



# Vaccines and The National Vaccine Injury Compensation Program

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*“Well, we had us a misfortune.” Tom turned eyes sad as a trout. . . “The thing was, damn, we had these here ‘noculations. You ever been ‘noculated?”*

*The man swore earnestly. Tom nodded. “Well, then, you know. Only thing was, we wound up sick, half the dang regiment. And come time for the fight at Chancellorsville our Surgeon Major—that’s a stumble-fingered man named Wormy Monroe—he up and reported us unfit for combat. So they went ahead and sent us back to mind the dang telegraph wires. We wasn’t allowed to ‘sociate with nobody. Old Lawrence there he went on up and argued, but wouldn’t nobody come near us. It was like he was carrying the plague. Lawrence said hang it, we ought to be the first ones in, we’d probably give the Rebs a disease and be more useful than any other outfit in the whole army. Matter of fact, way things turned, we probably would’ve been more use than most of them people. Anyway we wasn’t in it.”*

*—From Michael Shaara’s The Killer Angels, a novel about the Battle of Gettysburg.*

## Introduction

Although not always aware of it, Americans feel the great benefits of vaccines everyday. For the past two centuries, since Edward Jenner’s development of the smallpox vaccine, children have been successfully vaccinated against some of the world’s most deadly diseases. Most Americans agree that the use of vaccines to prevent infectious diseases represents “one of the most spectacularly effective public health initiatives this country has ever undertaken.”<sup>1</sup> Because of the enormous benefits of vaccination to society as a whole, all fifty states require children to be vaccinated against the seven common childhood diseases—polio, measles, mumps, rubella, diphtheria, pertussis (whooping cough) and tetanus.<sup>2</sup> Some states also require vaccination against hepatitis B, *Haemophilus influenzae* type b, and varicella (chicken pox). Mandatory vaccination has resulted in a dramatic decrease of the incidence of these deadly diseases.

The success of mass immunization, however, comes at a price. Many children, and sometimes their parents, suffer major injuries and death from the administration of vaccines. Although only a small percentage of the entire population experiences an adverse reaction to vaccination, this number of vaccine injury sufferers is not small. Since 1988, 5,773 people have claimed a vaccine-related injury or death.<sup>3</sup> As science progresses, physicians and researchers will continue to establish connections between vaccines and certain adverse reactions. In re-

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<sup>1</sup>H. Rep. 99-908 (1986) at 4, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345; Comm. Print 99-LL (1986), Subcomm. On Health and the Environment of the House Comm. On Energy and Commerce, Childhood Immunizations, at 1 (hereinafter “Childhood Immunizations”).

<sup>2</sup>H. Rep. 99-908, at 4, *reprinted in* 1986 U.S.C.C.A.N. at 6346.

<sup>3</sup>Monthly Statistics Report (through March 7, 2000), National Vaccine Injury Compensation Program. Available at <http://www.hrsa.gov.bhrp/vicp>. (Hereinafter “Monthly Statistics Report”).

response to the many injuries now known or suspected to be caused by vaccines, parent groups challenge the national and state objectives of universal vaccination.<sup>4</sup> Questions of fairness arise as to how to compensate those who suffer injuries or die in order to further the larger societal good of mass immunization. How can we reduce the number of adverse reactions suffered because of mandatory vaccination? How can we compensate those who experience these adverse reactions?

## The National Childhood Vaccine Injury Act of 1986

The federal government plays a leading role in vaccination by funding vaccine administration and by integrating the immunization efforts of the public and private sectors on national, state and local levels.<sup>5</sup> Congress repeatedly reaffirms this role of the federal government in order to ensure that the United States maintains a consistent national policy on childhood vaccination.<sup>6</sup> In 1986, Congress passed the National Childhood Vaccine Injury Act<sup>7</sup> (“Vaccine Act”). This legislation establishes a National Vaccine Program “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.”<sup>8</sup> The Vaccine Act also institutes the National Vaccine Injury Compensation Program

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<sup>4</sup>Such groups include the National Vaccine Information Center, formerly known as DPT, Dissatisfied Parents Together, and Freedom of Vaccination Choice.

<sup>5</sup>Childhood Immunizations, *supra* note 1, at 43.

<sup>6</sup>*Id.*; H. Rep. 99-908 (1986), at 5, *reprinted in* 1986 U.S.C.C.A.N at 6346.

<sup>7</sup>42 U.S.C. 300aa *et seq.*, P.L. 99-660, 100 Stat. 3755. The statute was enacted on November 14, 1986, and became effective on October 1, 1988.

<sup>8</sup>42 U.S.C. 300aa-1.

(“NVICP”), a federal, no-fault compensation system which awards money to the victims of vaccine-related injuries and death.<sup>9</sup>

This paper describes the FDA’s role in ensuring the safety of vaccines, the civil litigation alternative to compensation, and the events leading up to the passage of the Vaccine Act. The paper, however, focuses on the NVICP, the actual operation of this compensation program, and the program’s effects on the compensation and prevention of adverse reactions to mandatory vaccinations. The paper also examines whether Congress’s goals in passing the Vaccine Act have been achieved and what reforms may be necessary in order to further these goals.

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<sup>9</sup>42 U.S.C. 300aa-10.

## Chapter I.

### **The Food and Drug Administration: Regulation of Vaccines and Vaccine Manufacturers**

#### **A.**

### **History of the FDA Regulation of Vaccines and Vaccine Manufacturers.**

The federal government has licensed and regulated the vaccine industry since the 1902 Virus Serums and Toxins Act (“Virus Act”).<sup>10</sup> This Act required the regulation of “the sale of viruses, serums, toxins, and analogous products. . .” in interstate and foreign commerce.<sup>11</sup> Congress passed the Virus Act because one contaminated diphtheria lot caused the deaths of ten school children in St. Louis, Missouri.<sup>12</sup> The Act was passed four years before the Food and Drug Act of 1906, the precursor to the Federal Food, Drug and Cosmetic Act, and the Virus Act may have been the first consumer health law in the United States<sup>13</sup> Under the Virus Act, the Secretary of the Treasury issued licenses to vaccine manufacturers and regulated vaccines according to standards promulgated by an interagency board.<sup>14</sup> This board authorized the Public Health Service’s Hygienic Laboratory to inspect vaccine manufacturing facilities, to issue and revoke licenses, and to “ensure, in whatever ways possible, the safety and efficacy of

<sup>10</sup>Childhood Immunizations, *supra* note 1, at 44.

<sup>11</sup>*Id.*

<sup>12</sup>William R. Pendergast, *Biologic Drugs*, in *Food and Drug Law*, Food and Drug Law Institute, 1991, at 306.

<sup>13</sup>*Id.* at 303, 308.

<sup>14</sup>Childhood Immunizations, *supra* note 1, at 44..

biologics.”<sup>15</sup> The National Microbiological Institute of the National Institutes of Health (NIH) took over the regulation of the vaccine industry in 1948 and, in 1955, the NIH Division of Biologics assumed the regulation of biologics.<sup>16</sup> In 1972, responsibility for regulating the vaccine industry was finally transferred to the Food and Drug Administration (FDA) and its Bureau of Biologics.<sup>17</sup> Although now under a new name—the FDA Center for Biologics Evaluation and Research—the FDA continues to bear primary responsibility for the regulation of vaccines.

B. \_\_\_\_\_

The Review of Biological Products.

Immediately after the FDA assumed responsibility for regulating vaccines, the FDA announced that all biological products licensed before July 1, 1972, including vaccines, would be reviewed for safety, purity and potency.<sup>18</sup> This biologics review was also intended to determine whether pre-1972 biological products were effective for their labeled uses and not misbranded under the FDCA.<sup>19</sup> The FDA set forth regulations<sup>20</sup> assigning the task of reviewing these biological products to six independent advisory review panels.<sup>21</sup> The panels

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<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> 37 Fed. Reg. 16,679, *Biological Products, Procedures for Review of Safety, Effectiveness, and Labeling* (August 18, 1972).

<sup>19</sup> *Id.*

<sup>20</sup> These regulations can be found at 21 C.F.R. 601.25.

<sup>21</sup> 39 Fed. Reg. 21176, *Certain Biological Products, Request for Data and Information Regarding Safety, Effectiveness, and Labeling Review* (June 19, 1974).

consisted of non-FDA qualified experts and each panel reviewed a specific category of biological products. Panels reviewed the following types of vaccines: (1) bacterial vaccines and bacterial antigens with “no U.S. standards of potency”; (2) bacterial vaccines and toxoids with “U.S. standards of potency”; and (3) viral and rickettsial vaccines.<sup>22</sup> Each advisory committee was required to classify the reviewed vaccines into one of three categories:

(1.)

Category I: Biological products determined by the panel to be safe, effective and not misbranded;<sup>23</sup>

(2.)

Category II: Biological products determined to be unsafe, ineffective or misbranded;<sup>24</sup> and,

(3.)

Category III: Biological products determined not to fall within either Category I or II because insufficient data exists for classification and, therefore, further testing is required.<sup>25</sup>

Category III biologics were divided into two subcategories:

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<sup>22</sup> *Id.*

<sup>23</sup> 21 C.F.R. 601.25(e)(1).

<sup>24</sup> 21 C.F.R. 601.25(e)(2).

<sup>25</sup> 21 C.F.R. 601.25(e)(3).



(a.)

Category IIIA: Biological products recommended for continued licensing, manufacturing and marketing while further study is being conducted.

(b.)

Category IIIB: Biological products that a panel recommends should not be marketed or licensed for general use while further studies are being conducted.<sup>26</sup>

The results of these studies show that most pre-1972 vaccines were safe and effective. However, the FDA revoked a substantial number of vaccine licenses as a result of this biologics review. The Panel on Review of Viral Vaccines and Rickettsial Vaccines evaluated the safety, effectiveness and labeling of 72 such viral and rickettsial vaccines.<sup>27</sup> This review included the evaluation of many manufacturers' variations of the smallpox, measles, mumps and rubella vaccines.<sup>28</sup> The panel concluded that: (1) 45 products be placed in Category I; (2) 6 products be placed in Category II; (3) 5 products be placed in Category IIIA; and (4) 16 products be placed in Category IIIB.<sup>29</sup> The FDA revoked the licenses of those biologics in Categories II and IIIB.<sup>30</sup>

The Panel on Review of Bacterial Vaccines and Toxoids, which evaluated such vaccines as diphtheria, pertussis and tetanus, placed many vaccines in Cate-

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<sup>26</sup> *Id.*

<sup>27</sup> 47 Fed. Reg. 24696, *Viral and Rickettsial Vaccines; Implementation of Efficacy Review* (June 8, 1982).

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

gories I and IIIA, and only one vaccine in Category IIIB.<sup>31</sup> The panel, however, devised a new category, Category IIIC, in order to clarify that certain of its recommendations for revocations of licenses were based on administrative and procedural problems rather than scientific evaluation of the products.<sup>32</sup> The FDA placed the panel's "Category IIIC" vaccines in Category IIIB because the available data was insufficient to confirm the safety and effectiveness of these vaccines. Thus, another 16 vaccines, mostly variations of the DPT vaccine, were added to Category IIIB. The Panel on Review of Bacterial Vaccines and Bacterial Antigens placed no vaccines in Category I and listed eight vaccines in Category IIIA.<sup>33</sup> Following the publication of the results of these panels, the FDA required that all Category IIIA products be reclassified as Category I or Category II products according to certain procedures.<sup>34</sup>

### C.

#### FDA Regulation of Vaccines and Vaccine Manufacturers.

The FDA regulates vaccines as "biological products" subject to the provisions of the Public Health Service Act ("PHSA")<sup>35</sup>, a statute which revised and incorporated the Virus Act of 1902.<sup>36</sup> A "biological product" is "any virus,

<sup>31</sup>50 Fed. Reg. 51002, *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review* (December 13, 1985).

<sup>32</sup>*Id.* at 51106.

<sup>33</sup>44 Fed. Reg. 1544, *Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency"* (January 5, 1979).

<sup>34</sup>21 C.F.R. 601.26. Reclassification procedures to determine that licensed biological products are safe, effective and not misbranded under prescribed, recommended, or suggested conditions of use.

<sup>35</sup>42 U.S.C. 201-300.

<sup>36</sup>Pendergast, *supra* note 12, at 310.

therapeutic serum, toxin, anti-toxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man. . . .”<sup>37</sup> The FDA also regulates vaccines as “drugs” under the Federal Food, Drug and Cosmetics Act (“FDCA”).<sup>38</sup> Originally, the drafters of the FDCA were not going to apply the FDCA to biological products covered by the Virus Act;<sup>39</sup> but, because six women died in early 1938 from tetanus after receiving injections of a biologic, the FDCA drafters dropped language stating that the FDCA would not “be construed. . . as in any way applying to the products to which the [Virus] Act is applicable.”<sup>40</sup> Thus, the FDCA does extend to vaccines, in addition to the coverage provided by the PHSA.

In order to ensure the safety and efficacy of the vaccine supply, the FDA comprehensively regulates the clinical trials, manufacturing, licensing, labeling and reporting of adverse experiences of vaccines.<sup>41</sup>

## 1. \_\_\_\_\_

### FDA Regulation and Licensing of Vaccine Manufacturers.

The FDA inspects the facilities of vaccine manufacturers and investigates all aspects of the manufacturing process.<sup>42</sup> “Establishment Standards” reg-

<sup>37</sup>21 C.F.R. 600.3 Definitions.

<sup>38</sup>21 U.S.C. 301-392.

<sup>39</sup>Pendergast, *supra* note 12, at 309, *citing* N.Y. Times, March 31, 1938, at L25, col. 6.

<sup>40</sup>*Id.*, *citing* Comm. Print 4, Federal Food, Drug, and Cosmetic Act, 75<sup>th</sup> Cong., 3d Sess. §1001(c), March 5, 1938.

<sup>41</sup>21 C.F.R. 600 *et seq.*, Chapter I—Food and Drug Administration, Department of Health and Human Services, Subchapter F—Biologics.

