

2018

## Liability for Vaccine Injury: The United States, the European Union, and the Developing World

Mary S. Holland

Follow this and additional works at: <https://scholarlycommons.law.emory.edu/elj>

---

### Recommended Citation

Mary S. Holland, *Liability for Vaccine Injury: The United States, the European Union, and the Developing World*, 67 Emory L. J. 415 (2018).

Available at: <https://scholarlycommons.law.emory.edu/elj/vol67/iss3/3>

This Article is brought to you for free and open access by the Journals at Emory Law Scholarly Commons. It has been accepted for inclusion in Emory Law Journal by an authorized editor of Emory Law Scholarly Commons. For more information, please contact [law-scholarly-commons@emory.edu](mailto:law-scholarly-commons@emory.edu).

# LIABILITY FOR VACCINE INJURY: THE UNITED STATES, THE EUROPEAN UNION, AND THE DEVELOPING WORLD

Mary S. Holland\*

INTRODUCTION .....	416
I. THE 1986 U.S. NATIONAL CHILDHOOD VACCINE INJURY ACT .....	417
A. <i>Stakeholders</i> .....	420
B. <i>The Legislative Compromise</i> .....	423
C. <i>Preemption of Design Defect Claims</i> .....	424
D. <i>The National Vaccine Injury Compensation Program</i> .....	425
E. <i>The Vaccine Injury Table</i> .....	427
F. <i>Limitation of Compensation and Damages</i> .....	429
G. <i>Opt-Out Procedure</i> .....	430
H. <i>Liability Protection for “Unavoidably Unsafe” Products</i> .....	431
I. <i>The Problems of the Vaccine Act</i> .....	432
J. <i>HHS Administrative Changes in the 1990s</i> .....	433
K. <i>Compensating Victims</i> .....	435
L. <i>Bruesewitz v. Wyeth</i> .....	436
M. <i>The Supreme Court’s Decision</i> .....	438
N. <i>The Dissent</i> .....	443
O. <i>The Impact of the Vaccine Act and the Bruesewitz Decision</i> ....	444
P. <i>Empirical Research on Vaccine Injury Before and After the         Vaccine Act</i> .....	445
Q. <i>Liability Protection in Emergencies: The PREP Act</i> .....	447
II. THE EUROPEAN UNION’S DIFFERENT APPROACH .....	451
A. <i>N.W. v. Sanofi Pasteur MSD SNC</i> .....	452
B. <i>Commentary on the ECJ Decision</i> .....	457
III. THE COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS .....	460
CONCLUSION .....	462

---

\* Faculty and Director, Graduate Lawyering Program, NYU School of Law. I am grateful to the Throver Symposium at the Emory School of Law and to Todd Rosenbaum and Ethel Pura Santa Ana Vara for critical research assistance.

## INTRODUCTION

The 2017 Thrombolytic Symposium focused on how law addresses serious global public health challenges. One critical way the world community addresses disease is through vaccination. The World Health Organization (WHO) and other national health bodies strongly recommend vaccines in many circumstances.<sup>1</sup> Yet there is a scientific consensus that vaccines can and do cause harm and death in certain individuals, even when vaccines are properly manufactured and appropriately administered. So, who should bear this risk? Of course, the individual bears all the physical risk, both of protection from disease and potential adverse side effects. But what of the financial risk of potential vaccine harms? Who should pay—the manufacturer, the individual, the government, or some combination thereof?

This Article looks at current models for vaccine injury liability in the United States and the European Union, and also focuses on possibilities for the developing world in the future. In the United States, vaccine manufacturers have attained an extremely high level of liability protection through legislation and judicial interpretation. The 1986 National Childhood Vaccine Injury Act (the Vaccine Act); the 2005 Public Readiness and Emergency Preparedness Act (the PREP Act); and *Bruesewitz v. Wyeth LLC*, the U.S. Supreme Court's decision interpreting the Vaccine Act, together afford vaccine manufacturers almost blanket liability protection from damages for vaccine harms.<sup>2</sup>

In June 2017, the Court of Justice of the European Union (ECJ) provided guidance in a vaccine injury case that strikes a remarkably different balance. In E.U. countries, an injured person has the right to seek compensation in civil court and to allege that a vaccine is unreasonably dangerous or defective. The ECJ held that an injured party may bring “serious, specific and consistent evidence,” and can prevail if this evidence shows that the vaccine is “the most plausible explanation for the occurrence of the damage.”<sup>3</sup> The plaintiff can assert this claim even if a scientific consensus that a vaccine can cause the alleged injury does not yet exist.

---

<sup>1</sup> See *Immunization, Vaccines and Biologicals: WHO Recommendations for Routine Immunization—Summary Tables*, WORLD HEALTH ORG. (Apr. 3, 2017), [http://www.who.int/immunization/policy/immunization\\_tables/en/](http://www.who.int/immunization/policy/immunization_tables/en/); *Recommended Vaccines by Age*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> (last updated Nov. 22, 2016).

