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# National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?

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Last year, Congress enacted legislation creating an innovative method of resolving claims for childhood vaccine injuries.<sup>1</sup> It establishes a mandatory no-fault compensation system for persons injured through childhood vaccines. After the no-fault proceedings, the claimant has the option of accepting the compensation awarded, if the injury were found to be vaccine-related, or bringing a civil action against the vaccine manufacturer in which several limitations on the manufacturer's tort liability would apply. The legislation responded to two concerns: (1) liability for these injuries was causing United States manufacturers to stop producing vaccines, and (2) children injured by vaccines were often without a source of payment or compensation for their medical and rehabilitative needs, leading to greater resort to the tort system for some form of financial relief.<sup>2</sup>

Expanding tort liability and the tort system's impediment to product development have been concerns raised by manufacturers in other industries who are seeking reform in the product liability area through state and federal legislation. Efforts to enact a federal product liability bill have been ongoing since the late 1970s with legislation first introduced in the House of Representatives in 1980 by Rep. Richardson Preyer<sup>3</sup> and in the Senate in 1982 by Senator Robert W. Kasten.<sup>4</sup> The severity of the product liability problem may vary from industry to industry, but a common factor is the unpredictability of product liability rules which continually have been expanding in favor of the plaintiff.<sup>5</sup> Proponents of product liability reform argue that some of these expansions of liability have been unfair, and that the unpredictable nature of variable product liability rules makes it difficult to make reasonable actuarial assessments of future liability risks.<sup>6</sup>

The approach Congress took in the National Childhood Vaccine Injury Act of 1986—which on the one hand sets up a no-fault compensation system and on the

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1. S. 1744, 99th Cong., 2d Sess. Title XXI, 132 CONG. REC. H11,597-606 (1986).

2. See H.R. REP. NO. 908, 99th Cong., 2d Sess., pt. 1, at 4-5, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6344-46 [Hereinafter HOUSE REPORT].

3. See H.R. 7921, 96th Cong., 2d Sess. (1980).

4. See S. 2631, 97th Cong., 2d Sess. (1982).

5. See S. Rep. No. 442, 99th Cong., 2d Sess. at 5-8 (1986).

6. *Hearings before the Subcommittee on Commerce, Consumer Protection, and Competitiveness of the House Energy and Commerce Committee*, 100th Cong., 1st Sess. (1987) (Statement of V. Schwartz).

other hand modifies the tort law rules for injured persons who choose not to accept compensation through that system—could be viewed as either a panacea for the vaccine liability problem or as a precedent for an approach that Congress could take in addressing the broader product liability problem. This Article will explain that the dual compensation system/tort reform approach was a response to a unique situation with childhood vaccines, and that this type of approach would not work in a broad product liability bill.

### *Childhood Vaccine Crisis*

The National Childhood Vaccine Injury Act addressed a crisis situation that existed for products that provide tremendous societal benefits. Vaccines to protect against serious and life-threatening diseases such as pertussis (“whooping cough”), diphtheria, tetanus, measles, mumps, rubella, polio, and small pox, are, without doubt, vital products. It has been stated that “[v]accines have contributed more to public health in this country than any other medical product, device, or procedure.”<sup>7</sup> Because vaccines contain biological material, however, they carry a risk of adverse effects. The Sabin polio vaccine, for example, is a live polio vaccine which contains a greatly weakened or attenuated polio virus.<sup>8</sup> Since it is administered orally and does not require boosters, it has replaced the Salk (injection) polio vaccine which is no longer manufactured in the United States.<sup>9</sup> There is an unavoidable risk with the Sabin vaccine, however, as it reproduces the weakened polio virus in the intestinal tract which in very rare cases is a virulent virus rather than the weakened Sabin virus.<sup>10</sup> When this occurs, the person who received the virus and persons coming in contact with that person may develop polio. Despite the risk of this unfortunate occurrence, society has benefitted from its dramatic decrease in the incidence of polio, a disease which killed or crippled hundreds of thousands of victims in the 19th and 20th centuries. In reporting the National Childhood Vaccine Injury Act, the House Committee on Energy and Commerce noted:

Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children’s deaths each year and has substantially reduced the effects resulting from disease. Billions of medical and health-related dollars have been saved by immunizations. And, through the development of vaccines to prevent childhood diseases, significant scientific progress has been made in the development of vaccines to prevent other types of diseases. In brief, the Nation’s efforts to protect its children by preventing disease have been—by every measure—a success.<sup>11</sup>

Recently, however, an increase in tort lawsuits for injuries associated with vaccines caused a number of United States vaccine manufacturers to withdraw from

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7. See P. Huber, *Will the New Vaccine Statute Give a Shot in the Arm to Tort Reform?*, Legal Times, Mar. 9, 1987, at 9, col. 1–3.