<sup>42</sup>21 C.F.R. 600.20 Inspectors; 21 C.F.R. 600.21 Time of inspection; 21 C.F.R. 600.22 Duties of inspector.

ulate the personnel and work place of the vaccine manufacturer,<sup>43</sup> providing specific rules for live vaccine work areas<sup>44</sup> and live vaccine processing.<sup>45</sup> Vaccine manufacturers must make and retain records so that “successive steps in the manufacture and distribution of any lot may be traced by an inspector” at any time during the process.<sup>46</sup> Moreover, vaccine manufacturers must retain samples of vaccines because the FDA tests the samples for safety and efficacy.<sup>47</sup> In order to ensure that vaccine supplies remain safe, the FDA goes so far as to regulate the specific temperature at which certain vaccines are shipped, i.e., the live measles and rubella virus vaccine must remain at 10 degrees Celsius or colder during shipment.<sup>48</sup>

The licensing of vaccine manufacturers is a detailed process with specific requirements,<sup>49</sup> although the FDA is trying to “reduce unnecessary burdens for industry without diminishing public health protection.”<sup>50</sup> Before December 1999, a vaccine manufacturer had to apply to the FDA for two licenses—one for the manufacturing plant, an establishment license, and a license for the vaccine, a product license. Currently, a vaccine manufacturer only has to file a single “biologics license” in order to market a biological product in interstate com-

merce.<sup>51</sup> The manufacturer submits an application for a biologics license to the

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<sup>43</sup>21 C.F.R. 600.10 Personnel; 21 C.F.R. 600.11 Physical establishment, equipment, animals and care.

<sup>44</sup>21 C.F.R. 600.10(c)(4).

<sup>45</sup>21 C.F.R. 600.11(e)(4).

<sup>46</sup>21 C.F.R. 600.12 Records.

<sup>47</sup>21 C.F.R. 600.13 Retention samples.

<sup>48</sup>21 C.F.R. 600.15 Temperatures during shipment.

<sup>49</sup>21 C.F.R. 601 Licensing.

<sup>50</sup>64 Fed. Reg. 56441-01, *Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License* (October 20, 1999). Effective December 20, 1999.

<sup>51</sup>*Id.*

Director of the Center for Biologics Evaluation and Research at the FDA with, among other information, “data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity and potency. . . .”<sup>52</sup> After approving a license, the FDA may also revoke or suspend licenses granted to vaccine manufacturers.<sup>53</sup> In addition, the FDA must approve any changes in the labeling of a vaccine<sup>54</sup> and any “major changes” in the product, production process, quality controls, equipment, facilities, or responsible personnel.<sup>55</sup>

## 2. \_\_\_\_\_

### FDA Regulation of Vaccines.

Even after the FDA licenses a product, every lot of the vaccine must be tested for conformity with vaccine standards before release to the general public.<sup>56</sup> The FDA regulates the safety of vaccines rigorously, requiring a general safety test for the detection of extraneous toxic contaminants,<sup>57</sup> and tests for the sterility of the vaccine,<sup>58</sup> the purity of the vaccine,<sup>59</sup> and the identity of the vaccine (after all labeling requirements are met).<sup>60</sup> The FDA regulates the potency standards of vaccines,<sup>61</sup> as well as the limits of potency. For example, the

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<sup>52</sup>21 C.F.R. 601.2 Applications for biologics licenses, procedures for filing.

<sup>53</sup>21 C.F.R. 601.5 Revocation of license; 21 C.F.R. 601.6 Suspension of license.

<sup>54</sup>21 C.F.R. 601.12(f)(1)-(4). Labeling changes.

<sup>55</sup>21 C.F.R. 601.12(b) Changes to an approved application.

<sup>56</sup>21 C.F.R. 610.1 Tests prior to release required for each lot.

<sup>57</sup>21 C.F.R. 610.11 General safety.

<sup>58</sup>21 C.F.R. 610.12 Sterility.

<sup>59</sup>21 C.F.R. 610.13 Purity.

<sup>60</sup>21 C.F.R. 610.14 Identity.

<sup>61</sup>21 C.F.R. 610.20 Standard preparations

potency of the pertussis vaccine cannot be less than 12 units per total immunizing dose.<sup>62</sup> The FDA also sets dating periods for licensed biological products so that a vaccine will produce the intended effect and “retain its safety, purity, and potency. . . .”<sup>63</sup> For example, the inactive poliovirus vaccine can be stored for one year by the manufacturer at a specific temperature and for two years from the date of manufacture after the vaccine has left the manufacturer’s storage.<sup>64</sup> Between 1985 and 1995, the FDA issued only three vaccine recalls—one for particulates in a vaccine lot, one for mislabeling, and one for violations of good manufacturing practices at a plant.<sup>65</sup>

### 3. \_\_\_\_\_

#### FDA Regulation of Vaccine Labeling.

Regulation of vaccine labeling is one of the most important parts of the FDA’s regulation of vaccine manufacturers because Congress integrates these labeling requirements into the NVICP, and absolves from liability the manufacturer who complies with these labeling regulations. The FDA ensures that the vaccine manufacturer provides both a complete container and package label.<sup>66</sup> A container label must include such information as the proper name of the product, the name, address and license number of the manufacturer, the lot

<sup>62</sup>21 C.F.R. 610.21 Limits of potency.

<sup>63</sup>21 C.F.R. 610.53 Dating periods for licensed biological products.

<sup>64</sup>*Id.*

<sup>65</sup>Isadora B. Stehlin, *How FDA Works to Ensure Vaccine Safety*, FDA Consumer (December 1995). Located at [www.fda.gov/cber/vaers/articles.htm](http://www.fda.gov/cber/vaers/articles.htm).

<sup>66</sup>21 C.F.R. 610.60 Container label; 21 C.F.R. 610.61 Package label.

number and the expiration date.<sup>67</sup> The FDA requires more information on the package label, i.e., the preservative used, the recommended storage temperature, the route of administration recommended, the inactive ingredients when a safety factor (i.e., mercury in vaccines), and the identity of each microorganism used in manufacture.<sup>68</sup>

#### 4.

##### FDA Monitoring of Adverse Events.

Finally, the FDA monitors and records reports about adverse events associated with vaccines in order to determine whether any vaccines or vaccine lots have a higher rate of adverse effects. By law, vaccine manufacturers must report to the FDA any adverse experience within 15 days of receiving information about the adverse event.<sup>69</sup> The FDA, in conjunction with the Centers for Disease Control and Prevention (CDC), manages the Vaccine Adverse Event Reporting System (VAERS) to keep track of the information provided by vaccine manufacturers, as well as reports made by physicians, patients or parents of patients. About 85% of the reports to VAERS describe only minor adverse reactions to vaccines, such as fever or swelling; while 15% of the reports document serious adverse events, such as seizures, life-threatening illnesses, or deaths.<sup>70</sup>

Because about 10,000 VAERS reports are received each year, the FDA focuses

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<sup>67</sup>21 C.F.R. 610.60(a) Full label.

<sup>68</sup>21 C.F.R. 610.61(e)(h)(k)(n) and (q).

<sup>69</sup>21 C.F.R. 600.80 Postmarketing reporting of adverse experience.

<sup>70</sup>*What is the Vaccine Adverse Event Reporting System (VAERS)?* Located at <http://www.fda.gov/cber/vaers/what.htm>.

most of its attention on the serious adverse reactions to vaccines.<sup>71</sup>

The FDA and the CDC developed VAERS in response to the Vaccine Act's requirement that administrators and manufacturers of vaccines report specified adverse events occurring within specified time intervals after the administration of vaccines.<sup>72</sup> Although the Vaccine Act requirements and the Code of Federal Regulations overlap, licensed manufacturers of vaccines need not submit duplicate reports to VAERS and the FDA.<sup>73</sup> However, manufacturers of vaccines must comply with the more expansive requirements of §600.80 of the C.F.R.<sup>74</sup> Because VAERS is a passive reporting system, many adverse reactions to vaccines may not be reported.<sup>75</sup> Moreover, the Department of Health and Human Services (HHS) has stated that one cannot reliably establish causation between a vaccine and an injury without "substantial analysis" of VAERS data.<sup>76</sup> In fact, HHS describes VAERS reports as "anecdotal" evidence.<sup>77</sup> Although HHS recognizes the usefulness of VAERS, "it is unwilling to overstate its importance by using temporal relationships to define a new [Vaccine Injury] Table,"<sup>78</sup> a table which lists the vaccines covered by the Vaccine Act and the injuries presumed to be caused by those vaccines.

#### D.

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<sup>71</sup>*Id.*

<sup>72</sup>42 U.S.C. 300aa-25 Recording and reporting of information.

<sup>73</sup>59 Fed. Reg. 54034, 54035, *Adverse Experience Reporting Requirements for Licensed Biological Products* (October 27, 1994).

<sup>74</sup>*Id.*

<sup>75</sup>Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. of Pharmacy and Law 249, 268 (1996).

<sup>76</sup>60 Fed. Reg. 7678, 7685 (Feb. 8, 1995).

<sup>77</sup>*Id.*

<sup>78</sup>*Id.*



Conclusion: Limited Effect of FDA Regulation.

Even after all of the above-described FDA regulation of vaccines and monitoring of adverse events, vaccines are still not 100% safe. Adverse reactions to vaccines will always occur simply because of the nature of vaccines. Vaccines create an artificial immunity in the human body by introducing “small amounts of disease-causing agents which stimulate the immune system to produce antibodies specific to that disease.”<sup>79</sup> These antibodies attack invading viruses or bacteria and protect the vaccinated person from infection.<sup>80</sup> A physician cannot predict whether a particular child will suffer an adverse reaction to a vaccine and, therefore, vaccine-related injuries or death are extremely difficult to prevent.<sup>81</sup>

Because vaccines must be administered in order to protect the general population from disease and because some children will definitely be injured as a result of mandatory vaccination, the question arises as to how vaccine-injured children should be compensated for their adverse reactions to vaccines.

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<sup>79</sup>Childhood Immunizations, *supra* note 1, at 4.

<sup>80</sup>*Id.*

<sup>81</sup>H. Rep. 99-908, at 6, *reprinted in* 1986 U.S.C.C.A.N., at 6347.

## Chapter II.

### How Do We Confront the Adverse Effects of Vaccination?

#### One Alternative: The Civil Tort System

The civil tort system offers one means of compensating children and adults who suffer vaccine-related injuries or death. A person damaged by a vaccine can sue or seek a settlement arrangement with the vaccine manufacturer. As with all product liability litigation, the process of receiving compensation for a vaccine injury is lengthy and extremely expensive. As the history of vaccine litigation demonstrates, the civil tort system is unsatisfactory for both vaccine-injured persons and vaccine manufacturers, and also presents a real threat to the supply of vaccines in the United States.

#### A.

##### Theories of Liability.

State law governs almost the entire area of product liability law, and, therefore, a person injured by a defective vaccine must bring a product liability action in a state court. Most people injured by a vaccine seek to hold a vaccine manufacturer strictly liable for the defective vaccine. The Restatement Second of Torts (§ 402A) provides that a vaccine manufacturer “who sells any product in a defective condition unreasonably dangerous to the user or consumer... is subject to liability for physical harm thereby caused to the ultimate user or

consumer”, even though the vaccine manufacturer “has exercised all possible care in the preparation and sale of his product. . . .”<sup>82</sup>

Comment k to § 402A of the Restatement, however, provides an exception to this rule of strict liability.<sup>83</sup> Comment k addresses the problem of unavoidably unsafe products, such as vaccines.<sup>84</sup> Because vaccine manufacturers “supply the public with an apparently useful and desirable product,” vaccine manufacturers will not be held strictly liable for defective vaccines when the vaccines have been properly prepared and accompanied by correct directions and warnings.<sup>85</sup> According to one court, the comment k exemption for unavoidably unsafe products “is premised on the ground that it would be ‘against the public interest’ to apply strict liability to unavoidably dangerous products because of ‘the very serious tendency to stifle medical research and testing’.”<sup>86</sup> Thus, vaccine manufacturers often defend themselves against strict liability claims by arguing that (1) they manufacture products which are extremely useful to the general public but come with a small degree of risk and (2) the vaccines were properly prepared and the correct warning accompanied the vaccine.

Under the learned intermediary doctrine, a vaccine manufacturer satisfies its duty to warn the recipient of a vaccine by providing an adequate warning to the treating physician, not the actual vaccine recipient.<sup>87</sup> Therefore, a patient cannot hold the vaccine manufacturer liable for failure to warn if the manufacturer

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<sup>82</sup>§ 402A Restatement (Second) of Torts (1965).

<sup>83</sup>§ 402A Restatement (Second) of Torts, Comment k (1965).

<sup>84</sup>*Id.*

<sup>85</sup>*Id.*

<sup>86</sup>*Shackil v. Lederle Laboratories*, 116 N.J. 155 (N.J. 1989), *citing White v. Wyeth Laboratories*, 40 Ohio St.3d 390, 533 (1988).

<sup>87</sup>*Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5<sup>th</sup> Cir. 1974).

adequately warned the prescribing doctor. The learned intermediary doctrine does not apply, however, when vaccines are administered in mass immunization programs “where no individualized medical judgment intervenes between the manufacturer... and the ultimate consumer...”<sup>88</sup> Because many vaccines are given in such mass immunization programs,<sup>89</sup> manufacturers still face some liability for failing to provide direct warnings to the consumer.

Although plaintiffs bring most vaccine cases under a theory of strict liability, plaintiffs also sue vaccine manufacturers for negligent manufacturer or administration of vaccines<sup>90</sup>, breach of warranty, and failure to provide safer alternatives to a vaccine.<sup>91</sup>

## B. \_\_\_\_\_

### Failure of the Tort System.

During the 1980s, attention focused on the links between vaccines and certain injuries, especially neurological problems. For the first time, information about the possible harmful effects of vaccines became widely available. The sources primarily responsible for exposing the problem of vaccine injury to the American public include an award-winning 1982 television documentary entitled “DPT: Vaccine Roulette” (WRC-TV) and an 1985 book by Harris L. Coulter

<sup>88</sup>*Id.*, at 1276.

<sup>89</sup>Childhood Immunizations, *supra* note 1, at 60 (stating that “as much as 50% of certain vaccines are purchased and administered through public sector programs”).

<sup>90</sup>*Kearle v. Lederle Laboratories*, 172 Cal.App.3d 812, 218 Cal.Rptr.453 (1985).