<sup>2</sup> Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d (2012); National Childhood Vaccine Act, 42 U.S.C. §300aa-1 to -34 (2012); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

<sup>3</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC* (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

While some contend that this ECJ decision opens the floodgates to litigation, scholarly commentary disfavors this view. Empirical work indicates that leaving courthouse doors open elevates vaccine safety. While access to courts for vaccine injury in the United States is essentially closed, it is more open in Europe; accordingly, the ways in which developing countries proceed is at stake.

The U.S.-based Bill and Melinda Gates Foundation and other major intergovernmental, governmental, and private-sector actors have joined together recently to create a vaccine fund to respond to potential epidemic disease threats on a global basis. The new fund, the Coalition for Epidemic Preparedness Innovations (CEPI), has stated that it seeks to create liability protection and compensation mechanisms based on the U.S. model for vaccine liability. CEPI's intent to export the U.S. model warrants serious consideration and caution.

This Article seeks to explore these different liability regimes. Part I explores the liability protection mechanisms in the United States, including a review of the National Vaccine Injury Compensation Program (NVICP), the Supreme Court's *Bruesewitz v. Wyeth LLC* decision, and the PREP Act's compensation program. Part II discusses the June 2017 ECJ judgment of liability for vaccine injury and its implications in the European Union. Part III explores the liability standards that the new global CEPI is reviewing. This Article concludes that the E.U. model better balances the concerns of public health and individual rights, and thus is an important model for CEPI to consider.

## I. THE 1986 U.S. NATIONAL CHILDHOOD VACCINE INJURY ACT

Advancements in vaccine science and the concomitant development of vaccination policy dramatically changed public health in the United States during the twentieth century.<sup>4</sup> Many infectious diseases, including smallpox, polio, diphtheria, and rubella are extremely uncommon today, at least in part because of widespread uptake of vaccines.<sup>5</sup> Death rates from infectious disease

---

<sup>4</sup> See JAMES COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 16 (2006).

<sup>5</sup> See Gordon Shemin, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 467 (2008).

in the United States are low.<sup>6</sup> Many consider vaccination one of the most significant advances in public health.<sup>7</sup>

Science suggests that vaccine efficacy is based on herd immunity. This theory postulates that as the level of immunity within a community rises, chains of infectious disease transmission are interrupted, eventually resulting in elimination of those infections and their risk of harm to the public altogether.<sup>8</sup> The precise level of vaccination coverage necessary to achieve herd immunity depends on the disease and is difficult to determine empirically,<sup>9</sup> but the imprecise theory of herd immunity guides national immunization programs.<sup>10</sup>

The U.S. national immunization program builds on state laws that mandate children's vaccination prior to enrollment in daycare and preschool to prevent the transmission of infectious diseases among children at school.<sup>11</sup> In 1964, the Secretary of Health, Education, and Welfare<sup>12</sup> chartered the Advisory Committee on Immunization Practices (ACIP) pursuant to the Public Health Service Act<sup>13</sup> to support state efforts to prevent and control communicable diseases.<sup>14</sup> ACIP advises the states on public health and funds state vaccination programs.<sup>15</sup> ACIP's charter requires it to recommend when and for whom vaccines should be used to prevent disease.<sup>16</sup> It also requires that ACIP decide

---

<sup>6</sup> *Id.*; see also Mathew Herper & Robert Langreth, *Fear Factor*, FORBES (Sept. 27, 2007, 6:00 AM), [http://www.forbes.com/2007/09/26/vaccines-thimerosal-autism-biz-sci-cx\\_mh\\_rl\\_0927vaccines.html](http://www.forbes.com/2007/09/26/vaccines-thimerosal-autism-biz-sci-cx_mh_rl_0927vaccines.html).

<sup>7</sup> See *Ten Great Public Health Achievements—United States, 1900–1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241 (1999).

<sup>8</sup> See Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in LAW IN PUBLIC HEALTH PRACTICE 338, 340 (Richard A. Goodman et al. eds., 2d ed. 2007); Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 419–21 (2004) (describing herd immunity); Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 388 (2008) (describing the theory of herd immunity).

<sup>9</sup> See Malone & Hinman, *supra* note 8.

<sup>10</sup> See *id.* at 340, 354.

<sup>11</sup> See Javitt et al., *supra* note 8, at 388–89.

<sup>12</sup> The Department of Health, Education, and Welfare was renamed the Department of Health and Human Services in 1979, and its responsibilities concerning education were transferred to the newly created Department of Education. See *HHS Historical Highlights*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/historical-highlights/index.html> (last updated Feb. 10, 2017).

<sup>13</sup> 42 U.S.C. § 217a(a) (2012) (“The Secretary may . . . appoint such advisory councils or committees . . . for the purpose of advising him in connection with any of his functions.”); see also *ACIP Charter: Authority, Objective, and Description*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/acip/committee/charter.html> (last updated Apr. 20, 2016).