8. See A. David, *DTP: Drug Manufacturers’ Liability in Vaccine-Related Injuries*, 9 J. PROD. LIAB. 361, 376–77 (1986).

9. The Salk vaccine contains an *inactivated* or killed polio virus.

10. See A. David, *supra* note 8, at 376.

11. See HOUSE REPORT, *supra* note 2, at 4, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6345.

the market.<sup>12</sup> Faced with a dwindling vaccine supply and the imminent scarcity of a much-needed product, Congress stepped in. While some commentators argue that tort liability is a matter of state concern and, therefore, oppose federal legislation in this area, Congress recognized that the threat to the availability of childhood vaccines posed a *national* public health problem.<sup>13</sup>

In that regard, the most significant precedential value of the National Childhood Vaccine Injury Act is that it stands for the recognition that products liability is a matter of national concern. In a situation with one of the most severe liability problems and one of the greatest potential losses to society if those problems were not solved, a national solution was required. The House Energy and Commerce Committee noted:

The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine. Two States, Michigan and Massachusetts, produce their own DPT vaccine. Despite Congressional support, Federal vaccine stockpiles maintained by the Centers for Disease Control (CDC) have never reached CDC's recommended level of six-months' supply. Thus, the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.<sup>14</sup>

Not all products may present the same societal benefits as childhood vaccines, and the loss of some other products might not pose the same national health hazards. Those may have been concerns that motivated Congress to develop a no-fault compensation system for this particular product. But the recognition that products liability is a matter of interstate commerce and, therefore, is the responsibility of the federal government does transcend generally among all products.

#### *Childhood Vaccine Compensation Program*

The National Childhood Vaccine Injury Act of 1986 establishes a two-tiered system for obtaining compensation for injuries resulting from immunizations that state governments require children to receive as a condition of entry into school—vaccines for polio, diphtheria-pertussis-tetanus (DPT), and measles-mumps-rubella (MMR). The first tier is a mandatory “no-fault” system under which compensation for specific injuries related to childhood immunizations, listed in the Vaccine Injury Table, is to be paid out of a Trust Fund established by the Act. The Trust Fund is to be financed with the proceeds of an excise tax imposed on each dose of the covered childhood vaccines. Funding for the program has not yet been authorized by Congress, and the Act is not effective until that time.<sup>15</sup>

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12. *Id.*

13. *Id.* at 5, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6346. (“The availability and use of vaccines to prevent childhood diseases is among the Nation’s top public health priorities.”; “The Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries.”).

14. *Id.* at 7, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6348.

15. See S. Rich, *Administration Attacks Vaccine Law*, Wash. Post, March 6, 1987, at A6, col. 1.

If a person has been injured by a vaccine covered by the Act, a claim must first be brought through this no-fault compensation system before a tort lawsuit may be filed against a vaccine manufacturer. The Act's objective is to provide a more speedy and more certain compensation alternative to the tort system, so that litigation is the last resort.

A claim for compensation is made by filing a petition with a United States district court.<sup>16</sup> The petition must contain a variety of materials necessary to make a finding as to whether compensation is to be made, including evidence that the person received a vaccine listed in the Vaccine Injury Table of the Act or contracted polio from a recipient of an oral polio vaccine, and that the person sustained or had significantly aggravated an injury listed in the Table and within the time periods specified in the Table.<sup>17</sup> The Secretary of Health and Human Services must be named as the Respondent to all petitions for compensation. No other persons may intervene or otherwise be made a party to the compensation proceeding.<sup>18</sup> The district court then is to designate a special master to assist in obtaining evidence, information, and testimony, and to conduct hearings and prepare proposed findings of fact and conclusions of law and submit these findings to the district court.<sup>19</sup> After the special master submits his findings of fact or conclusions of law, the district court determines whether to award compensation.<sup>20</sup> In making that determination, the only issue is whether the injury is vaccine-related. There need be no showing that a vaccine manufacturer was at fault.