<sup>91</sup>*Johnson v. American Cyanamid Co.*, 239 Kan. 279 (1986); *Tomer v. Lederle Laboratories*, 828 F.2d 510 (9<sup>th</sup> Cir. 1987).

and Barbara Loe Fisher, “DPT: A Shot in the Dark.”<sup>92</sup> During this time, parents of children who suffered adverse reactions to vaccines became involved in the dissemination of information, forming groups such as Dissatisfied Parents Together (DPT), now known as the National Vaccine Information Center. It is not surprising that the publications and parent groups of the 1980s focused on the DPT or diphtheria, pertussis and tetanus vaccine. The pertussis component of the vaccine has more confirmed and suspected side effects than any other vaccine.<sup>93</sup>

Because of this public awareness about vaccine injuries, many parents brought lawsuits against vaccine manufacturers to recover for injuries and deaths allegedly caused by vaccines. Between January 1980 and March 1985, parents filed 299 suits against vaccine manufacturers, requesting \$2.52 billion in compensatory damages and \$960 million in punitive damages.<sup>94</sup> One vaccine manufacturer, Lederle Laboratories, testified before Congress in late 1984 that Lederle faced lawsuits amounting to 200 times its annual sales of the DPT vaccine.<sup>95</sup> The case of *Johnson v. American Cyanamid*<sup>96</sup> provides a perfect example of the enormous liability faced by vaccine manufacturers. The jury in that case awarded \$10 million in damages, including \$8 million in punitive damages.<sup>97</sup> Be-

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<sup>92</sup>Harris L. Coulter and Barbara Loe Fisher, *DPT: A Shot in the Dark*, Harcourt Brace, San Diego, 1985.

<sup>93</sup>Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines*, National Academy Press, 1991.

<sup>94</sup>Childhood Immunizations, *supra* note 1, at 85-86.

<sup>95</sup>*Id.* 72-73. Lederle, and other vaccine manufacturers, testified before the House Energy and Commerce Comm, Subcomm. On Health and the Environment. Hearings on H.R. 5810, 98<sup>th</sup> Congress, 2d Sess. Sept. 10 and Dec. 19, 1984.

<sup>96</sup>239 Kan. 279 (1986)(reversing the jury verdict on the basis that the manufacturer provided adequate warnings to the learned intermediary).

<sup>97</sup>*Id.* at 280.

cause of this and future lawsuits, vaccine manufacturers had difficulty obtaining and retaining product liability insurance to cover the losses related to vaccine injury cases. Insurance companies raised premiums, reduced policy limits, and even stopped insuring vaccine manufacturers.<sup>98</sup> One manufacturer, Connaught Laboratories, briefly withdrew from the market because of a lack of insurance.<sup>99</sup>

Plaintiffs had both strong incentives and disincentives to bring a claim for a vaccine-related injury or death. On the one hand, because courts were not deciding vaccine cases consistently, the potential liability of vaccine manufacturers appeared limitless and, therefore, plaintiffs had an incentive to seek multi-million dollar judgments from sympathetic juries. On the other hand, because plaintiffs often had to litigate a technical claim, the process of pursuing an action against a drug manufacturer was extremely long and expensive. Therefore, many people injured by vaccines did not take the chance of litigating their claims and, those who did often found themselves without compensation.

The costs and risks associated with the increase in litigation against vaccine manufacturers caused vaccine prices to rise dramatically. Between 1981 and 1986, the price of the polio vaccine increased from 40 cents to \$1.56 per dose; the measles vaccine from \$1.32 to \$3.43; the measles and rubella vaccine (MR) from \$1.89 to \$5.20; and the measles, mumps and rubella vaccine (MMR) from \$3.12 to \$8.47.<sup>100</sup> The DPT vaccine saw the greatest increase in price. In 1982,

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<sup>98</sup>Childhood Immunizations, *supra* note 1, at 73.

<sup>99</sup>*Id.*

<sup>100</sup>*Id.* at 61.

the DPT vaccine cost just 10 cents to 12 cents per dose. In 1984, the cost of the DPT vaccine was \$1.00 to \$2.80 per dose and, in 1986, the price of a DPT shot was \$3.01.<sup>101</sup> This increase in the cost of vaccines threatened the vaccine supply, especially since the CDC's recommended level of six-month's supply had never been reached.<sup>102</sup>

Because of the possibility of large civil damages, the loss of insurance, and the rise in vaccine prices, vaccine manufacturers simply left the market. In 1986, there was only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps and rubella vaccine (MMR), and two manufacturers of the DPT vaccine.<sup>103</sup> Two state health departments, one in Massachusetts and one Michigan, produced their own DPT vaccine for use within their own jurisdictions.<sup>104</sup> Congress warned that “the loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. . . 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>105</sup>

Obviously, the tort system could not ensure the supply of vaccines to the general public, nor satisfactorily compensate the victims of vaccine-related injuries or death. Legislation was necessary to address (1) “the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—

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<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> H. Rep. 99-908, at 7, *reprinted in* 1986 U.S.C.C.A.N., at 6348.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

of the current approach to those who have been damaged by a vaccine”; and (2) “ the instability and unpredictability of the childhood vaccine market.”<sup>106</sup> Congress responded to these problems by passing the National Childhood Vaccine Injury Act of 1986,<sup>107</sup> which established the Vaccine Injury Compensation Program. The NVICP was designed to protect vaccine manufacturers from strict liability for injuries due to the unavoidable risks of their products, and to compensate individuals injured by certain vaccines under a nofault federal program.

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<sup>106</sup> *Id.*

<sup>107</sup> 42 U.S.C. 300aa *et seq.*



## Chapter III.

### The National Vaccine Injury Compensation Program

The National Childhood Vaccine Injury Act of 1986 consists of two programs: (1) the National Vaccine Injury Compensation Program (NCIVP) and (2) the National Vaccine Program. This chapter will focus on the NCVIP and its attempt to remedy the compensation problems of injured vaccine recipients and the high prices and vaccine shortages created by the increased liability of vaccine manufacturers.

In order to ensure that manufacturers continued to produce vaccines necessary for the safety of the general population, the United States government assumed liability under the NVICP for injuries or deaths associated with particular vaccines. The NVICP also hoped to make the pursuit of compensation for a vaccine-related injury or death more attractive to plaintiffs by making the process faster and less adversarial. The House Report on the Vaccine Act called for a compensation program that administered awards “quickly, easily, and with certainty and generosity.”<sup>108</sup> The system of compensation was intended to be “fair, simple and easy to administer” and “to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury.”<sup>109</sup> An analysis of the NVICP will reveal the extent to

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<sup>108</sup>H. Rep. 99-908, at 3, *reprinted in* 1986 U.S.C.C.A.N., at 6344.

<sup>109</sup>H. Rep. 99-908, at 12, *reprinted in* 1986 U.S.C.C.A.N., at 6353.

which these goals have been accomplished.

A.

The Design of the NVICP.

1. \_\_\_\_\_

Location of the NVICP in the Court of Federal Claims.

Congress located the NVICP in the United States Court of Federal Claims, a court established by Congress in 1855 as the U.S. Court of Claims.<sup>110</sup> The Court of Federal Claims has nationwide jurisdiction in suits against the federal government for money judgments not sounding in tort.<sup>111</sup> In this way, Congress does not have to pass private bills to resolve claims against the United States. Some examples of claims heard by the Court of Federal Claims include: claims for compensation for the taking of property, claims arising under construction and supply contracts, claims by civilian and military personnel for back pay and retirement pay, and claims for the refund of federal income and excises taxes.<sup>112</sup> The Court of Federal Claims also has exclusive jurisdiction of cases involving patent and copyright infringement by the federal government and appellate jurisdiction of decisions made by the Indian Claims Commission.<sup>113</sup>

One may wonder why Congress placed the NVICP under the jurisdiction of a court of law when the NVICP clearly resembles other administrative compensation programs, such as that employed for delivering workman's compensation.

NVICP claims are adjudicated by a court of law rather than an executive branch

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<sup>110</sup>*The American Bench: Judges of the Nation*, 10<sup>th</sup> ed., Forster-Long, 1999, at 7. The U.S. Claims Court was renamed the U.S. Court of Federal Claims on October 29, 1992, pursuant to the Federal Courts Administration Act of 1992, P.L. 102-572, 106 Stat. 4506, 4516 (1992).

<sup>111</sup>*Id.*

<sup>112</sup>*Id.*

<sup>113</sup>*Id.*

agency because the parents of children with vaccine-related injuries worried that the Department of Health and Human Services (HHS), which is the logical place for the administration of the NVICP, was “too heavily involved in overseeing childhood immunization programs to administer the NVICP objectively.”<sup>114</sup>

Under the Act as it was originally passed, Congress placed jurisdiction of the NVICP with the United States District Courts. However, the District Courts were created as part of the “judicial Power” of the U.S. government under Article III of the Constitution.<sup>115</sup> Because the NVICP allows petitioners to either accept or reject the judgment of the decision-maker, the American Bar Association and the Judicial Conference of the United States questioned whether placing the NVICP in the District Courts violated the “case or controversy” requirement of the Constitution.<sup>116</sup> Article III, Section 2 of the Constitution provides that the “judicial Power shall extend” to enumerated “cases” or “controversies.”<sup>117</sup> Thus, courts created under Article III can only rule on concrete disputes and they may not issue “advisory opinions,” namely opinions on the constitutionality of legislative or executive actions that do not result from a definite case or controversy.<sup>118</sup> In order to avoid Article III District Courts issuing advisory opinions on NVICP cases, Congress amended the Vaccine Act in

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<sup>114</sup>Molly Treadway Johnson, Carol E. Drew, and Dean P. Miletich, *Use of Expert Testimony, Specialized Decision Makers, and Case-Management Innovations in the National Vaccine Injury Compensation Program*, Federal Judicial Center, 1998, at 9.

<sup>115</sup>U.S. Constitution, Article III, Section 1.

<sup>116</sup>H. Conf. Rep. 100-495, at 771 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, at 2313-1517

<sup>117</sup>U.S. Constitution, Article III, Section 2.

<sup>118</sup>Geoffrey R. Stone, Louis M. Seidman, Cass R. Sunstein, Mark V. Tushnet, *Constitutional Law*, 3d ed., Little Brown, 1996, at 88-90.

1987<sup>119</sup> to transfer jurisdiction for vaccine injury claims to an Article I court, the U.S. Court of Federal Claims. Article I courts are created by Congress under the Necessary and Proper Clause of the Constitution and are not bound by Article III's case or controversy requirement. Therefore, no constitutional problem arises regarding the Court of Federal Claims possibly issuing advisory opinions. Moreover, the Constitution does not require Article I courts to use juries as the Constitution requires of Article III courts.<sup>120</sup> Therefore, juries do not decide vaccine injury cases in the NVICP. No NVICP cases were ever heard in the District Courts as the NCIVP did not hear any claims until 1989.<sup>121</sup>

## 2. \_\_\_\_\_

### The Special Masters.

The Court of Federal Claims employs eight special masters to decide the eligibility of applicants for compensation under the NVICP.<sup>122</sup> One of these eight special masters serves as the chief special master and administers the office of special masters.<sup>123</sup> The special masters have jurisdiction to determine whether a petitioner is entitled to compensation and the amount of such compensation.<sup>124</sup>

According to the Vaccine Rules of the Office of the Special Master,<sup>125</sup> the special

<sup>119</sup>This amendment to the Vaccine Act was made as a part of the Omnibus Budget Reconciliation Act of 1987, P.L. 100-203, 101 Stat. 1330 (1987).

<sup>120</sup>H. Conf. Rep. 100-495, at 771 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, at 2313-1517.

<sup>121</sup>Johnson, Drew and Miletich, *supra* note 114, at 9.

<sup>122</sup>42 U.S.C. 300aa-12.

<sup>123</sup>42 U.S.C. 300aa-12(c)(1) and (6).

<sup>124</sup>42 U.S.C. 300aa-12(a).

<sup>125</sup>Rules of the United States Court of Federal Claims, Appendix J—Vaccine Rules of the Office of Special Master of the United States Court of Federal Claims. (Hereinafter “Vaccine

master “shall determine the nature of the proceedings, with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case. . . .”<sup>126</sup>

The decisions of special masters are final, subject only to the appellate procedure set forth in the statute.<sup>127</sup>

As of 1998, every special master in the NVICP has been an attorney,<sup>128</sup> even though Congress originally noted that “[n]o-fault vaccine compensation proceedings raise fewer legal issues than issues of medicine and masters need not be lawyers by training.”<sup>129</sup> Congress recommended that special masters be “well-advised on matters of health, medicine and public health.”<sup>130</sup> Despite this concern with the expertise of the special masters, the eight special masters appointed at the beginning of the NVICP only attended a two-day educational program to familiarize themselves with the complex medical questions at issue in vaccine injury cases.<sup>131</sup> The special masters appointed since the beginning of the program have received no such special training.<sup>132</sup> Special masters serve for a term of four years, subject to removal for “incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.”<sup>133</sup>

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Rule.”)

<sup>126</sup>Vaccine Rule 3(b).

<sup>127</sup>At the inception of the NVICP, special masters’ decisions had to be reviewed by the Court of Federal Claims which made the final decision in the case. The Vaccine Injury Compensation Technicals of the Omnibus Budget Reconciliation Act of 1989 transferred final decision-making authority to the special masters. P.L. 101-239, 101 Stat. 2285 (1989).

<sup>128</sup>Johnson, Drew and Miletich, *supra* note 114, at 14.

<sup>129</sup>H. Conf. Rep. 101-386, at 515 (1989), *reprinted in* 1989 U.S.C.C.A.N 3018, 3118.

<sup>130</sup>*Id.*

<sup>131</sup>Johnson, Drew and Miletich, *supra* note 114, at 15.

<sup>132</sup>*Id.*

<sup>133</sup>42 U.S.C. 300aa-12(c)(2) and (4).

3.

Petitioners Under the NVICP.