<sup>14</sup> See *ACIP Charter: Authority, Objective, and Description*, *supra* note 13.

<sup>15</sup> See *id.*

<sup>16</sup> See *id.*

which vaccines the federal government will subsidize for indigent children.<sup>17</sup> By 1981, all states made vaccination a prerequisite for school attendance unless applicable exemptions applied.<sup>18</sup> Today, ACIP's recommendations guide most state public health agencies in determining which vaccines to mandate for school entry.<sup>19</sup>

The success of the national vaccine program has come at a cost. Some children are permanently disabled or die from their vaccine exposures.<sup>20</sup> A broad spectrum of suspected and confirmed adverse vaccine events has grown in the decades from the beginning of mass vaccination.<sup>21</sup> Although the percentage of those who experience adverse reactions to vaccines is believed to be small,<sup>22</sup> thousands have been compensated for injury, and vaccine adverse events are almost certainly underreported.<sup>23</sup> In total, over 600,000 people in the

---

<sup>17</sup> See *id.*; see also *Vaccines for Children Program*, CTNS. FOR DISEASE CONTROL & PREVENTION (Apr. 24, 2014), <http://www.cdc.gov/vaccines/programs/vfc/index.html>.

<sup>18</sup> See Malone & Hinman, *supra* note 8, at 345 (“By the 1980–1981 school year, all 50 states had laws covering students first entering school. In most states, these laws affected children at all grade levels, as well as those involved in licensed preschool settings.”). State legislatures recognize three types of exemptions, all of which can be waived in the case of a public health emergency. See Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & L. 249, 260 (1995). All states recognize a medical exemption, whereby a physician certifies that the vaccine may be harmful to an individual. *Id.* Forty-seven states provide religious exemptions, with varying requirements regarding demonstrating the sincerity of one’s religious belief. *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NAT’L CONF. ST. LEGISLATURES (Dec. 20, 2017), <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>. Many states also provide broader philosophical exemptions, based on personal, philosophical, moral, or some other type of belief. *Id.* As of December 2017, eighteen states had philosophical exemptions. *Id.* California, Mississippi, and West Virginia are the only states that exclusively permit medical exemptions. *Id.*

<sup>19</sup> See Javitt et al., *supra* note 8, at 389.

<sup>20</sup> See U.S. DEP’T OF HEALTH RES. & HUMAN SERVS. ADMIN., NATIONAL VACCINE INJURY COMPENSATION PROGRAM MONTHLY STATISTICS REPORT (2017); *About VAERS*, U.S. DEP’T OF HEALTH & HUM. SERVS., <http://vaers.hhs.gov/about/index> (last visited Dec. 19, 2017); see also Regina Moreland, *Commentary, National Vaccine Injury Compensation Program: The Potential Impact of Cedillo for Vaccine-Related Autism Cases*, 29 J. LEGAL MED. 363, 367–68 (2008).

<sup>21</sup> See B.J. Ward, *Vaccine Adverse Events in the New Millennium: Is There Reason for Concern?*, 78 BULL. WORLD HEALTH ORG. 205, 206 (2000).

<sup>22</sup> See, e.g., *Possible Side-Effects from Vaccines*, CTNS. FOR DISEASE CONTROL & PREVENTION (Mar. 10, 2017), <https://www.cdc.gov/vaccines/vac-gen/side-effects.htm> (stating that the diphtheria-tetanus-acellular pertussis and measles, mumps, and rubella vaccines have severe side effects of “less than 1 out of a million doses”).

<sup>23</sup> As of July 5, 2017, 5,555 claims of the 16,517 that went before the NVICP have been compensated. U.S. DEP’T OF HEALTH RESOURCES & HUMAN SERVS. ADMIN., *supra* note 20, at 7. For information on why this number is likely too low, see *Odds of Vaccine Harm are One in a Million?*, NAT’L VACCINE INFO. CTR. (Sept. 15, 2017, 5:56 PM), <http://www.nvic.org/nvic-vaccine-news/september-2017/odds-of-vaccine-harm-are-one-in-a-million.aspx>.

United States have filed vaccine adverse event reports since 1990.<sup>24</sup> Furthermore, people receive little warning of the risks of vaccination because of minimal information requirements under the Vaccine Act.<sup>25</sup>

Between 1980 and 1986, people who claimed vaccine injury brought over three billion dollars of damages claims to U.S. civil courts against vaccine manufacturers.<sup>26</sup> Although some vaccine-injured plaintiffs' claims were successful, most went uncompensated because of the difficulty of proving causation in the tort system.<sup>27</sup> Many potential plaintiffs could not afford representation to bring their claims. Because legal costs were high and vaccine manufacturers argued they were unable to obtain cost-effective liability insurance, manufacturers began to leave what they asserted was an unprofitable market.<sup>28</sup> For example, Wyeth Laboratories temporarily halted production of the diphtheria, pertussis, and tetanus (DPT) vaccine in 1984 "because of extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance."<sup>29</sup> By 1985, four manufacturers produced the primary vaccines used in state vaccination programs.<sup>30</sup> Congress recognized a supply crisis.<sup>31</sup>