If the petitioner's injury is listed in the Table, and occurred within the time period set forth in the Table, there is a presumption that the injury was caused by the vaccine.<sup>21</sup> This presumption can be overcome by a preponderance of the evidence, submitted by the Secretary of Health and Human Services or a vaccine manufacturer, that a particular petitioner's injury is not vaccine-related.<sup>22</sup> Evidence that may be submitted to overcome the presumption includes proof of other infections, traumas or conditions, but does not include speculative or hypothetical matters or explanations.<sup>23</sup> Petitioners may also seek to prove that an injury not covered by the Table was caused by a vaccine. The entire proceeding, from date of filing through special master proceedings and court review, is to take place as expeditiously as possible and, in no case, should take more than one year.<sup>24</sup>

If the district court determines that an injury is vaccine-related, it will award compensation to be paid from the Trust Fund established by the Act.<sup>25</sup> Compensation

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16. S. 1744, *supra* note 1, at § 2111, 132 CONG. REC. H11,598-99 (1986).

17. *Id.* at § 2111(c), 132 CONG. REC. H11,599.

18. *Id.* at § 2112(b), 132 CONG. REC. H11,599.

19. *Id.* at § 2112(c), 132 CONG. REC. H11,599.

20. *Id.* at § 2112(d), 132 CONG. REC. H11,599.

21. *Id.* at § 2113(a), 132 CONG. REC. H11,599-600.

22. *Id.*

23. *Id.* at § 2113(b), 132 CONG. REC. H11,600; HOUSE REPORT, *supra* note 2, at 18, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6359.

24. S. 1744, *supra* note 1, at § 2112(d), 132 CONG. REC. H11,599; HOUSE REPORT, *supra* note 2, at 17, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6358.

25. S. 1744, *supra* note 1, at § 2115(a), 132 CONG. REC. H11,601.

is made for actual, unreimbursable medical expenses, rehabilitation costs, and lost wages.<sup>26</sup> The award is to include an amount to provide for reasonable attorneys' fees and other costs incurred in proceedings on the petition.<sup>27</sup> The court may, in its discretion, make an award for attorneys' fees and costs even if it does not award compensation on a petition, if it determines that the action was brought in good faith and that there was a reasonable basis for the claim for which the action was brought.<sup>28</sup> In addition, the court may award compensation for pain and suffering up to \$250,000.<sup>29</sup> In the case of death, a fixed award of \$250,000 is made.<sup>30</sup> Compensation under the program may not include punitive or exemplary damages or any form of compensation, other than death benefits or lost earnings, that is not for the health, education, or welfare of the injured person.<sup>31</sup>

There are provisions in the Act for adjustment of projected unreimbursable expenses after the initial judgment is made if the petitioner shows that the award is insufficient to meet its unreimbursable expenses.<sup>32</sup> The district court's judgment is the final determination of the compensation petition, except that either the petitioner or the Secretary of Health and Human Services may request a review of the judgment by the court of appeals for the circuit in which the district court is located.<sup>33</sup> The request for an appeal must be made and delivered to the other party within 60 days.<sup>34</sup>

After the judgment of the district court regarding the petition for compensation has become final, the petitioner may, within 90 days from that date, decide in writing either to accept the court's judgment or to file a tort action for damages for the vaccine-related injury or death. The petitioner's decision must be filed in writing even if the court has refused to award compensation. If the petitioner fails to file a decision in writing within the 90-day period, he or she will be deemed to have accepted the court's judgment.<sup>35</sup>

In sum, the compensation proceeding is relatively simple. There is no discovery, cross-examination, pleadings, or trial. The power of the special master to require evidence, submission of information, and require testimony, is intended to replace the usual rules of discovery in civil actions in federal courts. The only issues relevant to the compensation proceedings are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages. Congress structured the Act so as to encourage persons to take advantage of the compensation system by making it

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26. *Id.* The measure of lost earnings for adults is to be determined in accordance with accepted actuarial principles. In the case of a child who sustains a vaccine injury before the age of 18, compensation is awarded for a loss of earnings after the age of 18 determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, with offsets for appropriate taxes and the average cost of a health insurance policy. Payments for projected expenses are to be paid prospectively, on an annual basis.