Any person may file a petition for compensation under the NVICP if (1) he or she sustains a vaccine-related injury; or (2) is the legal representative of a minor or disabled person who suffers a vaccine-related injury; or (3) is the legal representative of any person who dies as a result of one of the vaccines specified in the statute.<sup>134</sup> A petitioner may file only one petition with respect to each administration of a vaccine.<sup>135</sup> Petitions are filed with the Court of Federal Claims which immediately forwards the petition to the chief special master for assignment to a special master.<sup>136</sup>

The Secretary of the Health and Human Services (HHS) is the respondent in all proceedings brought under the NVICP<sup>137</sup> and is represented by a team of about eighteen attorneys in the Vaccine Litigation Group of the Office of Constitutional and Specialized Torts at the Department of Justice.<sup>138</sup> Petitioners may proceed under the NVICP either pro se or with counsel; however, almost all petitioners retain attorneys to help them navigate the complexity of the NVICP. A vaccine manufacture can never be a party in a NVICP proceeding.<sup>139</sup>

Congress provided specific rules for NVICP petitioners who filed for compensation when the Vaccine Act became effective—October 1, 1988. A vaccine-

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<sup>134</sup>42 U.S.C. 300aa-11(b)(1)(A).

<sup>135</sup>42 U.S.C. 300aa-11(b)(2).

<sup>136</sup>42 U.S.C. 300aa-11(a)(1).

<sup>137</sup>42 U.S.C. 300aa-12(b)(1).

<sup>138</sup>Johnson, Drew and Miletich, *supra* note 114, at 12.

<sup>139</sup>42 U.S.C. 300aa-11(a)(3).

injured person with a civil action pending at this time could drop the lawsuit within two years of the effective date of the Act and then file a petition under the NVICP.<sup>140</sup> Any plaintiff who did not drop a lawsuit against a vaccine manufacturer could not file a petition under the NVICP.<sup>141</sup> Plaintiffs who sued vaccine manufacturers before the effective date of the Act and recovered nothing for a vaccine-related injury or death could still seek compensation under the NVICP.<sup>142</sup> However, if a plaintiff brought a civil action against a vaccine manufacturer and recovered damages, or settled with the manufacturer, that plaintiff could not file a petition under the NVICP.<sup>143</sup> Finally, Congress ruled that for vaccine injuries and deaths occurring *after* the effective date of the Vaccine Act, a civil action could not be filed against a vaccine manufacturer unless a petition for compensation was first filed and adjudicated under the NVICP.<sup>144</sup> Therefore, presently, all claims for compensation must proceed through the NVICP before the possibility of a civil suit against the manufacturer is even possible. Originally, the Vaccine Act did not allow petitioners to file with the NVICP unless the petitioner incurred over \$1,000 in unreimbursable expenses as a result of a vaccine-related injury.<sup>145</sup> Congress eliminated this requirement on October 21, 1998<sup>146</sup> in order to ensure that Medicaid recipients, military and Indian Health Service dependents and others unable to meet the \$1,000 requirement

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<sup>140</sup>42 U.S.C. 300aa-11(a)(5)(A).

<sup>141</sup>42 U.S.C. 300aa-11(a)(5)(B).

<sup>142</sup>42 U.S.C. 300aa-11(a)(4).

<sup>143</sup>42 U.S.C. 300aa-11(a)(7).

<sup>144</sup>42 U.S.C. 300aa-11(a)(2)(A).

<sup>145</sup>Formerly 42 U.S.C. 300aa-11(c)(1)(D)(i).

<sup>146</sup>P. L. 105-277, § 1502, 112 Stat. 2618-741, *reprinted in* 1998 U.S.C.C.A.N. This section is part of the “Vaccine Injury Compensation Program Modification Act.”



could still file for compensation under the NVICP.<sup>147</sup>

4.

The Vaccine Injury Table.

The Vaccine Injury Table represents one of the most controversial elements of the NVICP because the Table lists the vaccines covered by the NVICP and specifies the injuries presumed to be caused by these vaccines.

a.

Listed Vaccines.

Under the NVICP, petitioners can only recover for injuries or deaths caused by a vaccine listed on the Vaccine Injury Table.<sup>148</sup> The Table includes the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, Hepatitis B, Haemophilus influenzae type B, and varicella (chicken pox) vaccines.<sup>149</sup> Congress recently added Rotavirus for coverage under the NVICP.<sup>150</sup> In addition to listing these vaccines, the Table also includes the injuries presumed to be caused by the vaccine if they occur within a certain stated period of time.<sup>151</sup> A petitioner need not show negligence by the vaccine manufacturer or establish causation if she can demonstrate that she developed one of the

<sup>147</sup>National Vaccine Injury Compensation Program, Summary of Current Issues, Legislative Updates, July 1999, <http://www.hrsa.dhhs.gov/bhpr/vicp/sumcur.htm#7>.

<sup>148</sup>42 U.S.C. 300aa-11(c)(1)(A).

<sup>149</sup>42 U.S.C. 300aa-14(a).

<sup>150</sup>Rotavirus was added to the Vaccine Injury Table on October 22, 1998.

<sup>151</sup>42 U.S.C. 300aa-14(a).

listed vaccine injuries within the stipulated time. For instance, a petitioner who suffers from encephalopathy within 72 hours of a vaccine containing pertussis is entitled to a presumption that the pertussis vaccine caused the petitioner's injury.<sup>152</sup> Petitioners can also recover for injuries that are suffered as a complication of a Table injury if the injury occurs within the specified time period.<sup>153</sup> For example, if the petitioner who suffered encephalopathy from the DPT vaccine also suffers kidney failure as a result of the encephalopathy, then that petitioner can receive compensation for the costs of the kidney failure.<sup>154</sup>

The medical information in the Vaccine Injury Table comes from reports of the American Medical Association and the American Academy of Pediatrics, as well as studies on the adverse reactions of the listed vaccines.<sup>155</sup> The presumption provided by the Vaccine Injury Table is particularly important in light of the limited information available and difficulty in proving that certain vaccines cause certain injuries. Congress recognized the inaccuracy of the Table, stating that "the deeming of vaccine-relatedness adopted [in the Table] may provide compensation to some children whose illness is [sic] not, in fact vaccine-related."<sup>156</sup> Because of this inaccuracy, Congress specifically mandated in the Vaccine Act that studies be conducted of the pertussis vaccine and its related risks, and of the measles/mumps/rubella (MMR) vaccine and its related illnesses and conditions.<sup>157</sup> Congress also required a study of the possible adverse effects of other

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<sup>152</sup>*Id.*

<sup>153</sup>42 U.S.C. 300aa-11(c)(1)(D).

<sup>154</sup>This example was given in H. Rep. 99-908, at 19, *reprinted in* 1986 U.S.C.C.A.N., at 6360.

<sup>155</sup>Johnson, Drew and Miletich, *supra* note 114, at 13.

<sup>156</sup>H. Rep. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N., at 6359.

<sup>157</sup>P. L. 99-660, § 312 (1986). This study was done by the Institute of Medicine and pub-

vaccines administered during childhood.<sup>158</sup>

b. \_\_\_\_\_

Burden of Proof.

If the NVICP petitioner can show that a Table injury occurred within the time period stated in the Table, the petitioner is entitled to a presumption of causation. The burden of persuasion then shifts to HHS, the respondent, to prove by a preponderance of evidence that the “illness, disability, injury, condition or death described in the petition is due to factors unrelated to the administration of the vaccine.”<sup>159</sup>

Petitioners injured by a Table vaccine outside the stated period of time, or injured by a non-Table vaccine, can still receive compensation under the NVICP. Such petitioners have the burden of showing by a preponderance of the evidence that the vaccine caused the petitioner’s injury or death.<sup>160</sup> Congress noted that “simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.”<sup>161</sup> Thus, it is far easier for a petitioner to proceed under the NVICP

if the petitioner can show a Table injury that occurred within the stated time listed in 1991. See Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines, A Report of the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines*, National Academy Press (1991).

<sup>158</sup>P. L. 99-660, § 312 (1986). The Institute of Medicine conducted this report which was published in 1994. See Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, National Academy Press (1994).

<sup>159</sup>42 U.S.C. 300aa-13(a)(1)(B).

<sup>160</sup>42 U.S.C. 300aa-13(a)(1)(A).

<sup>161</sup>H. Rep. 99-908, at 15, *reprinted in* 1986 U.S.C.C.A.N., at 6356.

period.

The Vaccine Injury Table also includes “qualifications and aids” to interpreting the Table.<sup>162</sup> These qualifications and aids to interpretation provide definitions of such terms as “anaphylaxis”, “encephalopathy”, “residual seizure disorder”, “convulsion” and “brachial neuritis”. Symptoms and signs of these conditions are provided, as well as what information is necessary to prove the connection between the vaccine and the disease.

c. \_\_\_\_\_

Revision of the Table.

Modifications can and have been made to the Vaccine Injury Table. The Secretary of HHS has the authority to add injuries to be compensated under the NVICP or to delete listed injuries.<sup>163</sup> The Secretary may also change the time periods set forth in the Table.<sup>164</sup> Before being made, these changes must be reviewed by the Advisory Commission on Childhood Vaccines (ACCV).<sup>165</sup> This Commission is composed of health professionals, members of the public, including representatives of children who have suffered a vaccine-related injury or death, and federal officials, including the Director of the National Institutes of Health, the Director of the CDC, and the Commissioner of the FDA.<sup>166</sup> Any change made to the Vaccine Injury Table applies only to petitions filed after the

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<sup>162</sup>42 U.S.C. 300aa-14(b).

<sup>163</sup>42 U.S.C. 300aa-14(c)(3).

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup>Charter of the Advisory Commission on Childhood Vaccines, located at <http://www.hrsa.dhhs.gov/bhpr/vicp/charter.htm>.

modification has been made.<sup>167</sup>

On February 8, 1995, the Secretary of HHS made changes to the Vaccine Injury Table, severely curtailing the presumption of causation for those injured by the DPT vaccine.<sup>168</sup> The Secretary redefined “encephalopathy” so that the diagnosis of this disease requires more than 24 hours of diminished level of consciousness, “a criterion which is far more restrictive than that of the leading epidemiological study of pertussis vaccine injury.”<sup>169</sup> The Secretary also eliminated “residual seizure disorder” and “hypotonic, hyporesponsive episodes” as compensable injuries following the administration of the DPT vaccine.<sup>170</sup> Parents of an injured child challenged this revision by the Secretary of HHS, but the First Circuit Court of Appeals held that the Vaccine Act grants the Secretary the authority to change the Vaccine Injury Table.<sup>171</sup> Barbara Loe Fisher, the President of the National Vaccine Information Center, argues that “[t]he Secretary’s action to remove signs and conditions long recognized by the medical community as being vaccine-related has fatally compromised the system’s concept of presumption of causation and has unfairly increased the burden of proof for claimants.”<sup>172</sup>

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<sup>167</sup>42 U.S.C. 300aa-14(c)(4).

<sup>168</sup>60 Fed. Reg. 7678-1, *National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table* (February 8, 1995). The regulation became effective March 10, 1995.

<sup>169</sup>Testimony of Marcel Kinsbourne, a pediatric neurologist, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999.

<sup>170</sup>60 Fed. Reg. 7678-1, *supra* note 168.

<sup>171</sup>*O’Connell v. Shalala*, 79 F.3d 170 (1<sup>st</sup> Cir. 1996). *See also Terran v. Sec. of HHS*, 195 F.3d 1302 (Fed. Cir. 1999) (holding that the section of the Vaccine Act authorizing the Secretary of HHS to modify the Vaccine Injury Table does not violate the presentment clause or the nondelegation doctrine).

<sup>172</sup>Testimony of Barbara Loe Fisher, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999.

In order to ensure compensation for all children who suffer injuries by State-mandated vaccines, Congress requires that the Secretary amend the Vaccine Injury Table to include any vaccine recommended by the CDC for routine administration to children.<sup>173</sup> Before the Secretary adds additional vaccines to the Table, Congress must approve an excise tax for each new vaccine in order to ensure the financial stability of the NVICP.<sup>174</sup>

B. \_\_\_\_\_

The NVICP Proceedings.

1. \_\_\_\_\_

Conduct of Proceedings.

In passing the Vaccine Act, Congress specified that the rules applicable to NVICP proceedings must:

(a)

provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(b)

include flexible and informal standards of admissibility of evidence,

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<sup>173</sup>42 U.S.C. 300aa-14(e)(2).

<sup>174</sup>*Id.*

(c)

include the opportunity for summary judgment,

(d)

include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(e)

provide for limitations on discovery and allow special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.<sup>175</sup>

The special masters replaced the Federal Rules of Evidence and the Federal Rules of Civil Procedure with the more streamlined Vaccine Rules of the Office of Special Master of the U.S. Court of Federal Claims.<sup>176</sup> These Vaccine Rules attempt to make the process of receiving compensation for vaccine-related injuries much more informal than the traditional litigation route. The Rules call for an “off-the-record conference” with orally presented tentative findings and

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<sup>175</sup>42 U.S.C. 300aa-12(d)(2).

<sup>176</sup>Rules of the United States Court of Federal Claims, Appendix J—Vaccine Rules of the Office of Special Master of the United States Court of Federal Claims. (Hereinafter “Vaccine Rule.”) These rules can be located: (1) on Lexis in the LITGAT; CLRUL and GENFED; CLRUL databases; (2) on Westlaw in the US-RULES database, (3) in the United States Code Service (USCS) in one of the “Court Rules” volumes covering “Special Courts”, and (4) in the United States Code Annotated (USCA) in the Title 28 “Rules” volume.

conclusions within the first few months of the case,<sup>177</sup> informal telephone status conferences,<sup>178</sup> and informal discovery.<sup>179</sup> The special master is expected to disregard all statutory and common law rules of evidence and to consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties.<sup>180</sup> Furthermore, the special master may receive evidence or argument by telephone<sup>181</sup> and may decide the case without holding an evidentiary hearing.<sup>182</sup>

2.

Petition Content.

A petition to the NVICP must include almost all of the information necessary for the special master to rule on the case. Petitioners in the NVICP term this required initial production of documents “front-end loading.”<sup>183</sup> The practice of front-end loading was instituted in order to speed up the processing of claims and to avoid formal rules of discovery.<sup>184</sup> In addition to providing an affidavit and supporting documents demonstrating the alleged vaccine injury, the petitioner must also submit certain medical records specified by statute. This list of required medical records is quite expansive, including prenatal and birth records, medical records prior to vaccination, post-injury in and out-patient treatment

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<sup>177</sup>Vaccine Rule 5.