#### A. Stakeholders

The parents of vaccine-injured children, scientists, vaccine manufacturers, the American Academy of Pediatrics (AAP), the American Medical Association (AMA), and Congress were all displeased with the existing system. Tort litigation was costly, time-consuming, and usually undercompensated or failed to compensate victims.<sup>32</sup>

---

<sup>24</sup> See *Search the VAERS Database*, NAT'L VACCINE INFO. CTR., <http://www.medalerts.org/vaersdb/index.php> (last visited Dec. 17, 2017).

<sup>25</sup> See *History of Vaccine Information Statements*, CTRS. FOR DISEASE CONTROL & PREVENTION 4, <https://www.cdc.gov/vaccines/hcp/vis/downloads/vis-history.pdf>.

<sup>26</sup> See Shemin, *supra* note 5, at 469; see also Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 60 (1999).

<sup>27</sup> See Shemin, *supra* note 5, at 5; see also Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1859-60 (1995) (explaining that vaccine litigation is difficult in the civil court system because of the inability to raise design defect claims, the difficulty in establishing proximate cause, and the length of time it takes to litigate claims).

<sup>28</sup> See Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 152 (1988).

<sup>29</sup> *Vaccine Injury Compensation: Hearings on H.R. 5810 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 98th Cong. 295 (1984) [hereinafter *Hearings on H.R. 5810*] (statement of Daniel L. Shaw, Jr., M.D., Vice President for Medical Affairs, Wyeth Laboratories).

<sup>30</sup> See Neraas, *supra* note 28, at 152.

<sup>31</sup> See *id.* at 151-52; see also Shemin, *supra* note 5, at 470 n.50.

<sup>32</sup> See H.R. REP. NO. 99-908, at 6 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6347.

In 1977, before the crisis in childhood vaccine manufacturing, the AAP issued a policy statement advocating the creation of a program which would compensate those injured by compulsory vaccines.<sup>33</sup> In the early 1980s, a group of parents whose children were injured by the DPT vaccine formed a non-profit called Dissatisfied Parents Together, now known as the National Vaccine Information Center, to advocate for such a compensation program.<sup>34</sup> In 1981, the AAP published a detailed outline of such a compensation system.<sup>35</sup>

The parents wanted both victim compensation and safer vaccines for all children. To that end, the parents sought a system to compensate families and to create incentives for vaccine manufacturers to develop the safest vaccines possible. They believed that preserving plaintiffs' access to civil courts would apply the pressure necessary to keep vaccine manufacturers' practices safe.<sup>36</sup> As Jeffrey Schwartz, President of Dissatisfied Parents Together, explained:

[We] felt from the very beginning we could not support a bill that simply compensated children who are injured; that did not provide a strong mandate for the creation of safer vaccines, for the use of safer vaccines, for the implementation of a safer system for using the current vaccine. We would not agree to sweep the problem under the rug by paying off the families and the children who are damaged and let this process of administering a hazardous vaccination go on without a challenge.<sup>37</sup>

The parents said they “could not support, in fact would have to oppose, enactment of any bill which did not guarantee a child’s option to sue under the traditional common law principles of tort and contract.”<sup>38</sup>

Members of the scientific community joined the parents to support the creation of a hybrid compensation system including both administrative and tort elements. Scientists warned Congress of the dangers of eliminating tort liability altogether, including Dr. Jonas Salk, developer of the inactivated polio

---

<sup>33</sup> See COLGROVE, *supra* note 4, at 208.

<sup>34</sup> See HARRIS L. COULTER & BARBARA LOE FISHER, A SHOT IN THE DARK: WHY THE P IN THE DPT VACCINATION MAY BE HAZARDOUS TO YOUR CHILD’S HEALTH 213 (1991). The legal theory propounded by the parents, that the pertussis component of the DPT vaccine was the medical cause of their children’s injuries, was later validated by the federal courts. See, e.g., *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009) (allowing compensation for seizures caused by the DPT vaccine).

<sup>35</sup> See COLGROVE, *supra* note 4, at 208.

<sup>36</sup> See *id.*

<sup>37</sup> *National Childhood Vaccine-Injury Compensation Act: Hearing on S. 2117 Before the S. Comm. on Labor & Human Res.*, 98th Cong. 49 (1984) (statement of Jeffrey H. Schwartz, Dissatisfied Parents Together).

<sup>38</sup> *Id.* at 59 (emphasis omitted).



vaccine.<sup>39</sup> Dr. Salk testified regarding industry indemnification, stating that he had two serious concerns with regard to such legislation:

- One is the removal of the incentive for manufacturers and the scientific community to improve existing vaccines . . . .
- The other is the removal of the incentive to change policy when equally effective but safer vaccines already exist . . . .