27. *Id.* at § 2115(e), 132 CONG. REC. H11,601.

28. *Id.*

29. *Id.* at § 2115(a), 132 CONG. REC. H11,601.

30. *Id.*

31. *Id.* at § 2115(e), 132 CONG. REC. H11,601.

32. *Id.* at § 2112(f), 132 CONG. REC. H11,599.

33. *Id.* at § 2112(g), 132 CONG. REC. H11,599.

34. *Id.*

35. *Id.* at § 2121, 132 CONG. REC. H11,602.

(1) mandatory, (2) not based on proving fault for a vaccine-related injury, (3) speedy, and (4) fair in terms of the amount of compensation.

As a trade-off for the certainty of no-fault compensation and as an added incentive to have less resort to the tort system, the Act modifies tort law for vaccine injury suits in several respects. Except to the extent that the Act has established a rule of law for such actions, tort actions for vaccine-related injuries will be governed by applicable state law. Thus, tort litigation under these modifications of law is the secondary system of recovery for vaccine injuries.

First, the Act adopts the principle contained in comment k of section 402A of the *Restatement (Second) of Torts*, that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects if its products are properly prepared and accompanied by adequate directions and warnings.<sup>36</sup> Under the Act, a vaccine is presumed to be accompanied by proper directions and warnings if the manufacturer demonstrates that the directions and warnings comply in all material respects with relevant federal law governing the approval and labeling of the vaccine. This presumption may be overcome if the claimant shows that the manufacturer engaged in fraudulent conduct or intentionally or unlawfully withheld information in obtaining pre-market approval for the vaccine from the Federal Food and Drug Administration, or if the claimant shows by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with Federal Food and Drug Administration requirements. The legislative history to the Act explains that the comment k principle was adopted for tort lawsuits because the Act's crafters believed that claims based on injuries involving unavoidable risks of vaccines should be resolved in the no-fault compensation system rather than in the tort system. The Committee Report notes:

Given the existence of the compensation system in this bill, the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper direction or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.<sup>37</sup>

If a person's vaccine-related injury is what would be considered an "unavoidable" risk of the vaccine, and the vaccine was properly prepared and accompanied by proper warnings, a tort claim should be defeated.

Second, vaccine manufacturers may not be held liable in tort lawsuits for their failure to provide warnings directly to the vaccine recipient, rather than physicians.<sup>38</sup> This provision overrules several court decisions that have held drug manufacturers liable for failure to provide direct warnings to the patient rather than to an intermediary such as a doctor, nurse, or pharmacist who can be expected to

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36. *Id.* at § 2122(b), 132 CONG. REC. H11,603.

37. HOUSE REPORT, *supra* note 2, at 26, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6367.

38. S. 1744, *supra* note 1, at § 2122(c), 132 CONG. REC. H11,603.

know about the product and its risks, and who is responsible for informing the patient.<sup>39</sup>

Third, a vaccine manufacturer will be protected against punitive damages in a tort lawsuit if it shows that its product complied with applicable requirements under the Federal Food, Drug and Cosmetic Act and specified provisions of the Public Health Service Act.<sup>40</sup> The legislative history explains the rationale for this provision:

The Committee believes that punitive damages should be assessed only where particularly reprehensible, conscious behavior is involved. Where a manufacturer has attempted in good faith to comply with a government standard—even if the standard provides inadequate protection to the public—the manufacturer should not be assessed punitive damages absent evidence that it engaged in reprehensible behavior that directly resulted in the establishment of maintenance of the standard's inadequacy.<sup>41</sup>

This protection against punitive damages will not apply if the manufacturer (1) engaged in fraud or intentional and wrongful withholding of information from the Secretary of Health and Human Services during any phase of a proceeding for approval of the vaccine, (2) intentionally or wrongfully withheld information relating to the safety or efficacy of the vaccine after its approval, or (3) engaged in other criminal or illegal activity relating to the safety and effectiveness of the vaccine. In addition, trials will be divided into separate proceedings on liability, compensatory damages, and punitive damages, so that evidence on the extent of the claimants' injury or on actions of the defendant that allegedly justify punitive damages does not prejudice the findings as to causation and fault.