<sup>178</sup>Vaccine Rule 6.

<sup>179</sup>Vaccine Rule 7(a).

<sup>180</sup>Vaccine Rule 8(b).

<sup>181</sup>Vaccine Rule 8(b) and (c).

<sup>182</sup>Vaccine Rule 8(d).

<sup>183</sup>Johnson, Drew and Miletich, *supra* note 114, at 25.

<sup>184</sup>*Id.*



records, vaccination records associated with the vaccine allegedly causing the injury, and, if applicable, a death certificate and autopsy results.<sup>185</sup> The petitioner must also identify any required records which are unavailable and the reason for their unavailability.<sup>186</sup>

The respondent, HHS, must review these medical and other records within 30 days and determine whether the HHS can evaluate the merits of the claim based on the submitted documentation. HHS must then file a report which “set[s] forth a full and complete statement of respondent’s position as to why an award should or should not be granted.”<sup>187</sup> This report must contain HHS’s medical analysis of the petitioner’s claims and any legal arguments HHS may have in opposition to the petition.

Special masters and respondents’ attorneys find that front-end loading is helpful because the main issues of the case are apparent from the outset.<sup>188</sup> A few petitioner’s attorneys, however, are not satisfied with the front-end loading process because it is difficult and time-consuming to gather all the required documents, some of which are not even relevant to the claim.<sup>189</sup>

### 3.

#### Experts.

Expert testimony is extremely important to the NVICP because a special

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<sup>185</sup>42 U.S.C. 300-11(c)(2).

<sup>186</sup>42 U.S.C. 300-11(c)(3).

<sup>187</sup>Vaccine Rule 4(a) and (b).

<sup>188</sup>Johnson, Drew and Miletich, *supra* note 114, at 26.

<sup>189</sup>*Id.* at 27.

master may not award compensation to a petitioner “based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion.”<sup>190</sup> Determinations of compensability often require expert testimony on the timing of petitioner’s symptoms, on the medical evidence showing causation, and on the absence of factors unrelated to the administration of the vaccine that may have caused the injury. Because special masters often rely on experts in the NVICP, affidavits of experts must accompany both the petitioner’s and respondent’s initial filings.<sup>191</sup>

Special masters hold hearings with expert testimony in a “high percentage of their cases, with estimates ranging from 30% to 80%.”<sup>192</sup> Experts often testify on both the entitlement and damages issues.<sup>193</sup> Usually, the petitioner and respondent have one expert witness for each issue.<sup>194</sup> Most petitioner experts at the entitlement hearings are the treating physicians of the injured child, although some attorneys for petitioners retain experts who have previously testified at an NVICP hearing.<sup>195</sup> The experts who prepare the respondent’s initial expert report often testify for the respondent, or the respondent hires experts gained through referrals from the Division of Vaccine Injury Compensation at HHS.<sup>196</sup> Special masters, respondents and petitioners all find pediatric neurologists to be the most useful type of testifying witness for the entitlement hearing.<sup>197</sup> Life-care planners and rehabilitation consultants are the experts

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<sup>190</sup>42 U.S.C. 300aa-13(a)(1).

<sup>191</sup>42 U.S.C. 300aa-11(c); Vaccine Rule 4(b).

<sup>192</sup>Johnson, Drew and Miletich, *supra* note 114, at 30.

<sup>193</sup>*Id.*

<sup>194</sup>*Id.*

<sup>195</sup>*Id.* at 31.

<sup>196</sup>*Id.*

<sup>197</sup>*Id.*

most likely to testify on the question of damages.<sup>198</sup>

Although special masters have the authority to retain “independent medical experts to assist in the evaluation of medical issues associated with eligibility for compensation,”<sup>199</sup> special masters have never appointed an expert.<sup>200</sup> One special master explained that special masters don’t utilize court-appointed experts because special masters have the scientific and medical expertise necessary to make a decision, unlike generalist judges.<sup>201</sup> Special masters can also consult sources not presented by the parties, such as medical textbooks and other medical literature.<sup>202</sup> Thus, the special masters of the NVICP feel they do not need court-appointed experts.

Expert witnesses are not only examined and cross-examined by the attorneys for the petitioner and respondent, they are also questioned by the special master, usually after the direct and cross-examination.<sup>203</sup> Sometimes, however, the special master will ask all the questions of an expert witness.<sup>204</sup> A majority of both petitioners’ and respondents’ attorneys believe that this direct examination of experts by the special master is an efficient procedure, so long as the special master waits until after the direct and cross-examination and only asks questions to clarify previous testimony or bring out particular issues.<sup>205</sup> A few attorneys find this practice of questioning experts inappropriate because the

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<sup>198</sup> *Id.*

<sup>199</sup> H. Conf. Rep. 101-386, at 516 (1989) *reprinted in* 1989 U.S.C.C.A.N 3018, at 3118. *See also* 42 U.S.C. 300aa-12(d)(3)(B)(iii).

<sup>200</sup> Johnson, Drew and Miletich, *supra* note 114, at 33.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> *Id.* at 35.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.* at 36.

special master acts as an advocate for one side during the hearing.<sup>206</sup>

C.

Compensation Recoverable.

1.

Financing of Compensation.

Petitioners in the NVICP are compensated differently depending on *when* they suffered a vaccine-related injury.<sup>207</sup> Damage awards for injuries occurring after the effective date of the Vaccine Act are much more generous than those awards for injuries occurring before October 1, 1988.<sup>208</sup> This distinction between pre-Act and post-Act cases is based on the funding provided by Congress. Pre-Act cases are funded by appropriations to HHS.<sup>209</sup> Congress appropriated \$80 million per year for fiscal years 1989 to 1992, and \$110 million per year until pre-Act cases no longer require compensation.<sup>210</sup> Payments for post-Act cases are made from the Vaccine Injury Trust Fund, a fund supported by an excise tax on vaccine sales.<sup>211</sup> This excise tax of 75 cents per dose is imposed on each vaccine covered under the NVICP.<sup>212</sup> About \$1.4 billion is currently available in the Trust Fund to compensate victims who suffer post-Act vaccine-related

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<sup>206</sup> *Id.*

<sup>207</sup> 42 U.S.C. 300aa-15(a) and (b).

<sup>208</sup> Monthly Statistics Report.

<sup>209</sup> 42 U.S.C. 300aa-15(i)(1).

<sup>210</sup> 42 U.S.C. 300aa-15(j).

<sup>211</sup> 42 U.S.C. 300aa-15(i)(2).

<sup>212</sup> Testimony of Thomas E. Balbier, Jr., Director of the NVICP, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, Sept. 28, 1999.

injuries.<sup>213</sup>

2.

Conventional Damages.

Compensation available under the NVICP can be divided into four different types: (1) medical and rehabilitative care, (2) death benefits, (3) lost wages or earnings, and (4) pain and suffering.<sup>214</sup>

First, the NVICP provides compensation for a wide range of both past and future medical care, including the expenses of “rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.”<sup>215</sup> In its report to Congress, the House Committee recognized that “injured children often have special or unusual health care and education needs” and, therefore, the Vaccine Act provides “flexibility in compensation awards by its broad description of compensable care.”<sup>216</sup> Moreover, Congress specifically provided that “the amount of compensation for residential and custodial care... shall be sufficient to enable the compensated person to remain living at home.”<sup>217</sup> Both pre-Act and post-Act petitioners can be compensated for these actual unreimbursable medical

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<sup>213</sup>*Id.*

<sup>214</sup>H. Rep. 99-908, at 21, *reprinted in* 1986 U.S.C.C.A.N., at 6361.

<sup>215</sup>42 U.S.C. 300aa-15(a)(1)(A)(iii)(II) and (a)(1)(b)(iii).

<sup>216</sup>H. Rep. 99-908, at 21, *reprinted in* 1986 U.S.C.C.A.N., at 6361.

<sup>217</sup>42 U.S.C. 300aa-15(c).

and educational expenses.

Both pre and post-Act petitioners can receive only \$250,000 for a vaccine-related death.<sup>218</sup> The post-Act petitioner can receive compensation for actual and anticipated loss of earnings,<sup>219</sup> as well as \$250,000 for actual and projected pain and suffering and emotional distress from the vaccine-related injury.<sup>220</sup> Likewise, the pre-Act petitioner can receive compensation for lost earnings, pain and suffering, and reasonable attorneys' fees and costs, but the combination of these three expenses cannot exceed \$30,000.<sup>221</sup>

The NVICP completely forbids compensation for punitive or exemplary damages.<sup>222</sup> In fact, the NVICP disallows any form of compensation that does not cover the health, education or welfare of the injured person.<sup>223</sup>

### 3. \_\_\_\_\_

#### Costs of Proceedings.

##### a. \_\_\_\_\_

#### Attorneys' Fees.

The NVICP awards compensation to petitioners' attorneys for "reasonable" fees and expenses incurred in bringing a claim for compensation.<sup>224</sup> Even where

<sup>218</sup>42 U.S.C. 300aa-15(a)(2).

<sup>219</sup>42 U.S.C. 300aa-15(a)(3)(A) and (B).

<sup>220</sup>42 U.S.C. 300aa-15(a)(4).

<sup>221</sup>42 U.S.C. 300aa-15(b).

<sup>222</sup>42 U.S.C. 300aa-15(d)(1).

<sup>223</sup>42 U.S.C. 300aa-15(d)(2).

<sup>224</sup>42 U.S.C. 300aa-15(e).

the Court of Federal Claims finds the petitioner ineligible to receive compensation under the Program, the petitioner's attorney may recover fees and costs, so long as the petition for compensation was "brought in good faith and there was a reasonable basis for the claim. . . ." <sup>225</sup> The determination of the reasonable amount of attorneys' fees and costs is entirely within the discretion of the special master, and a special master may use her knowledge of attorneys' billing practices in comparison with those of other attorneys regularly engaging in NVICP compensation proceedings to help determine the reasonableness of claimed fees under particular circumstances. <sup>226</sup>

Attorneys' fees are calculated in the NVICP by using the lodestar method of multiplying the reasonable amount of hours expended by a reasonable rate per hour depending on the facts of the case. <sup>227</sup> Awarding between \$90 and \$300 per hour, courts determine the reasonableness of an attorney's hourly rate in a particular case by looking at the normal compensation rates for attorneys, the difficulty of the work in question, the skill level of the attorney involved, and other like factors. <sup>228</sup> Even though all petitioners' attorneys with a good faith basis for a claim receive money for fees and expenses, those attorneys who suc-

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<sup>225</sup>42 U.S.C. 300aa-15(e)(1).

<sup>226</sup>*Saxton v Secretary of HHS*, 3 F.3d 1517 (1993).

<sup>227</sup>See *Monteverdi v. Secretary of HHS*, 19 Cl. Ct. 409, 414 (1990); *Dunham v. Secretary of HHS*, 18 Cl. Ct. 633, 641 (1989).

<sup>228</sup>See *Willcox v. Secretary of HHS*, 18 Cl. Ct. 870 (1989)(awarding \$125 per hour for an Anderson, Indiana attorney); *Clark v. Secretary of HHS*, 19 Cl. Ct. 113 (1989)(awarding \$292.30 per hour for partners in a law firm); *Whitledge v. Secretary of HHS*, 19 Cl. Ct. 144 (1989)(awarding \$225 per hour for Boston attorneys); *Doe v. Secretary of HHS*, 19 Cl. Ct. 439 (1990)(awarding \$90 per hour for a general practitioner in Vermont); and *Holton v. Secretary of HHS*, 24 Cl. Ct. 391 (1991)(awarding \$200 per hour for an experienced litigation partner from Sacramento, California and \$100 per hour for an inexperienced associate of the same firm).

cessfully bring a petition for a vaccine injury receive more compensation than those attorneys who lose claims in the NVICP.<sup>229</sup> Based on 786 petitioners whose requests for compensation generated published opinions, successful attorneys received a mean fee of \$22,052 (+/-8671), while unsuccessful attorneys received a mean fee of only \$14,053 (+/-8749).<sup>230</sup> Attorneys may not charge the petitioner any additional fees in order to supplement the award made by the special master.<sup>231</sup>

The awarding of attorneys' fees has been the subject of dispute in more NVICP decisions than any other aspect of the Program.<sup>232</sup> More than 250, or 28%, of the published special master decisions address questions about allowable attorneys fees and expenses.<sup>233</sup> Five appellate court decisions discuss attorneys' fees as well.<sup>234</sup> Attorneys in the program complain that the fees are inadequate and take too long to process, and the procedure under which government attorneys review and comment on petitioners' attorneys' fees is unfair.<sup>235</sup> Attorneys comment that "[b]ecause of the restrictions on attorneys' fees there are few experienced attorneys willing to handle these unusual cases" and that "[t]he low fees awarded to attorneys discourage claims under the [Vaccine] Act."<sup>236</sup>

Because attorneys are not adequately compensated for their work in the NVICP, there exists a real threat that attorneys will not be available to litigate these

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<sup>229</sup>Derry Ridgeway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. Health, Pol. Pol'y & L. 59, 75 (February 1999).

<sup>230</sup>*Id.*

<sup>231</sup>42 U.S.C. 300aa-15(e)(3).

<sup>232</sup>Ridgeway, *supra* note 229, at 75.

<sup>233</sup>*Id.*

<sup>234</sup>*Id.*

<sup>235</sup>Johnson, Drew and Miletich, *supra* note 114, at 45.

<sup>236</sup>*Id.*



vaccine-injury claims, and that the ones who are available will not be the most competent or successful attorneys.<sup>237</sup> The court is, in essence, prescribing a lower level of attorney quality by setting attorney fees at such reduced rates.<sup>238</sup> Moreover, because the Vaccine Act establishes a \$30,000 cap on pre-Act compensation for loss of earnings, pain and suffering and attorneys fees,<sup>239</sup> an attorneys' interest in being paid is in direct conflict with her client's interest in receiving compensation for an injury.<sup>240</sup> This cap may force attorneys to limit hours spent on a pre-Act injury case or to forego an appeal.<sup>241</sup>

b. \_\_\_\_\_

Fees of Experts.