Therefore, such legislation should provide for:

- Encouragement of research and development of vaccines free of the untoward side effects for which indemnification is to be provided.<sup>40</sup>

By contrast, the pharmaceutical and medical communities opposed any liability for vaccine manufacturers, citing threats to the vaccine supply and public health.<sup>41</sup> Their representatives pushed for a no-fault administrative system to be the exclusive remedy for victims. They stated:

The proposed compensation system must be the exclusive remedy of claimants and not merely an alternative to remedies currently available.

. . . .

. . . Given the important goals of promoting the vaccination of children and assuring the ready availability of vaccine to meet that objective, legislation should be fashioned to help achieve those goals. Permitting claimants to continue to bring tort actions against manufacturers and providers will not achieve desired goals, in our view, since sufficient protection is not provided from the increasingly high expense of litigation that is driving manufacturer costs up—costs that have been asserted as forcing companies out of vaccine production.<sup>42</sup>

The vaccine manufacturers argued that they, “as well as vaccine recipients, can be victims of the excesses and vagaries of the current tort system.”<sup>43</sup> The industry’s proposed legislation would have allowed almost no role for the tort system. Industry representatives advocated that the only basis for a civil claim

---

<sup>39</sup> See *id.* at 164 (statement of Jonas Salk, M.D., the Salk Inst. for Biological Studies).

<sup>40</sup> *Id.* at 166.

<sup>41</sup> See *id.* at 189 (statement of Dr. Alan R. Nelson, M.D., American Medical Association).

<sup>42</sup> *Id.* at 186, 189.

<sup>43</sup> *Id.* at 264 (statement of Richard Bogash, President, Wyeth Laboratories).

should be when a corporation deviates from government standards in manufacturing or a healthcare practitioner commits malpractice.<sup>44</sup>

### *B. The Legislative Compromise*

The AAP and the industry worked closely with the members of Dissatisfied Parents Together to draft legislation that would become the Vaccine Act.<sup>45</sup> The draft was completed in the House Committee on Energy and Commerce's (Committee) Health and Environment Subcommittee (Subcommittee), and Jeffrey Schwartz served the Committee as Environmental Counsel from 1973 to 1979.<sup>46</sup> As Barbara Loe Fisher, a co-founder of Dissatisfied Parents Together<sup>47</sup> wrote: "Parents . . . supported the concept that a federal compensation system would result in official recognition of the reality of vaccine deaths and injuries and would help make vaccine safety a priority in United States health care."<sup>48</sup>

Congress passed the Vaccine Act in October 1986, after four years of deliberations, to balance the goals of victim injury compensation, stable vaccine supply, and the creation of safer vaccines.<sup>49</sup> The Committee accompanied the Vaccine Act with House Report 9-908 (the 1986 Report), which includes a section-by-section analysis of the Vaccine Act's provisions and explanation of its intentions.<sup>50</sup> The 1986 Report evidences Congress' purpose to generously compensate victims of vaccine injury, ensure the vaccine supply, and improve vaccine safety.<sup>51</sup> Congress viewed child victims of vaccine injury as veterans in the war on disease; they deserved compensation just like soldiers injured on the battlefield.<sup>52</sup>

Part of the Vaccine Act's compromise is that families must file a claim in the NVICP within three years of the first manifestation of injury.<sup>53</sup> The Vaccine Act requires that claimants exhaust their administrative remedies first

---

<sup>44</sup> See *id.* at 278 (statement of John E. Lyons, President, Merck Sharp & Dohme).

<sup>45</sup> See COULTER & FISHER, *supra* note 34, at 213-14; see also COLGROVE, *supra* note 4, at 214.

<sup>46</sup> See *Hearings on H.R. 5810, supra* note 29, at 80 (statement of Jeffrey H. Schwartz, Dissatisfied Parents Together).

<sup>47</sup> See *Biography, Barbara Loe Fisher*, NAT'L VACCINE INFO. CTR., <http://www.nvic.org/about/barbaraloefisher.aspx> (last visited Dec. 17, 2017).

<sup>48</sup> COULTER & FISHER, *supra* note 34, at 213-14.

<sup>49</sup> See H.R. REP. 99-908, at 1 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344.

<sup>50</sup> *Id.* at 8-35, 1986 U.S.C.C.A.N. at 6349-76.

<sup>51</sup> See *id.* at 9-10, 20-22, 1986 U.S.C.C.A.N. at 6350-51, 6361-63.

<sup>52</sup> 132 CONG. REC. 30,751, 30,760 (1986) (statement of Rep. Waxman); see also Henry A. Waxman, *When a Vaccine Injures a Child: A No-Fault Way to Compensate*, WASH. POST, Oct. 9, 1986, at A27.