#### *A Solution to the Vaccine Liability Problem?*

The approach Congress took to address the children's vaccine liability problem, which creates a no-fault system as the primary method of compensation, is, undeniably, a response to a unique problem.

First, children's vaccines are unlike other products. Children are required by law in every state to be immunized in order to attend public school. The fact that state governments require children to undergo a risk in order to protect society as a whole, was seen by Congress as justification for development of a national fund to compensate children who are injured because of these risks.<sup>42</sup>

Second, unlike some other products, the incidence of serious injury with children's vaccines is very low.<sup>43</sup> Thus, a vaccine compensation system can be self-funding by adding a very small excise tax to the price of vaccines.<sup>44</sup> It would not be as easy to finance a compensation system for other products which have higher

39. See, e.g., *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984) (Warnings associated with polio vaccine must be provided to patient); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974) (same rule); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968) (same rule).

40. S. 1744, *supra* note 1, at § 2123, 132 CONG. REC. H11,603.

41. See HOUSE REPORT, *supra* note 2, at 28–29, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6369–70.

42. See *id.* at 6, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6347.

43. *Id.*

44. As noted above, the funding mechanism for the vaccine compensation program has not been established.

incidences of serious injury and, therefore, would require funding from outside sources, such as general revenues.

Third, the children's vaccine liability insurance situation was more widely felt than the liability crisis that exists with most other products. Most of the vaccine manufacturers in the United States have withdrawn from the market.<sup>45</sup> The loss of even one more manufacturer could mean that some children would be unable to receive vaccines, which would create a very serious public health problem.<sup>46</sup>

Based on these justifications for having a no-fault compensation system for vaccines, Congress set out to achieve two objectives: to provide an expeditious method of compensating children who are injured because of vaccines and to make liability for vaccine manufacturers more predictable so that the supply of vaccines in the United States will be adequate.<sup>47</sup> Assuming Congress sets the Act in operation by authorizing an excise tax to fund the compensation program, its success will be determined over time. At present, a few considerations lend to its prognosis.

The first of Congress' objectives, to create an efficient method of providing adequate compensation for vaccine-injured persons, can be achieved only if the compensation proceedings are not abused. The overriding guideline of those proceedings is simplification. The burden will be on the district courts and the appointed special masters to administer the compensation program within these guidelines. Attempts by either side to interject discovery into these proceedings or to raise issues other than causation of the injury and the extent of damages, will defeat this objective.

The second objective, to make vaccine liability more predictable, will be accomplished only if the no-fault compensation program becomes the primary means of redress for vaccine-related injuries, meaning that the majority of claims that otherwise would be resolved in the tort system are resolved in the compensation system. Congress could have more greatly assured this result by making the no-fault compensation system the exclusive remedy for persons injured by vaccines.<sup>48</sup> Instead, Congress attempted to make the compensation program an appealing alternative to tort litigation and to reduce incentives for persons to choose tort suits as a means for resolving vaccine injury claims. It did so in several ways.

First, the Act makes the filing of a petition in the no-fault compensation system mandatory before a tort lawsuit may be filed. In deciding whether to file a lawsuit, a petitioner who has been awarded compensation will weigh this assured and immediate recovery against the *possibility* of greater recovery at some time in the

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45. See *supra* text accompanying note 14.

46. See HOUSE REPORT, *supra* note 2, at 7, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6348. One can find a similar reduction in the number of sporting goods manufacturers, but one does not find as direct adverse health impacts. See 133 CONG. REC. S2,999 (March 11, 1987) (statement of Sen. Kasten).

47. See HOUSE REPORT, *supra* note 2, at 7, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6348.

48. A report by the American Medical Association Ad Hoc Committee on Vaccine Injury Compensation explains that the goals of continued availability of vaccines, development of improved vaccines, and participation of health workers in vaccine programs will not be met unless a federal no-fault compensation system is the *exclusive remedy* of claimants and not merely an alternative to tort litigation. See M. Goldsmith, *AMA Offers Recommendations for Vaccine Injury Compensation*, 252 J. AM. MED. ASS'N 2937, 2939 (Dec. 7, 1984).

