive for manufacturers to improve vaccine safety. If, as proposed, Congress eliminates the post-election civil action option for VICP petitioners, the threat of product liability will no longer naturally urge this scientific and technological innovation.¹⁵⁵ Competition will not naturally provide the impetus for vaccine improvements as it encourages improvements in other products. With the tax-rebate combination, Congress can encourage manufacturers to lower wholesale vaccine costs and actually contribute a greater amount of money to the Compensation Program without shifting cost to buyers. Furthermore, unlike a flat tax acting alone, a flat tax combined with a risk-based rebate will still provide an indirect warning about a vaccine's safety.

83. With a flat tax/risk-based rebate program, Congress would tax manufacturers based on every dose of vaccine they produce. Regardless of the type of vaccine produced, manufacturers would pay the same flat fee. If a pharmaceutical company produces one million diphtheria vaccine doses, two million chicken pox vaccine doses, and three million polio vaccine doses, it would pay a tax equal to six million times a set fee (probably less than \$0.80).¹⁵⁶ The money paid in taxes would be deposited into the Vaccine Trust Fund, and used primarily for paying VICP administration costs and no-fault awards to injured consumers.

84. After the VICP compensates injured consumers, a manufacturer would receive a percentage of the tax it paid in the form of a rebate. Since the flat tax will be actuarially set above the minimum revenue needed to run the program, part of the surplus funding would be returned to manufacturers based on how much the VICP paid to petitioners for injuries from that particular manufacturer's vaccine. The money remaining in the Trust fund after the VICP pays the rebates would be used to expand the VICP's coverage.

85. The Advisory Committee that oversees the VICP should commission an actuarial study of what the optimal flat tax would be if the goal was to create a sufficient surplus to expand Compensation Program coverage without a waiting period, and what sort of formula the Compensation Program should use to establish the rebate. Establishing a flat tax is relatively easy. The Advisory Committee can

¹⁵⁵ See Margaret I. Lyle, Note, *Mass Tort Claims and the Corporate Tortfeasor: Bankruptcy Reorganization and Legislative Compensation Versus the Common-Law Tort System*, 61 TEX. L. REV. 1297, 1352-55 (1983) (discussing how government assumption of compensation costs in overwhelming liability cases defeats market incentives for safety).

¹⁵⁶ The first proposal for a flat tax to reduce the Trust Fund Surplus was suggested at \$0.51 per dose. See *Current VICP Issues*, *supra* note 41. The current flat tax rate is \$0.75. See I.R.C. § 4131(b) (Supp. 1997).

pick the target revenue goal and project the number of doses that will be manufactured in a given year. Though actual numbers of injuries and doses of vaccines produced may vary in one year, they should be close to the projections, which can be based on historical data and routine public health estimation of need.¹⁵⁷

86. Congress and the National Vaccine Advisory Committee can use this flat tax to keep the vaccine market stable. With a risk-based tax, such as the one that the Compensation Program previously used, manufacturers have less of an incentive to produce riskier vaccines, such as the pertussis vaccine, because they pay higher taxes. By relating the actual amount paid in taxes only to the number of doses a manufacturer produces, pharmaceutical companies would contribute to the Vaccine Trust Fund in proportion to the magnitude of their individual business, whether they produce one type of vaccine or many types of vaccines. This may help reverse the vaccine industry's monopolistic trend by eliminating any positive or negative incentives for producing one or more vaccines. With a flat tax all manufacturers, not just the richest ones, will be able to afford to pay the tax and still make a profit.

87. The tax revenue surplus in excess of the Compensation Program costs would then be available for rebates. The Advisory Committee can establish a merit-based system for the rebate. With a merit-based system, the Advisory Committee does not have to treat manufacturers equally, even when they produce a vaccine for the same disease. This means that if one form of the polio vaccine is safer than another, the manufacturer with the safest vaccine will get the most money back, if the Advisory Committee equates merit with safety. Under a safety formula, the maximum rebate will go to the manufacturers of vaccines with the fewest injuries, and the lowest rebate to manufacturers of vaccines with the most injuries. Merit might also be related to other factors, such as lower wholesale prices or profit-making, which might make vaccines more affordable to the poor. The Advisory Committee might consider money invested in vaccine safety research and development as meritorious. Alternatively, the rebate can reward a manufacturer who responds to a crisis with a full refund of the tax. Because the VICP currently has a surplus, this formula can be tested with actual, rather than projected, data.