<sup>53</sup> See National Childhood Vaccine Act, 42 U.S.C. § 300aa-16(a)(2) (2012).

by bringing their claims to the NVICP.<sup>54</sup> But, at least in theory, it allows them to exit the NVICP and bring a civil action in federal district or state court after filing on two conditions. First, the claimant can opt out of the compensation program if the special master fails to hand down a decision within the statutorily prescribed period of 240 days.<sup>55</sup> Second, the claimant may reject the special master's decision if she is dissatisfied with it and file a civil suit if the Vaccine Act's other provisions do not preempt litigation.<sup>56</sup> So, while the Vaccine Act circumscribes plaintiffs' access to state and federal courts, it does not eliminate it.<sup>57</sup>

In practice, few people turn down NVICP awards to test their luck in civil court. Even before *Bruesewitz v. Wyeth LLC* foreclosed the opportunity to sue for vaccine design defects,<sup>58</sup> fewer than 0.5% of successful claimants who received an award in the compensation program rejected it.<sup>59</sup> “[V]irtually all” unsuccessful claimants declined to initiate suits in civil court.<sup>60</sup> In a recent study of the NVICP, Stanford professor Nora Freeman Engstrom concluded that although Congress intended the NVICP to complement the civil justice system, in fact, “the [N]VICP typically functions as an exclusive remedy.”<sup>61</sup>

### C. Preemption of Design Defect Claims

The availability of civil action for vaccine design defects was left somewhat murky in the statute, whether by intent or oversight. The Vaccine Act's legislative history suggests that Congress intended that victims, who had duly filed in the NVICP, could still bring design defect claims against vaccine manufacturers to civil court under the Vaccine Act.<sup>62</sup> When presenting the Vaccine Act to the full House of Representatives for vote, Representative

---

<sup>54</sup> See *id.* § 300aa-11(a).

<sup>55</sup> See *id.* § 300aa-12(d)(3)(A)(ii).

<sup>56</sup> See *id.* § 300aa-21(a); see also Nitin Shah, Note, *When Injury Is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, 96 VA. L. REV. 199, 203 (2010).

<sup>57</sup> See § 300aa-21(a).

<sup>58</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231–32 (2011) (“Provided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable. State-law design-defect claims are therefore pre-empted.”).

<sup>59</sup> Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. PA. L. REV. 1631, 1673 (2015).

<sup>60</sup> *Id.* (quoting STANLEY A. PLOTKIN ET AL., *VACCINES* 1673 (5th ed. 2008)).

<sup>61</sup> *Id.* at 1673.

<sup>62</sup> See § 300aa-22(b). Claims of design defect implicate an entire product line based on the theory that the risks the product poses to the consumer outweigh any utility she would derive from using it. This contrasts with construction or manufacturing defects, which usually involve aberrational departures from the product's intended design. See MARK A. GEISTFELD, *PRINCIPLES OF PRODUCTS LIABILITY* 85 (2006).

Waxman, the bill's sponsor, stated that civil claims for "inadequately researched" vaccines would be preserved.<sup>63</sup> Waxman's description of such a claim, that a vaccine's design did not take adequate account of avoidable safety risks, suggests a design defect claim.<sup>64</sup>

The Committee explicitly rejected the opportunity to create a broad exemption for all design defect claims when it drafted the Vaccine Act. It considered proposals that would have explicitly preempted all design defect claims, but the final version did not contain such provisions.<sup>65</sup> By rejecting language that would have barred all design defect claims, Congress showed its intent to permit courts to decide on a case-by-case basis which side effects were genuinely "unavoidabl[e]."<sup>66</sup> The Committee emphasized that it had not decided, as a matter of law, which, if any, vaccines were unavoidably unsafe: "This question is left to the courts to determine in accordance with applicable law."<sup>67</sup>

#### *D. The National Vaccine Injury Compensation Program*

The Vaccine Act's drafters considered the creation of the NVICP among the Vaccine Act's most significant components. The NVICP was intended to "provide[] reimbursement for a wide range of medical and rehabilitative care for those injured by any vaccine designated by . . . [ACIP] for 'routine administration to children.'"<sup>68</sup> The NVICP was a reaction to the twin threats of litigation against vaccine manufacturers and grossly insufficient compensation to victims that together risked the vaccine program's viability.<sup>69</sup> The NVICP was conceived as a no-fault administrative regime, meaning that the claimant did not have to prove the vaccine caused the injury so long as the injury occurred within specified time limits.<sup>70</sup> Within certain time intervals, the program administrators would presume that the vaccine caused the injury, even if on a rare occasion that was not the case.<sup>71</sup> The Committee intended that the

---

<sup>63</sup> 132 CONG. REC. 30,751, 30,760 (1986) (statement of Rep. Waxman); *see also* Waxman, *supra* note 52.

<sup>64</sup> *See* Shah, *supra* note 56, at 231 n.147.

<sup>65</sup> *See generally* H.R. REP. NO. 100-391(I), at 691 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> COLGROVE, *supra* note 4, at 215; *see also* 42 U.S.C. § 300aa-14(e)(1)(A), (e)(2) (2012).