future if a tort lawsuit is successful. Second, the compensation provided for in the no-fault compensation program covers the petitioner's actual unreimbursable expenses and may compensate for pain and suffering. Third, the Act adopts three principles of tort law that, in the vaccine lawsuit context, may modify the rules that would otherwise apply in some states, making it more difficult for claimants to recover in a tort lawsuit. Despite these incentives for a claimant to accept a compensation award in the no-fault program system, it is uncertain whether more claims will be resolved through the program. Congress did not remove countervailing incentives that may favor tort litigation. For example, the prospect of a higher contingency fee may prompt claimants' attorneys to encourage claimants to reject the award and file a tort lawsuit. In light of the tort law modifications established by the Act, however, a realistic claimant's attorney would carefully consider the prospects of a successful tort lawsuit against the assurance of compensation already awarded. Furthermore, even though the tort law standards established by the Act follow general principles of tort law and will actually change the law in only some states,<sup>49</sup> judges may be less likely to find ways to expand tort liability for vaccine manufacturers given the existence of a no-fault compensation alternative. But these are considerations that may influence the course of individual claims, and it is difficult to forecast the outcome in the aggregate—a point that creates doubt as to whether greater predictability for vaccine liability will be achieved.

Congress may have decided to retain the tort system for vaccine injury claims, at the expense of greater predictability, as a means of providing incentives for the manufacture of safe vaccines. For example, under the Act, vaccine manufacturers will be subject to liability in tort lawsuits if vaccines are not properly prepared or are not accompanied by adequate directions or warnings. It could be argued that under a no-fault compensation program, particularly where compensation derives from a general fund and is not linked to individual responsibility, expeditious and certain compensation is provided for at the expense of removing those incentives. The argument would be that the absence of a linkage between fault and payment for injuries removes incentives for vaccine manufacturers to act safely. Interestingly, representatives of professional consumer groups and trial attorneys have consistently opposed the establishment of fault standards of liability in federal products liability legislation proposed in Congress, on the theory that absolute liability is the greatest incentive for safety.<sup>50</sup> A fundamental principle of tort theory, however, is that placing liability on persons who act wrongfully creates incentives for safety. For this reason, it could be argued that an exclusive no-fault compensation system might not provide safety incentives.

In order to accomplish this objective within the framework of an exclusive no-fault compensation system, other methods of penalizing unsafe conduct and

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49. The unavoidably unsafe principle, for example, is followed by most courts. See, e.g., *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 90 (2d Cir. 1980).

50. See, e.g., S. 100, *Product Liability Act: Hearing before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation*, 99th Cong., 1st Sess. 77-85 (1985) (Statement of Gene Kimmelman, Legislative Director, Consumer Federation of America).

rewarding safe conduct could be developed. For example, instead of funding the program through an excise tax, some method could be developed for making assessments on vaccine manufacturers in accordance to the incidences of injuries related to their products.

### *A Window for the Future?*

The structure of the no-fault compensation system for vaccine injuries signifies that this type of system may work, if at all, in very narrowly defined situations. The Act's no-fault system is designed for specified products and specific illnesses that will "trigger" compensation. Under the Table in the Act, it is relatively simple to determine whether a claimant's injury is vaccine-related.

Attempts to create broader compensation systems for product injuries have been made in Congress. In the 99th Congress, the Senate Commerce Committee considered a proposal to establish a compensation system for all products.<sup>51</sup> After months of evaluation of this proposal, including receipt of comments from professional consumer groups and representatives of manufacturers, all of whom were dissatisfied with the proposal, the Senate Commerce Committee gave up on this approach.<sup>52</sup> The fundamental problem with establishing a claims system to cover all products was trying to define the "trigger" for compensation. Since it is not practical or feasible to attempt to list every single product that currently is subject to tort liability, and to list every imaginable injury, illness, or disease that may be caused by all products, a broad products claims system would have to contain some alternative "trigger." The proposed Senate bill attempted to frame a "trigger" along the strictest lines of strict liability standards.