88. By making the rebate optional the risk element would encourage manufacturers to improve vaccine safety without further penalizing them, as liability would, when improvement is impossible. The rebate could spawn more than just research and development on vaccines to lower injuries and increase

¹⁵⁷ In implementing the flat tax Congress could include an incentive for manufacturers to lower vaccine costs by tying the tax to the wholesale per-dose cost of the vaccine. Typically, lowering price might raise concerns about lowering vaccine safety, however, the risk-based rebate described in the next section could overcome those concerns. The strongest argument against tying external factors to the tax is that doing so alters the flat nature of the tax even if the variables are unrelated to the risk of injury.

rebate amounts. Manufacturers might subsidize public screenings to better identify who should not take a vaccine. Manufacturers could produce multi-language translations of warnings for non-English vaccine users, reducing some of the burden for producing warnings that the CDC currently shoulders. Manufacturers might pay for state-based continuing medical education to update learned intermediaries on vaccine risks and benefits.

D. Expand the Vaccine Injury Table and the Aids to Interpretation

89. One of the benefits of the original VICP legislation is that it allows notice-and-comment rulemaking by the Secretary of Health and Human Services to amend the Vaccine Injury Table as well as the Aids to Interpretation. This allows both to reflect accurately scientific knowledge about injuries and present-day vaccine recommendations for children (and some adults) without an additional act of Congress. If the Third Restatement does influence the adjudication of vaccine injury disputes in the civil courts, as measured by increasing number of petitioners accepting VICP awards because state remedies are unlikely, then consider the Third Restatement's effect on claims for vaccines and injuries that the VICP excludes. Individuals injured by a VICP-excluded vaccine, or consumers whose type of injury are not covered by Compensation Program, may literally lack a forum to adjudicate their claims and award compensation in meritorious cases.

90. Vaccines that prevent non-childhood diseases may be used less frequently than the vaccines historically included in the VICP, but they are no less beneficial to society. The Secretary of Health and Human Services should use the VICP's notice-and-comment rulemaking authority to expand the Vaccine Injury Table and the Aids to Interpretation to include these other vaccines, and fully describe the symptoms that demonstrate a causal connection between the vaccine and an injury. With the tax and Trust Fund already in place, and with a current surplus, the Secretary has very few structural barriers to expanding the program. This is not to suggest that the Secretary is immune to political considerations, but with manufacturers placated by preemption of state remedies for childhood vaccines, their Congressional supporters should be amenable to a similar liability scheme for other vaccines.

91. Expanding the Compensation Program will also reduce legal confusion about which forums are appropriate for which injuries. What happens when an injured petitioner to the VICP received two or more vaccines at the same time, one covered and one excluded by the VICP? VICP case law suggests that an arbiter in the Compensation Program does not have to force an injured petitioner to decide which vaccine caused the injury when the symptoms they exhibit are related to more

than one Compensation Program *covered* vaccine.¹⁵⁸ However, separating symptoms on the Vaccine Injury Table and the Aids to Interpretation from similar symptoms for excluded vaccines may be impossible. A single, unified vaccine injury forum would greatly reduce the potential for confusion, as well as create a cadre of very experienced adjudicators.

E. Add Consumer Protection Language

92. In addition to expanding the Vaccine Injury Table and the Aids to Interpretation to create a wider, more encompassing Compensation Program, Congress should update and create additional legislative history through hearings, the Congressional Record, public debate, and a purposes clause at the beginning of the Vaccine Act. Hopefully, this legislative history will reflect a sincere desire to benefit injured consumers as an important part of encouraging vaccine use. Currently, the Secretary has a mandate from the Compensation Program to seek out and encourage safer vaccines.¹⁵⁹ This is not equivalent to saying that an explicit purpose behind the Vaccine Act is to provide consumers legal protection from vaccine injuries.

93. Though sometimes superficial, especially in the face of contrary provisions explicitly benefiting manufacturers, consumer protection language has a strong role to play in vaccine injury compensation. An explicit intent to protect consumers helps the Federal Claims Court and Special Masters who administer the no-fault process, as well as the federal courts involved in the appeals process, to construe the statute effectively and accurately.¹⁶⁰ In turn, this consumer protection language helps these judicial actors enforce a balance between social, manufacturing, and consumer interests. Moreover, obvious Congressional intent sends a message to everyone involved in the manufacturing process that individuals should not be forced to bear the entire risk when manufacturers and the rest of society literally benefit at their expense.

F. Warn all Relevant Parties

¹⁵⁸ See *DiLeo v. Secretary Dep't Health & Human Servs.*, 23 Cl. Ct. 796, 799-800 (1991).