<sup>69</sup> *See* Schaefer v. Am. Cyanamid Co., 20 F.3d 1, 2 (1st Cir. 1994); *see also* Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007).

<sup>70</sup> *See* Engstrom, *supra* note 59, at 1638-40, 1637 n.21.

<sup>71</sup> *See* H.R. REP. 99-908, at 15 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6356.

program compensate children who suffered adverse effects from vaccinations “quickly, easily, and with certainty and generosity.”<sup>72</sup>

The U.S. Court of Federal Claims oversees the NVICP.<sup>73</sup> The Court of Federal Claims is responsible for appointing and removing the chief special master and associate special masters, who serve four-year terms.<sup>74</sup> Special masters manage and decide individual cases.<sup>75</sup> They review vaccine injury claims in two phases: causation and compensation.<sup>76</sup> Special masters are ordinarily lawyers; the majority previously represented the U.S. government in various capacities.<sup>77</sup> In effect, they are specialized judges, developing expertise and knowledge regarding vaccine injury.

Congress intended that the proceedings under the NVICP be less adversarial and more informal than lawsuits in civil court.<sup>78</sup> According to Fisher, “the stated purpose of the [Vaccine Act] was to err on the side of compensating potential vaccine victims in order to offer an effective alternative to vaccine injury lawsuits.”<sup>79</sup> The Vaccine Act contemplated a forum that would “streamline the process for plaintiffs.”<sup>80</sup> To this end, Congress relaxed both procedural and evidentiary rules.<sup>81</sup> Special masters do not wear judicial robes, can ask questions of witnesses directly, and can hold hearings over the telephone.<sup>82</sup> The right to pretrial discovery of information from the opposing party or third-party vaccine manufacturers is not automatic, but the special masters may grant it.<sup>83</sup>

The Secretary of the U.S. Department of Health and Human Services (HHS) serves as the respondent to a claimant’s petition; lawyers from the U.S.

---

<sup>72</sup> *Id.* at 3, 1986 U.S.C.C.A.N. at 6344; *see also* Shalala v. Whitecotton, 514 U.S. 268, 270 (1995); Advisory Comm’n on Childhood Vaccines, Dep’t of Health & Human Servs., Transcript of Meeting of Nov. 18, 2008, at 8, <http://www.nvic.org/injury-compensation/vaccineinjury.aspx> (statement of Barbara Loe Fisher).

<sup>73</sup> *See* § 300aa-12(c).

<sup>74</sup> *See id.*

<sup>75</sup> *See id.* § 300aa-12(d).

<sup>76</sup> *See generally* OFFICE OF SPECIAL MASTERS, U.S. COURT OF FED. CLAIMS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (2004).

<sup>77</sup> *See, e.g., Special Masters – Biographies*, U.S. CT. FED. CLAIMS, <http://www.uscfc.uscourts.gov/special-masters-biographies> (last visited Dec. 18, 2017).

<sup>78</sup> *See* Shalala v. Whitecotton, 514 U.S. 268, 270 (1995).

<sup>79</sup> Advisory Comm’n on Childhood Vaccines, Dep’t of Health & Human Servs., *supra* note 72; *see also* H.R. REP. 99–908, at 12–13 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6353–54.

<sup>80</sup> COLGROVE, *supra* note 4, at 215.

<sup>81</sup> *See id.*

<sup>82</sup> *See* 42 U.S.C. § 300aa-12(c)(1), (d)(2)(A) (2012). §300aa-12(d)(2)(A) states the guidelines for the VICP are to: “provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions.”

<sup>83</sup> *See id.* § 300aa-12(d)(2).

Department of Justice (DOJ) represent HHS. Respondent HHS may concede, settle, or oppose claims, arguing insufficient evidence to prove causation.<sup>84</sup> Vaccine manufacturers are not parties to the litigation and bear no liability;<sup>85</sup> compensation comes out of a consumer-funded trust fund.<sup>86</sup> Litigated case decisions and some settlement agreements are available on the Federal Court of Claims website.<sup>87</sup>

The NVICP pays the claimants' reasonable attorney's fees, although some petitioners may file pro se to represent themselves as well.<sup>88</sup> The NVICP's compensation practices for lawyers often make it difficult for claimants to find professional representation.<sup>89</sup>

The special masters' decisions are due a high level of deference by higher courts. Reviewing courts may only reverse and remand a special master's decisions if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>90</sup> Petitioners and the DOJ may appeal cases to the Court of Federal Claims, the Court of Appeals for the Federal Circuit, and, ultimately, to the U.S. Supreme Court.<sup>91</sup>

### E. *The Vaccine Injury Table*

Congress intended that the Vaccine Act's primary mechanism for ensuring victim compensation would be the Vaccine Injury Table (Table), a decision aid to facilitate quick, administrative resolution of claims.<sup>92</sup> The Table is meant to relieve claimants from shouldering the burden of proving causation in a field that the Court of Appeals described as "bereft of complete and direct proof of how vaccines affect the human body."<sup>93</sup> The Vaccine Act accomplishes this by creating statutory presumptions of causation for certain injuries and adverse events stipulated in the Table.<sup>94</sup> Congress included recognized vaccine-induced

---

<sup>84</sup> See *id.* § 300aa-12(b)(1) (noting that the HHS Secretary is the only defendant).