In addition to attorneys' fees, the Vaccine Act specifically awards compensation for costs incurred by an attorney in any proceeding on a petition.<sup>242</sup> Thus, the fees of expert witnesses are expenses of the petitioner's attorney and, therefore, paid in the same manner as attorneys' fees. Because of the importance of expert testimony from doctors and other highly trained medical professionals in proceedings for compensation under the NVICP, one court held that the \$30 per day cap on recoverable expenses for expert testimony contained in Federal Rules of Civil Procedure would not apply to the NVICP.<sup>243</sup> However, special

<sup>237</sup>See Lisa J. Steel, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?* 63 Geo. Wash. L. Rev. 144, 164 (Nov. 1994); Ridgeway, *supra* note 229, at 75.

<sup>238</sup>*Id.*

<sup>239</sup>42 U.S.C. 300aa-15(b).

<sup>240</sup>Steel, *supra* note 237, at 165.

<sup>241</sup>*Id.*

<sup>242</sup>42 U.S.C. 300aa-15(e)(1).

<sup>243</sup>*Strother v. Secretary of HHS*, 18 Cl. Ct. 816, at 826 (1989), *on remand*, 1990 WL 299273

masters may completely deny compensation for an expert medical witness if the special master deems the testimony of the expert to be unreasonable.<sup>244</sup> The special master may also reduce a requested fee found to be unreasonable under the circumstances of the case.<sup>245</sup> These restrictions on compensation for expert medical witnesses may prevent petitioners from hiring the most qualified experts<sup>246</sup> and, therefore, hurt the ability of petitioners to recover for vaccine-related injuries.

#### 4.

##### Process for Appeals.

Both the petitioner and the respondent can apply to the U.S. Court of Federal Claims for review of the special master's decision.<sup>247</sup> The Court of Federal Claims may then take one of three actions: (1) sustain the special master's decision; (2) set aside the special master's decision as "arbitrary, capricious, an abuse of discretion..."; or (3) remand the petition for further action.<sup>248</sup> If neither party objects to the special master's decision, the Court of Federal Claims immediately enters judgment in accordance with the decision of the

(Cl. Ct. 1990), order entered by, 21 Cl. Ct. 365 (Fed. Cir. 1990), aff'd, 950 F2d 731 (Fed Cir. 1991).

<sup>244</sup>See *Perreira v. Secretary of HHS*, 27 Fed. Cl. 29 (1992), *aff'd*, 33 F.3d 1375 (Fed. Cir. 1994)(finding that the petitioner had no definitive medical evidence to support the claim and, therefore, the testimony of the medical expert was found to be unreasonable and not compensable).

<sup>245</sup>See *Estrada v. Secretary of HHS*, 29 Fed. Cl. 78 (1993)(approving the special master's reduction of the reimbursement for fees paid to a lifecare planner in establishing the projected expenses of care for the petitioner's son because the special master found the expert's role in the case to be minimal).

<sup>246</sup>Steel, *supra* note 237, at 166.

<sup>247</sup>42 U.S.C. 300aa-12(e)(1).

<sup>248</sup>42 U.S.C. 300aa-12(e)(2).

special master.<sup>249</sup> However, if either party disagrees with the decision of the Court of Federal Claims, an appeal can be made to the Court of Appeals for the Federal Circuit.<sup>250</sup> The Court of Appeals applies de novo review of the determination of the Court of Federal Claims as to whether the special master’s decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.<sup>251</sup> Two cases refer to this standard of review as a “highly deferential”<sup>252</sup> and, therefore, it is very unlikely that a special master’s decision will be overturned.

After the Court of Federal Claims enters its judgment, or the Court of Appeals for the Federal Circuit rules on an appeal, the petitioner must elect either (1) to accept the judgment, whether compensation is awarded or not, or (2) to file a civil action for damages for the vaccine-related injury or death.<sup>253</sup> An “election” must be made within 90 days of the judgment.<sup>254</sup> If a petitioner accepts the compensation awarded or the judgment of the court, the petitioner is then barred from bringing a civil action for damages against a vaccine manufacturer or administrator.<sup>255</sup> Therefore, after the whole process of the NVICP, a petitioner may ultimately reject the judgment of the Court of Federal Claims and proceed with a civil action against the manufacturer of the vaccine that caused the injury or death. However, as will be seen in the next chapter, the Vaccine

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<sup>249</sup>42 U.S.C. 300aa-12(e)(3).

<sup>250</sup>42 U.S.C. 300aa-12(f).

<sup>251</sup>*Cucuras v. HHS*, 993 F.2d 1525, 1527 (Fed. Cir. 1993); *Jay v. HHS*, 998 F.2d 979, 982 (Fed. Cir. 1993); *Hellebrand v. HHS*, 999 F.2d 1565, 1569 (Fed. Cir. 1993).

<sup>252</sup>*Cucuras*, 993 F.2d at 1527; *Munn v. Secretary of HHS*, 970 F.2d. 863, 869 (Fed. Cir. 1992).

<sup>253</sup>42 U.S.C. 300aa-21(a); Vaccine Rule 33(a).

<sup>254</sup>*Id.*

<sup>255</sup>*Id.*

Act limits the liability of vaccine manufacturers sued by petitioners who reject the NVICP judgment.<sup>256</sup>

D.

Program Statistics.

1.

Petitions Filed.

As of March 7, 2000, a total of 5,773 petitions have been filed under the NVICP.<sup>257</sup> Petitioners filed 4,254 petitions for pre-Act injuries, while 1,519 petitions have been filed for post-Act injuries.<sup>258</sup> Almost all of the pre-Act claims have been fully adjudicated, and all remaining pre-Act claims are in the adjudication process. Of all the claims filed under the NVICP, the largest percentage of the petitions (around 70%) allege an injury or death caused by the pertussis vaccine.<sup>259</sup> Although adults can receive compensation under the NVICP, the vast majority of claims have been filed on behalf of children injured or killed by vaccines.<sup>260</sup>

2.

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<sup>256</sup>42 U.S.C. 300aa-22.

<sup>257</sup>Monthly Statistics Report.

<sup>258</sup>*Id.*

<sup>259</sup>Johnson, Drew and Miletich, *supra* note 114, at 19.

<sup>260</sup>Ridgway, *supra* note 229, at 64.

Adjudication.

The special masters of the NVICP adjudicated 5,083 cases as of March 7, 2000.<sup>261</sup> The special masters found 1,515 petitions eligible for compensation, while 3,568 cases have been dismissed or found not compensable.<sup>262</sup> The NVICP, therefore, dismisses more than two-thirds of all petitions filed. This staggering statistic has led many to believe that the NVICP is not working and is unfair to petitioners.<sup>263</sup>

### 3. —

#### Awards.

So far, \$1,115 million has been paid in awards and attorneys' fees—\$821.6 million for pre-Act cases and \$293.4 million in post-Act cases.<sup>264</sup> Individual awards range from one hundred and twenty dollars to \$8.4 million.<sup>265</sup> Compensation is more frequently awarded in post-Act cases as compared with Pre-Act cases.<sup>266</sup> For example, the 1999 pre-Act injury award average was \$855,474 (58 cases), while the 1999 post-Act injury award average was \$1,433,319 (33 cases).<sup>267</sup> Obviously, the highest award amounts are in vaccine injury cases since compensation for death is capped at \$250,000 plus reasonable attorneys' fees and costs.

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<sup>261</sup>Monthly Statistics Report.

<sup>262</sup>*Id.*

<sup>263</sup>Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 Wm & Mary L. Rev. 309, 320 (December 1999); Steel, *supra* note 237, at 173.

<sup>264</sup>Monthly Statistics Report.

<sup>265</sup>*Id.*

<sup>266</sup>Johnson, Drew and Miletich, *supra* note 114, at 21.

<sup>267</sup>Monthly Statistics Report.

## Chapter IV.

### The Liability of Vaccine Manufacturers after the National Vaccine Injury Compensation Program

Congress could have made the Vaccine Act the only avenue of compensation for people injured or killed by vaccines. Instead, Congress leaves vaccine manufacturers liable under state law for damages to those petitioners who reject the judgment of the NVICP. In this way, Congress preserves the traditional authority of states to hold manufacturers liable for defective products.<sup>268</sup> The Vaccine Act, however, does place certain restrictions on the civil actions brought by petitioners rejecting the judgment of the NVICP. The Act limits the liability of vaccine manufacturers in four important ways.

#### A. \_\_\_\_\_

##### NVICP Limitations on Manufacturer Liability.

#### 1. \_\_\_\_\_

##### Unavoidable Adverse Side Effects.

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<sup>268</sup>See *Abbot v. American Cyanamid*, 844 F.2d 1108 (4<sup>th</sup> Cir. 1988)(holding that the federal law regulating vaccine design and labeling does not preempt state common-law liability for design defect or failure to warn).

First, the Act relieves manufacturers from liability for injuries caused by the unavoidable side effects of vaccines, as long as the vaccines are properly prepared and accompanied by adequate warnings.<sup>269</sup> In this way, the Act adopts comment k to § 402A of the Restatement of Torts, which provides an exception to the strict liability doctrine for unavoidably unsafe products.<sup>270</sup> Congress decided to apply comment k to every vaccine covered by the Act because of the fear that sympathetic juries will “find it difficult to rule in favor of the ‘innocent’ manufacturer if the equally ‘innocent’ child has to bear the risk of loss with no other possibility of recompense.”<sup>271</sup> By providing immunity for vaccine manufacturers who adequately prepare and label vaccines, Congress sought to fulfill one of its main goals of the Act—the protection of the vaccine supply and the few remaining manufacturers of vaccines. Congress argued that because the Vaccine Act includes a compensation program, “comment k is appropriate and necessary as the policy for civil actions seeking damages in tort.”<sup>272</sup>

Criticism has been made that the blanket application of comment k removes incentives for vaccine manufacturers to improve the design of their products.<sup>273</sup> By insulating manufacturers who properly prepare and label their vaccines, “the Vaccine Act implicitly announces that the Federal Government is satisfied with the current state of vaccine safety, and that the Government will not use the tort system to encourage manufacturers to improve their vaccines.”<sup>274</sup>

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<sup>269</sup>42 U.S.C. 300aa-22(b)(1).

<sup>270</sup>H. Rep. 99-908, at 25-26, reprinted in 1986 U.S.C.C.A.N., at 6366-67.

<sup>271</sup>*Id.* at 26, reprinted in 1986 U.S.C.C.A.N., at 6367.

<sup>272</sup>*Id.*

<sup>273</sup>Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons From the Vaccine Act*, 44 Am. U. L. Rev. 1853, 1896 (June 1995).

<sup>274</sup>*Id.*

In fact, the scientific history of the DPT vaccine illustrates that the government has known about a safer pertussis vaccine since the 1950's, but has not mandated the production of this non-cellular version of the vaccine.<sup>275</sup> Currently, most vaccine manufacturers only make the whole-cell pertussis vaccine, a vaccine from which the disease-causing element of pertussis is not removed. However, in 1961, the FDA approved the non-cellular pertussis vaccine of Eli Lilly & Company.<sup>276</sup> Tests done in 1967 comparing the non-cellular and whole-cellular pertussis vaccines showed that the whole-cellular vaccine had a much higher rate of adverse effects than the non-cellular vaccine.<sup>277</sup> Eli Lilly stopped producing the non-cellular pertussis vaccine in 1971, and Wyeth Laboratories attempted to purchase Eli Lilly's license; but, because FDA regulations require manufacturers of the same vaccines to have separate licenses, Wyeth could not purchase the license from Lilly.<sup>278</sup> Wyeth, instead, produced its own non-cellular pertussis vaccine, which the FDA refused to license due to possible toxicity and a lack of evidence proving that the non-cellular vaccine was better than the whole cell pertussis vaccine.<sup>279</sup> More recently, the FDA licensed a purified, less reactive acellular pertussis vaccine, DtaP, and the CDC recommended its use for older children in 1991 and for infants in 1996.<sup>280</sup> Thus, in light of this history, the pertussis component of the vaccine may not be an "unavoidably unsafe"

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<sup>275</sup>*Id.* at 1891.

<sup>276</sup>*Id.*

<sup>277</sup>*Id.*

<sup>278</sup>*Id.*

<sup>279</sup>*Id.* at 1892.

<sup>280</sup>Testimony of Barbara Loe Fisher, President of the National Vaccine Information Center, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999. (Hereinafter "Testimony of Fisher").



product deserving comment k protection.<sup>281</sup>

2.

Statutory Presumption of Due Care in Packaging and Warning.

Second, the Vaccine Act creates a presumption that a vaccine is properly labeled and accompanied by adequate warnings if the vaccine manufacturer can show that it complied with FDA standards governing the approval and labeling of the vaccine.<sup>282</sup> Thus, a vaccine manufacturer will not be held liable if it can show that it followed all requirements under 21 U.S.C. § 301 et seq. of the Federal Food, Drug and Cosmetic Act (described in chapter I above) and under 41 U.S.C. §262 of the Public Health Service Act.<sup>283</sup>

This presumption can be overcome, however, but only upon a demonstration that (1) the manufacturer engaged in fraudulent conduct or intentionally withheld information in obtaining premarket approval from the FDA;<sup>284</sup> or (2) the manufacturer intentionally withheld information relating to the safety or efficacy of the vaccine after its approval;<sup>285</sup> or (3) it is shown by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with the FDCA and the PHSA.<sup>286</sup> Congress explained that the establishment of this presumption was intended “to make clear its view that only

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<sup>281</sup>Cantor, *supra* note 273, at 1892.

<sup>282</sup>42 U.S.C. 300aa-22(b)(2).

<sup>283</sup>*Id.*

<sup>284</sup>42 U.S.C. 300aa-22(b)(2)(A); 42 U.S.C. 300aa-23(d)(2)(A).

<sup>285</sup>42 U.S.C. 300aa-22(b)(2)(A); 42 U.S.C. 300aa-23(d)(2)(B).