¹⁵⁹ See *National Childhood Vaccine Injury Act*, 42 U.S.C. § 300aa-27 (1994).

¹⁶⁰ See *Rodriguez v. Secretary Dep't Health & Human Servs.*, 34 Fed. Cl. 57, 60 (1995) (affirming Special Master's decision to dismiss claim against VICP, and pointedly attacking petitioner's failure to cite supportive legislative history); see also *Staples v. Secretary Dep't Health & Human Servs.*, 30 Fed. Cl. 348, 356-59 (1994) (affirming decision to dismiss VICP claim based on construction of legislative history as evidence of Congress' intent to exclude claims for vaccine preventable diseases contracted from community exposure).

94. Congress should amend the Vaccine Act to require manufacturers to provide warnings to both consumers and to health care providers.¹⁶¹ There is no legitimate reason to minimize a manufacturer's duty to warn of a vaccine's inherent dangers if there will be no liability for such a failure to warn. The Third Restatement is only awkward and inefficient at requiring the warning go to the person most likely to put the information to good use. In reality, there are many times when a consumer and learned intermediary need to work together to form an opinion as to whether taking a vaccine is a good idea. This cooperation is impossible without the correct warnings. Despite other concerns, safety must be a central interest for Congress.

95. Contrary to the inevitable argument that these multiple warnings will require too much time and money from manufacturers, this is the smallest contribution that the manufacturers can make to vaccine safety in return for a ban on individual defective warning liability. Legislators should look to the successful experiment with warnings and oral contraceptives as a vision of the multilevel warnings that should accompany vaccines. Pharmaceutical manufacturers currently include written warnings with all oral contraceptive packages without diminishing the information that goes to health care professionals.¹⁶² There is no reason to assume that manufacturers could not do the same for vaccines.

96. To accomplish the most widespread and effective warnings, Congress would only have to mandate direct consumer warnings. Regardless of a legal mandate, manufacturers would already be inclined to warn health care professionals about the risks and benefits of a vaccine as part of their marketing strategies. Furthermore, because the Third Restatement and the VICP do not eliminate malpractice liability for health care providers, those duty-bound learned intermediaries would likely seek out this information without prompting. In contrast, consumers are in an untenable position. Not only are consumers required by law to take vaccines, but they lack the political power to force manufacturers to deal with them directly and often do not have enough knowledge to question independently the risks and benefits of a vaccine.

97. These consumers with the least access to information are literally the most at risk from vaccines. Therefore, it is important for this legislative amendment to require that manufacturers design warnings to educate the intended audience reasonably and effectively. This means that a manufacturer would not satisfy its duty to warn by providing a learned intermediary with a simplified, non-technical warning. Nor would a manufacturer satisfy its duty to warn a consumer with a complex and virtually "plain-language-free" warning designed for scientists.

¹⁶¹ See National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-22(c) (1994) (absolving manufacturers of liability for failing to warn consumers directly).

¹⁶² See SECOND RESTATEMENT, *supra* note 16, § 6 cmt. e.

98. If there is no liability for failing to warn, Congress needs to consider how it will enforce this warning provision. Regulatory oversight might be insufficient by itself, therefore, Congress may want to consider adjusting the VICP petition process to aid enforcement. Congress could require a petitioner to submit information related to the vaccine warning associated with his or her claim. This would help the Department of Health and Human Services gather data on the manufacturers, and if necessary, commence internal administrative proceedings to investigate and penalize a manufacturer for noncompliance.

99. If, at the end of an investigatory process addressing a manufacturer's noncompliance, an administrative law judge held that a manufacturer failed to provide reasonable and adequate warnings, a number of relevant penalties would be available. First, such a penalty could suspend a manufacturer's right to receive a tax rebate. The penalty could be an additional fine, or require the manufacturer to submit to more frequent and stricter scrutiny of the warnings by the FDA. In outrageous cases of fraud and abuse, the manufacturer's vaccine could be excluded entirely from the VICP, reimposing civil liability under the standards currently specified in the VICP legislation allowing punitive damages. The reporting measures in conjunction with these possible licensing and administrative penalties against a manufacturer should ensure compliance with comprehensive warning legislation in the absence of civil liability.