The Senate Bill, S. 1999, required manufacturers to make payment of actual, unreimbursable economic losses ("net economic loss") if a product were "unreasonably dangerous" and a proximate cause of the claimant's harm while being used in a manner intended or anticipated by the manufacturer.<sup>53</sup> A manufacturer would not be required to pay the claim if the claimant was grossly negligent.<sup>54</sup> The Bill established a presumption that a product is "unreasonably dangerous," which the manufacturer could rebut by showing that the product's utility so outweighed the risk of harm that it was reasonable to produce it, or that the risk of harm was apparent or was a matter of common knowledge.<sup>55</sup> The Bill spelled out the warnings or instructions that must have been provided to rebut the presumption that the product was "unreasonably dangerous."<sup>56</sup> It also established a presumption of proximate cause in certain situations involving toxic harm.<sup>57</sup>

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51. S. 1999, 99th Cong., 2d Sess. (1986).

52. See *Product Liability Voluntary Claims and Uniform Standards Act: Hearings Before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation*, 99th Cong., 2d Sess. 104-148 (1986).

53. S. 1999, *supra* note 51, at § 205(a) (1986).

54. *Id.*

55. *Id.* at § 205(b).

56. *Id.* at § 205(b) and (c).

57. *Id.* at § 205(d).

Based on these guidelines, a manufacturer would have to determine whether a claim should be paid and notify the claimant.<sup>58</sup> If a claim were denied, the claimant would have the option of filing a civil action to obtain compensation for “net economic loss” under the standards outlined above, or filing a tort lawsuit governed by the tort rules in Title III of the Act, which would restrict the liability of manufacturers in some respects.

Obviously, this “trigger” for payment of compensation in an “expedited products liability claims procedure” was very different from the Vaccine Injury Table which lists the products and related injuries that are compensable. The products liability “trigger” looked like a very detailed jury instruction in a products liability lawsuit.

Given the complexity and subjective nature of the determination whether compensation should be paid under this expedited products liability claims procedure, it was not perceived as an appealing alternative to litigation. Representatives of both sides of the issue agreed that this approach would simply generate uncertainty and litigation over whether a particular product should give rise to compensation, and that it would not serve the goal of expeditiously providing compensation for injured persons.

After months of study, the Senate Commerce Committee abandoned the attempt to design a broad products compensation system and worked on procedures to foster settlement of products liability lawsuits.<sup>59</sup> The lesson learned from this exercise, however, is useful. An injury compensation system can serve the goal of expeditiously providing compensation only if the event which triggers payment is clearly defined and applicable on some objective basis. The National Childhood Vaccine Injury Act did this by listing vaccines and vaccine-related injuries in a Table in the Act. In workers’ compensation, the triggering event is an injury “arising out of and in the course of the employment.”<sup>60</sup> Unless a simple and objective “trigger” is developed for all types of product injuries, a broad-scale product compensation system is not achievable. Short of creating absolute liability for every injury in which a product was somehow involved, there would have to be a workable, objective guideline for determining whether a product defect caused the injury. Given the complexity of determining “defectiveness”—as evidenced by the myriad of standards applied by courts—it seems unlikely that this could be accomplished.

### CONCLUSION

The National Childhood Vaccine Injury Act of 1986 is a unique response to the severe liability problems of a particular type of product. Whether the Act will actually be made operative by an authorization of funding for the compensation program and whether it is a successful resolution of those liability concerns remains to be seen. But two comments can be made on its precedential value.

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58. *Id.* at § 206.

59. S. 2760, 99th Cong., 2d Sess. (1986).

60. See generally A. LARSON, WORKMEN’S COMPENSATION § 6 (Desk ed. 1987).

First, by enacting this legislation Congress recognized its responsibility for major products liability problems. Congress has in the past acknowledged its interstate commerce responsibility for products by enacting legislation regulating product safety—the Consumer Product Safety Act,<sup>61</sup> the Federal Food, Drug, and Cosmetic Act,<sup>62</sup> the National Traffic and Motor Vehicle Safety Act,<sup>63</sup> and so on—but this step into products liability is a groundbreaker.

Second, the approach to the vaccine liability problem is unlikely to be followed on a broader basis. This is true for several reasons. The mandatory nature of childhood immunizations and the ability to fund a compensation program without outside sources may have motivated Congress to take this approach. In addition, the inability to define an objective “trigger” would thwart development of a broad product-injury compensation program. The bottom line—this particular approach to liability problems is unlikely to be a window for the future.

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61. 15 U.S.C. § 2051 *et seq.* (1983).

62. 21 U.S.C. § 301 *et seq.* (1983).

63. 15 U.S.C. § 1381 *et seq.* (1983).