<sup>286</sup>42 U.S.C. 300aa-22(b)(2)(B).

those significant failures to warn or provide directions that clearly pertain to vaccine safety and that clearly arise from substantial wrongdoing on the part of the manufacturer ought to result in liability.”<sup>287</sup>

### 3.

#### Direct Warnings.

Third, the Vaccine Act prohibits claims based on the vaccine manufacturer’s failure to provide direct warnings to the vaccine recipient.<sup>288</sup> Thus, the Act adopts the learned intermediary doctrine described in chapter II above, which states that a manufacturer is not held liable for any failure to warn if the manufacturer provides adequate warning to a learned intermediary such as a doctor, nurse or pharmacist. This learned intermediary is expected to know about the vaccine and to take responsibility for informing the vaccine recipient about the benefits and risks of the vaccine.<sup>289</sup>

There are, however, dangers to the NVICP’s adoption of the learned intermediary doctrine. First, as discussed above, most vaccinations are given at mass immunization clinics. Therefore, the learned intermediary rule of the NVICP does not protect children who do not have the benefit of a one-on-one relationship with a doctor when they are vaccinated.<sup>290</sup> These children and their parents may not be able to balance the benefits and risks of vaccination to them

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<sup>287</sup>H. Rep. 99-908, at 26, *reprinted in* 1986 U.S.C.C.A.N., at 6367.

<sup>288</sup>42 U.S.C. 300aa-22(c).

<sup>289</sup>H. Rep. 99-908, at 27, *reprinted in* 1986 U.S.C.C.A.N., at 6368.

<sup>290</sup>Cantor, *supra* note 273, at 1868.

individually.<sup>291</sup> Also, they will not have the requisite information to identify the signs of an adverse reaction to a vaccine.<sup>292</sup>

Second, even in the private physician's office, vaccinees and their parents may not receive information about the vaccine to be administered because the law of informed consent does not require the physician to disclose fully all the risks associated with a vaccine. Informed consent means only that the physician provides the patient with information ordinarily given as part of "customary practice".<sup>293</sup> Often physicians will not warn patients about the risks of a vaccine because the child or parent may reject the vaccine, unreasonably fearing the slight possibility of an adverse reaction.<sup>294</sup> One doctor commented in a deposition:

My feeling . . . was that there is an extremely minute percentage of people who will have the complications from the drug. I felt that, again, because I had never experienced [other practicing physicians] giving these warnings, it . . . wasn't necessary for me to do it; and . . . I felt . . . that giving the warning . . . could scare off parents from bringing children in for future vaccinations, which to me were much more important than the warning itself for the few number of people who are going to contract the disease. . . .<sup>295</sup>

Also, in the context of managed care, where doctors have an average of 12 minutes to treat a patient, providing warnings of vaccines simply may not be feasible within the given time restraints. Moreover, physicians may be swayed by the pro-vaccine environment of the United States, where all 50 states require vaccination to enter school and the President pronounces that vaccination

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<sup>291</sup> *Id.*

<sup>292</sup> *Id.* at 1873-74.

<sup>293</sup> *Id.* citing *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972).

<sup>294</sup> Cantor, *supra* note 273, at 1869.

<sup>295</sup> *Plummer v. Lederle Laboratories*, 819 F. 2d 349, 352 (2d Cir. 1987).

“ought to be like clean water and clean air. . . It ought to be part of the fabric of our life.”<sup>296</sup>

In Subpart C of the Vaccine Act—Assuring a Safer Childhood Vaccination Program in United States, Congress does attempt to remedy the fact that manufacturers are not required to provide direct information to the vaccine recipient. By requiring physicians who administer vaccines to record and report information about adverse reactions to vaccines,<sup>297</sup> the Vaccine Act helps to reestablish individualized risk assessments regarding vaccines.<sup>298</sup> For example, because of the reporting requirements, the physician of a child who suffers an adverse reaction to the first administration of the DPT vaccine may not give, or may delay, the second and third DPT doses.<sup>299</sup>

The Vaccine Act also requires the Secretary of HHS to “develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table.”<sup>300</sup> These materials must be published in the Federal Register<sup>301</sup> and allowed 60 days of public comment.<sup>302</sup> The Secretary of HHS develops and devises the vaccine information materials in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the CDC, and the FDA.<sup>303</sup> The materials

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<sup>296</sup>Cantor, *supra* note 273, at 1855, citing Paul Richter, *Child Vaccination Program is Pushed Health*, L.A. Times, Feb. 13, 1993, at A1.

<sup>297</sup>42 U.S.C. 300aa-25(a) and (b).

<sup>298</sup>Cantor, *supra* note 273, at 1874.

<sup>299</sup>*Id.*

<sup>300</sup>42 U.S.C. 300aa-26(a).

<sup>301</sup>42 U.S.C. 300aa-26(a).

<sup>302</sup>42 U.S.C. 300aa-26(b)(1).

<sup>303</sup>42 U.S.C. 300aa-26(b)(2).

must provide a concise description of both the benefits and risks of the vaccine, as well as a statement of the availability of the NVICP.<sup>304</sup> Health care providers must directly furnish this vaccine information to any recipient of a Table vaccine.<sup>305</sup> This information allows vaccine recipients and parents to weigh the benefits and risks of vaccination, and also gives vaccinees the knowledge necessary to spot an adverse reaction to a vaccine.

One must question whether the recording and informational requirements of the Vaccine Act adequately compensate for the protection lost by eliminating direct failure to warn causes of action against vaccine manufacturers.<sup>306</sup>

#### 4. \_\_\_\_\_

#### Punitive Damages.

Fourth, and finally, the Vaccine Act does not allow a claimant to recover punitive damages against a manufacturer who complied with the vaccine safety provisions of the FDCA and the PHSA, unless the manufacturer engaged in fraudulent conduct, or intentionally and wrongfully withheld information, or engaged in other criminal or illegal activity relating to the safety and effectiveness of vaccines.<sup>307</sup> Congress instituted this provision because “punitive damages should be assessed only where particularly reprehensible, conscious behavior is involved.”<sup>308</sup>

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<sup>304</sup>42 U.S.C. 300aa-26(c).

<sup>305</sup>42 U.S.C. 300aa-26(d).

<sup>306</sup>Cantor, *supra* note 273, at 1874.

<sup>307</sup>42 U.S.C. 300aa-23(d).

<sup>308</sup>H. Rep. 99-908, at 23, *reprinted in* 1986 U.S.C.C.A.N., at 6369.

B.

Restriction on Evidence from the NVICP.

In any stage of a civil action, the Vaccine Act forbids the introduction in evidence of the Vaccine Injury Table, any finding of fact or conclusion of law of the Court of Federal Claims or a special master, and the final judgment of the NVICP.<sup>309</sup> Thus, NVICP petitioners basically start over when they elect to bring a civil action against a vaccine manufacturer. Congress excludes this NVICP information because NVICP “[c]ompensation standards, evidence, and proceedings are sufficiently different from civil proceedings...that the findings made in compensation are not likely to be based on the more rigorous requirements of a tort proceeding and might confuse such civil actions.”<sup>310</sup>

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<sup>309</sup>42 U.S.C. 300aa-23(e).

<sup>310</sup>H. Rep. 99-908, at 29, *reprinted in* 1986 U.S.C.C.A.N., at 6370.

## Chapter V.

### Has the NVICP Achieved Its Goals?

#### Proposals for Reform

Congress established the National Vaccine Injury Compensation Program in order to accomplish two goals: (1) protection of the vaccine supply and the reduction of litigation against vaccine manufacturers and (2) compensation of individuals injured or killed by vaccines. How successful is the NVICP in achieving these two goals?

##### A. \_\_\_\_\_

##### First Goal: Protecting the Vaccine Supply and Reducing Vaccine Litigation.

There is ample proof that the vaccine supply is now stable. The Children's Defense Fund reports that between 1992 and 1997, immunization rates among children increased dramatically.<sup>311</sup> Since its institution, the NVICP has expanded to include four additional vaccines—Hepatitis B, Haemophilus influenzae type B, varicella, and rotavirus. Moreover, since 1990, no commercial manufacturer has left the vaccine market.<sup>312</sup> In fact, there are more than 300 vaccines

<sup>311</sup>Testimony of the Children's Defense Fund before the House Government Reform Comm., on "Vaccines: Finding a Balance Between Public Safety and Personal Choice," August 3, 1999.

<sup>312</sup>Ridgway, *supra* note 229, at 76.

in various stages of research and development, including an AIDs vaccine.<sup>313</sup> Thus, the NVICP appears successful in ensuring access to vaccines. Likewise, there has been a reduction in litigation against vaccine manufacturers. Since the establishment of the NVICP, civil actions against vaccine manufacturers have all but disappeared.<sup>314</sup> Because claims for vaccine-related injuries and deaths are now channeled through the NVICP, and because petitioners who reject the judgment of the NVICP can only sue vaccine manufacturers on limited theories of liability, very few claims have been filed in tort against vaccine manufacturers. In fact, before February 1999, not one post-NVICP civil case has been decided at the appellate level.<sup>315</sup> A vaccine-injured person who receives an award from the NVICP is not likely “to give up that bird in the hand in return for a larger, but more speculative, tort law award.”<sup>316</sup> Moreover, petitioners who lose their claims in the NVICP under the relaxed rules of evidence, “may see no point in trying to overcome tort law’s more serious obstacles to recovery.”<sup>317</sup> Likewise, losing attorneys who have already been compensated by the NVICP have little incentive to pursue a civil action.<sup>318</sup> Therefore, the NVICP does appear to reduce the liability and litigation expenses of vaccine manufacturers.

One case from the First Circuit Court of Appeals, however, provides a new theory under which vaccine-injured people may sue vaccine manufacturers. The

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<sup>313</sup>Testimony of Thomas E. Balbier, Jr., Director of the NVICP, before the House Government Reform Comm., Subcomm. on Criminal Justice, Drug Policy and Human Resources, September 28, 1999.

<sup>314</sup>Ridgway, *supra* note 229, at 77.

<sup>315</sup>*Id.*

<sup>316</sup>*Schafer v. American Cyanamid Co.*, 20 F.2d 1, 6 (1<sup>st</sup> Cir. 1994).

<sup>317</sup>*Id.*

<sup>318</sup>Ridgway, *supra* note 229, at 78.



court in *Schafer v. American Cyanamid*<sup>319</sup> held that the families of those injured by vaccines can sue for loss of companionship and consortium even after the vaccine-injured person has received an award from the NVICP. In *Schafer*, the mother of a child vaccinated against polio actually contracted the disease and accepted an award of \$750,000 from the NVICP.<sup>320</sup> American Cyanamid argued that to allow the child and father to sue in tort for damages would so seriously interfere with the Vaccine Act's basic purposes that the court must read the Act as implicitly barring their claim, just as the Act bars a civil action by the mother.<sup>321</sup> The court reasoned that this interpretation of the Act does not follow the text or the legislative history of the Act, and would impermissibly preempt state law.<sup>322</sup> It remains to be seen how many individuals actually use this theory of liability as a means of recovering damages from vaccine manufacturers in addition to awards made by the NVICP.

On the whole, the NVICP has done a particularly good job at achieving the first goal of Congress in passing the Vaccine Act. Vaccines are available and at reasonable costs due to the reduction of litigation against vaccine manufacturers. Manufacturers continue to produce old vaccines and are developing new vaccines for administration to the children of the United States. Unfortunately, the NVICP has not been as successful in fulfilling Congress's second goal.

B.

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<sup>319</sup>20 F.3d 1 (1<sup>st</sup> Cir. 1994).

<sup>320</sup>*Id.* at 3.

<sup>321</sup>*Id.*

<sup>322</sup>*Id.* at 5-7.

## Second Goal: Compensating Injured Vaccinees.

Congress intended the NVICP to operate in a quick, easy and fair manner, with compensation awarded generously. The NVICP was also designed to be non-adversarial and accommodating to the unique and tragic claims of children injured or killed by vaccines. In many ways, the NVICP has failed to achieve these objectives. The September 28, 1999 testimony before the House Committee on Government Reform highlights this failing of the NVICP to compensate fairly, efficiently and adequately those who suffer because of the universal vaccination policy of the United States. The hearing, entitled “Compensating Vaccine Injuries: Are Reforms Needed?”, demonstrates the recent and ongoing dissatisfaction with the compensation goal of the NVICP and suggests reforms to correct the NVICP.<sup>323</sup> Within the context of this hearing, this section will discuss the major inadequacies of the NVICP and propose changes so that the NVICP can achieve its original goal of generously compensating injured vaccinees.

### 1. \_\_\_\_\_

#### Length of NVICP Proceedings.

The Vaccine Act mandates that a special master’s decision “be issued as expeditiously as practicable but not later than 240 days...after the date the petition was filed.”<sup>324</sup> Thus, Congress intended the proceedings of the NVICP

<sup>323</sup>Testimony before the House Government Reform Comm., Subcomm. on Criminal Justice, Drug Policy and Human Resources, September 28, 1999.

<sup>324</sup>42 U.S.C. 300aa-12(d)(3)(A)(ii).

to last no longer than eight months. However, many cases continue for years, sometimes taking up to nine years to reach a final determination.<sup>325</sup> One parent testified that it took seven and a half years from the time she applied to the NVICP to the time she gained access to the funds awarded.<sup>326</sup> Moreover, of the 67 petitioner's attorneys responding to a questionnaire sent by the Federal Judicial Center, 38% said that the time from filing a petition to disposition of the case in a traditional civil action is "shorter" or "much shorter" than the NVICP proceedings.<sup>327</sup> 31% said that the timing of NVICP proceedings and traditional civil litigation is "about the same."<sup>328</sup> Only 27% responded that civil litigation takes "longer" or "much longer" than the NVICP.<sup>329</sup> Thus, more than two-thirds of the attorneys surveyed stated that the NVICP takes the same amount of time or longer than traditional litigation.

The Deputy Director of the Torts Branch of the Justice Department, John Lodge Euler, argues that lengthy NVICP proceedings can be attributed to the extreme complexity of the medical issues, the difficulty in determining a "custom tailored plan of lifetime medical care", and the unavailability of documentation from petitioners to support requests for specific items of compensation.<sup>330</sup>

In order to eradicate these time-consuming aspects of the NVICP, the establish-

<sup>325</sup>Testimony of Comm. Chairman John L. Mica before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999. (Hereinafter "Testimony of Mica").

<sup>326</sup>Testimony of Linda Mulhauser, parent, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999. (Hereinafter "Testimony of Mulhauser").

<sup>327</sup>Johnson, Drew and Miletich, *supra* note 114, at 47.