IV. CONCLUSION

100. Richard Neely colorfully suggested that "[o]nly people who believe in Tinker Bell [can] have any firm expectation that Congress will do anything" to improve product liability.¹⁶³ As for Senate Bill 2760, one of the VICP's precursor bills, he found it "complicated but largely useless" as well as full of "weasel language."¹⁶⁴ Judge Neely also predicted that the House would eventually "gut" the clear and convincing standard to be applied to jury decisions in design cases—a standard he grudgingly valued.¹⁶⁵

101. Surprise Judge Neely, fairies are real! Not only did Congress manage to retain the clear and convincing standard,¹⁶⁶ they also managed to implement a workable program that alleviated the vaccine market stress. This demonstrates that, despite criticism and doubt, Congress is capable of identifying significant problems and implementing effective change. Moreover, Congress is an appropriate

¹⁶³ See NEELY, *supra* note 59, at 80.

¹⁶⁴ See *id.* at 161.

¹⁶⁵ See *id.*

¹⁶⁶ See National Childhood Vaccine Injury Act, § 300aa-22(b)(2)(B) (1994).

agent for change for the national vaccine market because it is swifter and more unifying than individual state legislatures or judicial districts. Consequently, as problems arise inside and outside of the VICP, Congress should not be afraid to seriously contemplate these challenges and to search out new solutions. Whether Congress decides to implement one or none of the changes this Note proposes, it must maintain its primary concern for public health and a balanced vaccine liability scheme.

102. **Appendix A:** Comparing Vaccine Liability in Civil Courts

An Injury that Results from:	Second Restatement Standards	VICP Standards	Third Restatement Standards	Potential VICP Standards Under the Third Restatement
Defectively Manufactured Vaccine with Avoidable Injury	Type: Strict Liability Test: Did the manufacturer make this vaccine erroneously? (Yes = liability)	Type: Strict Liability Test: Did the manufacturer make this vaccine erroneously? (Yes = liability)	Type: Strict Liability Test: Did the manufacturer make this vaccine erroneously? (Yes = liability)	Type: Strict Liability Test: Did the manufacturer make this vaccine erroneously? (Yes = liability)
Defectively Designed Vaccine with Unavoidable Injury (Adverse Side-effect)	Type: Negligence Test: Would a reasonable person find the risks posed by this vaccine design unreasonable by a preponderance of the evidence? (Yes = liability)	Type: Limited Negligence Test: Would a reasonable person find the risks posed by this vaccine design unreasonable by clear and convincing evidence? (Yes = liability)	Type: New Learned Intermediary Test: Would a doctor prescribe this vaccine to any class of patients? (No = liability)	Type: New Learned Intermediary Test: Would a doctor prescribe this vaccine to any class of patients? Did any other reasonable design exist? (No = liability)
Inadequate Warning or Instruction as to Learned Intermediary	Type: Negligence Test: Was a doctor warned when in a position to evaluate and give	Type: Learned Intermediary Test: Were reasonable warnings given to a prescribing	Type: Learned Intermediary Test: Were reasonable warnings given to a	Type: Learned Intermediary Test: Did the printed warning to the health care provider

	adequate warnings to the user? (No = Liability)	health care provider? (No = liability)	health care provider? (No = liability)	conform with statutory requirements? (No = liability)
Inadequate Warning or Instructions to Consumer	Type: Negligence Test: Were reasonable warnings given to the consumer when no health care provider was in an evaluative position? (No = liability)	Type: Prohibited except fraud/abuse Test: Did the manufacturer purposefully conceal the dangerousness of the vaccine? (Yes = liability)	Type: Negligence Test: Were reasonable warnings given to the consumer when no health care provider was in an evaluative position? (No = liability)	Type: Prohibited except fraud/abuse Test: Did the manufacturer purposefully conceal the dangerousness of the vaccine? (Yes = liability)

103. **Appendix B: Process for Creating the Flat Tax and Risk-based Rebate Using Hypothetical Data**

Step 1: Estimate program costs.

Determine the total number of dollars necessary to run an expanded VICP with a 20% surplus for one year.

<\$40,000,000 in program expenses, \$10,000,000 surplus>

Step 2: How many doses of vaccine will the VICP have to cover during the program year?

Use epidemiological and industry data to predict the number of doses of vaccines manufacturers will produce that year.

<200,000,000 doses of four different vaccines produced by two different manufacturers>

Step 3: Determine the flat tax.

Divide the total from **Step 1** by the number of doses of vaccine in **Step 2** to determine a flat tax.

<\$(50,000,000/200,000,000 doses) = \$0.25 tax per dose of vaccine>

To determine how much each manufacturer will pay in total taxes multiply the tax by the number of doses of vaccine they make.

<(\$0.25)(50,000,000 doses)(2 vaccines) = \$25,000,000 tax to the Trust Fund>

Step 4: What is the maximum amount of money the VICP could return to manufacturers in the form of a rebate?