<sup>328</sup>*Id.*

<sup>329</sup>*Id.*

<sup>330</sup>Testimony of John Lodge Euler, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999.

ment of causation should be simplified (more on this below). Moreover, once the special master determines eligibility for compensation, the Justice Department should step away from the case and not participate in the determination of damages. One mother explains that after the special master deemed her son eligible for compensation, she and her attorney had “an item by item fight to obtain even the smallest needs on [her son’s] life care plan.”<sup>331</sup> The DOJ attorney even contested such “petty matters” as whether the injured vaccinee would benefit from a \$10 special needs door knob.<sup>332</sup> This mother described her experience with the NVICP as “a totally exhausting and extremely adversarial process of nickel and dime arguments.”<sup>333</sup> This type of adversarial adjudication, especially when a child has already been found harmed by a vaccine, so contradicts the original design of the NVICP that it must be changed. A fair and generous settlement should be reached soon after eligibility for compensation has been determined. Hearings during the damages phase of NVICP cases should be strictly avoided. In his opening remarks at the hearing on vaccine compensation reform, Committee Chairman Mica raised the possibility that the government favor and facilitate mediation in place of the present NVICP litigation.<sup>334</sup> Further investigation into this alternative may prove useful in alleviating the lengthy process encountered by NVICP petitioners stuck in the damages phase of the proceedings.

One particularly troubling problem arises because of the extreme length of the

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<sup>331</sup>Testimony of Mulhauser.

<sup>332</sup>*Id.*

<sup>333</sup>*Id.*

<sup>334</sup>Testimony of Mica.

NVICP process. Attorneys are unwilling to take these vaccine injury claims because they are paid so little and paid *after* the case has ended. One petitioner’s attorney stated that “[m]y fees and costs were handled in such a way that my firm had to ‘carry’ me for years and we lost a great deal of money by virtue of my participation in the Program.”<sup>335</sup> NVICP attorneys will be paid no matter if they win or lose the case. Why not allow petitioners’ attorneys to receive interim payments for fees and costs during the entire compensation process?<sup>336</sup> In this way, attorneys will not have to wait up to nine years to be paid for their work in the NVICP. Because NVICP proceedings take so long to resolve, interim payments will allow petitioners’ attorneys to remain in the NVICP and will level the playing field between these attorneys and the salaried attorneys and experts of the respondent.<sup>337</sup>

2. \_\_\_\_\_

Adversarial Nature of Proceedings.

As pointed out above by one disappointed parent, the NVICP has been anything but non-adversarial. Even the special masters who hear NVICP claims believe that the attorneys for the respondent are “over-litigating” and “behaving like adversaries,” contrary to what Congress intended.<sup>338</sup> Petitioner’s attorneys’ comments about the adversarial nature of the NVICP include:

“The intent of the program has been lost because the government lawyers

<sup>335</sup>Johnson, Drew and Miletich, *supra* note 114, at 45.

<sup>336</sup>Testimony of Fisher.

<sup>337</sup>*Id.*

<sup>338</sup>Johnson, Drew and Miletich, *supra* note 114, at 44.

want to defeat every claim at all costs and for any reason. . . . There is now no difference in the level of litigation than if the case were in state or federal court.”

“I feel the respondent has never embraced the spirit of the Vaccine Program or tried to properly implement it in the manner Congress intended. Every vaccine attorney has [his or her] own horror story about how the respondent has perverted the system. The respondent has done everything he can to circumvent and narrow the scope of the Program.”<sup>339</sup>

However, one attorney does believe that “[t]he respondents have made a good effort (in most instances) to minimize the adversarial atmosphere of the proceedings.”<sup>340</sup> Although complementing the respondent, note that this attorney still describes the “atmosphere” of the NVICP as adversarial.

Two experts who have participated in the NVICP, one who serves as an expert for the petitioner and one who reviews claims for the respondent, also agree that the nature of the NVICP proceedings is adversarial. The petitioner’s expert, who also testifies for plaintiffs and defendants in vaccine injury civil actions, notes that the “respondent’s defense against petitions. . . has become increasingly stubborn and aggressive, to the point that in its spirit, it is now indistinguishable from the adversarial manner in which some civil lawsuits are conducted.”<sup>341</sup> The expert for the respondent described the NVICP proceedings as a “contentious, vituperative, decibel-escalating exchange.”<sup>342</sup>

<sup>339</sup>*Id.* at 45. Of the thirty-nine petitioner’s attorneys who provided narrative comments on the NVICP, seven cited the litigiousness of the respondent’s attorneys as a problem. Seven of petitioner’s attorneys also commented negatively on the length of time it takes for NVICP claims to be processed. Attorneys most complained about the NVICP’s handling of attorney’s fees (12 out of the 39 providing comments).

<sup>340</sup>*Id.* at 46.

<sup>341</sup>Testimony of Marcel Kinsbourne, before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999. (Hereinafter “Testimony of Kinsbourne”).

<sup>342</sup>Testimony of Arnold D. Gale, M.D., before the House Government Reform Comm., Subcomm. On Criminal Justice, Drug Policy and Human Resources, September 28, 1999. (Hereinafter, “Testimony of Gale”).

Both experts state that attorneys for the petitioner and respondent seek to discredit the other side's experts by accusations of bias and ad hominem attacks, rather than appropriately challenging the medical testimony of the expert physicians.<sup>343</sup> Experts will not voluntarily testify in the NVICP if their professional credibility is constantly questioned. Medical experts are indispensable to the operation of the NVICP and resistance by such experts to testify will severely curtail petitioners' access to the NVICP. Note that in response to the Vaccine Act's mandate to review the adverse events associated with childhood vaccines,<sup>344</sup> the Institute of Medicine found "many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines," including "an inadequate understanding of the biological mechanisms underlying adverse events following natural infection or immunization."<sup>345</sup> Because of this medical uncertainty as to the adverse effects of vaccination, NVICP expert witnesses should be allowed to present sound medical testimony without challenge to their professional credibility.

### 3.

#### Loss of the Presumption of Vaccine Injury.

With the establishment of the Vaccine Injury Table, the Vaccine Act pro-

<sup>343</sup>Testimony of Kinsbourne; Testimony of Gale.

<sup>344</sup>42 U.S.C. 300a-1.

<sup>345</sup>Institute of Medicine (Vaccine Safety Committee), *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, ed. Kathleen R. Stratton, Cynthia J. Howe, and Richard B. Johnston, Jr., National Academy Press, 1994. This quotation is taken from the Executive Summary of *Adverse Effects of Pertussis and Rubella Vaccines*, published by the Institute of Medicine in 1991 and included in the 1994 Report.

vides a presumption that the administration of a certain vaccine caused a child's injury or death. The Vaccine Injury Table not only reflects scientific studies on causation, but it also establishes a compensation policy.<sup>346</sup> Congress designed the original Vaccine Injury Table with a "cushion," which compensates injured vaccinees where science is unclear or uncertain.<sup>347</sup> The Secretary of HHS, however, has tightened this Table, arguing that scientific studies disprove causation between particular vaccines and injuries. Yet, as discussed above, there still exists a lack of scientific data and understanding to prove conclusively which adverse effects following a vaccination are actually caused by the vaccine and which are not. As argued by Barbara Loe Fisher, "the vacuum of scientific knowledge then and now demands that a no-fault vaccine injury compensation system must err on the side of presumption in the absence of a biologically demonstrated alternative cause."<sup>348</sup>

In its only hearing of a vaccine injury case, the Supreme Court increased the difficulty of proving a table injury by requiring that a claimant who establishes an injury during the table period must also show "that no evidence of the injury appeared before the vaccination."<sup>349</sup> Such stringent standard of proof requirements violate Congress's intention that injured vaccinees receive compensation where scientific knowledge of the cause of the injury is uncertain. As mentioned above, Congress explicitly noted that a few children may be compensated who were not, in fact, injured by a vaccine.<sup>350</sup> The Vaccine Trust Fund is not

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<sup>346</sup>Testimony of Mica.

<sup>347</sup>*Id.* See also Testimony of Kinsbourne.

<sup>348</sup>Testimony of Fisher.

<sup>349</sup>*Shalala v. Whitecotton*, 514 U.S. 268 (1995).

<sup>350</sup>H. Rep., 99-908, at 18, reprinted in 1986 U.S.C.C.A.N., at 6359.



strapped for cash. It presently holds \$1.4 billion dollars for the sole purpose of compensating injured vaccinees. Why not give the “benefit of the doubt” to vaccine-injured children, as the federal government does for veterans and law enforcement officials?<sup>351</sup> The original Vaccine Injury Table was intended to be inclusive, not exclusive.

A return to a strong presumption in favor of the injured vaccinee will not only be fair to those children who suffer injuries because of mandatory universal vaccination, but will also help to alleviate the extreme length and adversarial nature of the NVICP because protracted battles over causation will occur less frequently.

### C. \_\_\_\_\_

#### Eradicating the Tension Between the Two Goals of the NVICP.

A tension exists between the two goals of protecting the vaccine supply and compensating those injured by vaccines. Because the NVICP rejects the petitions of so many claimants, there are a large number of individuals available to sue vaccine manufacturers. Any restrictions on petitioner’s eligibility for compensation, such as the tightening of the Vaccine Injury Table, “augments the overall risk of civil action” against vaccine manufacturers and once again threatens the stability of the vaccine supply.<sup>352</sup> For this reason, as well as those mentioned above, the NVICP must utilize a presumption of causation that gives

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<sup>351</sup>Testimony of Mica.

<sup>352</sup>Ridgway, *supra* note 229, at 81-82.

petitioners the benefit of the doubt. In this way, fewer petitioners will be denied compensation and fewer plaintiffs will exist to sue vaccine manufacturers.

D.

Eradicating the Tension Between the NVICP and the Safety Goal of the Vaccine Act.

In the third subpart of the Vaccine Act, Congress describes the necessary procedures for assuring safer childhood vaccines. Such procedures include recording and reporting of information on adverse events,<sup>353</sup> distributing vaccine information materials to health care providers,<sup>354</sup> and mandating safer childhood vaccines.<sup>355</sup> This safety goal conflicts with the HHS Secretary's addition of new vaccines to the Vaccine Injury Table with one or no injuries presumed to be caused by that vaccine.<sup>356</sup> This practice of adding a vaccine without presumed injuries completely shields manufacturers from liability, while compensating few or no individuals harmed by the new vaccine. Little scientific evidence establishes causation for vaccines that have been around for decades; and almost no scientific proof of causation exists for new vaccines. Thus, with no presumption of causation provided in the Vaccine Injury Table, petitioners will find it very difficult to recover for their injuries. Plus, vaccine manufacturers will not be penalized for unsafe vaccines because of the restricted liability attached to vaccine manufacturers following the NVICP proceeding. With the scant scientific

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<sup>353</sup>42 U.S.C. 300aa-25.

<sup>354</sup>42 U.S.C. 300aa-26.

<sup>355</sup>42 U.S.C. 300aa-27.

<sup>356</sup>42 U.S.C. 300aa-14. Only the injury of anaphylaxis is specified for Hepatitis B, and only early-onset Hib disease is specified for Hemophilus influenzae type B. No injury is presumed to be caused by varicella (chicken pox).

information known about the adverse effects of new vaccines, the Vaccine Table must either provide a very broad presumption of causation or not list these new vaccines.

The addition of the Hepatitis B vaccine to the Vaccine Injury Table illustrates this point. Hepatitis B was added to the Table on August 6, 1997 with only one compensable injury—anaphylaxis.<sup>357</sup> However, medical reports and VAERS show that the Hepatitis B vaccine causes autoimmune diseases.<sup>358</sup> Thus, every petitioner with an autoimmune disease allegedly caused by Hepatitis B must prove by a preponderance of the evidence that the Hepatitis B vaccine caused the injury, even though persuasive medical evidence may be lacking. Either autoimmune diseases must be included in the Table as a presumed injury of the Hepatitis B vaccine, or the Hepatitis B vaccine should not be listed on the Table and those injured by this vaccine should be able to sue the Hepatitis B manufacturer under all possible theories of civil liability. Thus, the safety of the vaccine supply will be ensured and injured vaccines will be compensated.

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<sup>357</sup>42 U.S.C. 300aa-14.

<sup>358</sup>Testimony of Fisher; Testimony of Kinsbourne.

## Conclusion

With its establishment in 1986, the National Vaccine Injury Compensation Program solved the problems of vaccine shortages and costly litigation against vaccine manufacturers. The NVICP has also provided compensation to many children and adults injured and killed by vaccines. This Program, however, requires reforms in order to alleviate the length of the proceedings, the adversarial nature of the proceedings, and the loss of the broad presumption of causation provided in the original Vaccine Injury Table. With such reforms, the NVICP will provide the fast and generous compensation envisioned by the Congress that enacted the National Childhood Vaccine Injury Act.

Indeed, the NVICP provides a unique means of resolving the claims of vaccine injury and death. By forcing the federal government to accept responsibility for liability, the NVICP both protects the manufacturer and provides compensation to the injured consumer. Could the structure of the NVICP be used as a model for other types of tort cases?<sup>359</sup> Would the informal proceedings, the front-end loading, and the use of specialized decision-makers rather than juries in the NVICP actually work when applied to other types of claims?<sup>360</sup> Vaccines are very different than other consumer products in that they are mandated by the government and they benefit the whole of society.<sup>361</sup> However, suggestions have been made that the NVICP model, or parts thereof, be used to resolve

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<sup>359</sup>Johnson, Drew and Miletich, *supra* note 114, at 53.

<sup>360</sup>*Id.*

<sup>361</sup>*Id.*; *See also* Ridgeway, *supra* note 229, at 83.

product liability and mass tort cases, such as breast implants, toxic shock, asbestos, Agent Orange and other toxic substance exposures.<sup>362</sup>

The NVICP offers one means of altering a tort system that many believe is out of control, and the NVICP compensates those individuals who suffer because of the universal vaccination policy of the United States. Thus, because the NVICP may serve as the prototype for other compensation systems, and because the NVICP provides such a necessary service to the citizens of the United States, efforts should be made to remedy the defects of the NVICP and to perfect those aspects of the NVICP which work well.

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<sup>362</sup>*Id.* at 50; Ridgeway, *supra* note 229, at 84-86.