This sum can be calculated two ways. First, the Advisory Committee could decide on additional program objectives it would pay for out of the surplus, establishing a single amount. Though individual rebate amounts would vary, total manufacturer rebates could not exceed the remaining surplus. Using a rebate formula, *illustrated infra*,

manufacturers would actually have their rebates scaled to a \$5,000,000 surplus.

<NVAC wants to use \$5,000,000 for other program goals>

<\$5,000,000 in vaccine tax could be returned as a rebate>

<after calculating the rebate based on total surplus the rebate is adjusted proportionally so that they do not exceed \$5,000,000>

Or, the surplus can remain an aggregate \$10,00,000 and could be distributed using a rebate formula that will leave a surplus, as illustrated *infra*.

Step 5: What factors should determine the amount of a manufacturer's rebate?

In this instance Advisory Committee chooses two merit-related factors to determine the amount of rebate each manufacturer receives:

- a) the number of injuries the VICP must pay per 1,000,000 doses of vaccine that specific manufacturer produces, and
- b) the amount of profit the manufacturer makes on those 1,000,000 doses of vaccine.

The fewer the injuries and the lower the profit, the larger the rebate a manufacturer receives. In addition, the Advisory Committee can choose a constant, or a guaranteed rebate. Therefore if the rebate formula returns a negative figure the manufacturer receives only the predetermined rebate amount, and does not owe the VICP any money.

Step 6: What specific elements should an algebraic formula contain to reflect the preferred distribution of rebates to manufacturers?

In **Step 5** the Advisory Committee decided on the philosophical components of a formula, however, the formula must incorporate additional elements to make sure the rebates do not exceed the surplus, and that the formula takes into consideration the risk of each vaccine. Together these relevant elements are:

- the number of doses of vaccine a manufacturer produces
- the amount of profit the manufacturer makes on those vaccine doses

- the number of injuries that vaccine causes
- the tax a manufacturer pays on one vaccine
- the total number of vaccines a manufacturer produces
- the number of manufacturers making vaccines covered by the VICP
- VICP surplus
- the guaranteed 1% rebate amount
- the total number of rebates the VICP will have to pay
- the total number of injuries the VICP pays for the vaccines taxed in that year

Step 7: What does a rebate formula look like?

$$\text{Rebate for one vaccine} = \left\{ \frac{[S - (G)(V)]}{V} - [E + .01(P)] \right\} + G$$

S = surplus = total tax revenue - program costs

G = guaranteed return of 1% of the tax

V = # of vaccines involved, the same vaccine produced by different manufacturers count as separate vaccines, **not** the # of doses

E = VICP expenses for injuries from that vaccine = VICP costs divided by the total number of injuries, and then multiplied by the number of injuries for that single vaccine

P = manufacturer profit on a vaccine in dollars

Rebate for a manufacturer = rebates for each vaccine produced

Step 8: What would rebates using this formula look like?

The following table pulls together the hypothetical data described in this problem and shows four possible rebates.

	Vaccine A	Vaccine B	Vaccine C	Vaccine D
Produced by:	Manufacturer 1	Manufacturer 2	Manufacturer 1	Manufacturer 2
# of doses produced:	50M	50M	50M	50M
# of injuries per 50M ¹ doses	0	1000	2000	50000
VICP expenses for injuries this vaccine caused (E) = VICP costs (# injuries) injuries	$\frac{\$40M}{53,000} (0) = 0$	$\frac{\$40M}{53,000} (1,000) = \$754,717$	$\frac{\$40M}{53,000} (2,000) = \$1,509,434$	$\frac{\$40M}{53,000} (50,000) = \$37,735,849$
Tax manufacturer paid on vaccine (T):	$(\$0.25)(50M) = \$12.5 M$	$(\$0.25)(50M) = \$12.5 M$	$(\$0.25)(50M) = \$12.5 M$	$(\$0.25)(50M) = \$12.5 M$
Guaranteed rebate (G) = .01(T):	\$125,000	\$125,000	\$125,000	\$125,000
Profit (P):	\$1M	\$2M	\$3M	\$4M
Rebate amount:	\$2,490,000	\$1,725,283	\$960,566	\$125,000

Manufacturer 1 rebate: \$3,450,566

Manufacturer 2 rebate: \$1,850,283

Total rebates to manufacturers: \$5,300,849

Surplus left for the Advisory Committee to use in the VICP: \$4,699,151

¹ M is an abbreviation for million.