<sup>85</sup> See *id.* § 300aa-11(a)(3).

<sup>86</sup> See *id.* § 300aa-15(f)(4)(A).

<sup>87</sup> See *USFCF Vaccine Reported*, U.S. CT. FED. CLAIMS, <http://www.uscfc.uscourts.gov/aggregator/sources/7> (last visited Dec. 18, 2017).

<sup>88</sup> See § 300aa-15(e).

<sup>89</sup> Robert Moxley, *The "Vaccine Court" Is Hazardous to Your Health*, AM. CONSERVATIVE (Mar. 30, 2017), <http://www.theamericanconservative.com/articles/the-vaccine-court-is-hazardous-to-your-health/> ("The injured and their counsel (the latter economically oppressed by the program's prohibition against private attorneys fees) encounter a Kafkaesque system.").

<sup>90</sup> § 300aa-12(e)(2)(B), (f).

<sup>91</sup> See *id.* § 300aa-12(e)(1).

<sup>92</sup> See *id.* § 300aa-11(b).

<sup>93</sup> *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

<sup>94</sup> See *id.*

injuries in the Table when it passed the Vaccine Act, including anaphylaxis, paralytic polio, encephalopathy, and death, all within prescribed time periods after vaccination.<sup>95</sup>

If a claimant meets the Table's requirements for a specific injury, she is entitled to compensation with no need to prove causation. For instance, if an individual could demonstrate that encephalopathy occurred within fifteen days after she received the measles, mumps, and rubella (MMR) vaccine, she would qualify for compensation unless the Secretary of HHS could rebut the claim by proving that injury or death was caused by "factors unrelated to the administration of the vaccine."<sup>96</sup>

Notably, the Vaccine Act contains a provision allowing the Secretary of HHS to change the Table. By law, the Secretary can add or delete injuries and conditions for which compensation would be available and can change the applicable time periods by which the onset of symptoms must occur.<sup>97</sup> Despite initial protest, negotiators for the industry and doctors assured Fisher and other parents who assisted in drafting the Vaccine Act that such a provision was necessary so that the compensation program could become more generous for newly recognized vaccine injuries in the future.<sup>98</sup> They learned later, however, that the option to change the Table could cut both ways: it could eliminate avenues to compensation as well as expand them.<sup>99</sup>

The Vaccine Act also permits so-called "off-Table" or causation-in-fact claims for injuries not included in the Table. Petitioners whose claims do not fall within the Table have the burden to prove that a given vaccine's administration caused a specific injury by a preponderance of the evidence.<sup>100</sup> Thus for off-Table claims, "the 'heavy lifting must be done by the petitioner.'"<sup>101</sup> Likewise, the DOJ ordinarily assumes an adversarial posture when defending against off-Table claims.<sup>102</sup>

---

<sup>95</sup> See § 300aa-14(a).

<sup>96</sup> *Id.* § 300aa-13(a)(1)(B).

<sup>97</sup> *Id.* § 300aa-14(c).

<sup>98</sup> See discussion *infra* pp. 118–19; see also H.R. REP. 99–908, at 20 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6361; Advisory Comm'n on Childhood Vaccines, Dep't of Health & Human Servs., *supra* note 72, at 15–16.

<sup>99</sup> See Advisory Comm'n on Childhood Vaccines, Dep't of Health & Human Servs., *supra* note 72, at 15–16.

<sup>100</sup> See § 300aa-13(a)(1).

<sup>101</sup> Shemin, *supra* note 5, at 476 (quoting *Hodges v. Sec'y of the Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1992)).

<sup>102</sup> See *id.*

Extremely few new injuries have been added to the Table since 1986, but they include anaphylaxis within four hours of hepatitis B vaccination, shoulder injury related to vaccine administration after any vaccine within forty-eight hours, and vasovagal syncope within one hour after several vaccines.<sup>103</sup> Although nine new vaccines have been added to the schedule of federally recommended childhood vaccines, only these injuries have been added to the Table.<sup>104</sup>

When the NVICP began, about 74% of cases were resolved as on-Table injuries; today, 98% of cases are resolved off-Table, involving complex litigation over causation.<sup>105</sup> This kind of litigation is precisely what Congress intended to avoid by creating the NVICP.

#### *F. Limitation on Compensation and Damages*

Congressman Henry Waxman conceded that the Vaccine Act contained some unpopular compromises:

I recognize that the bill I have introduced is probably not the first choice of most parties to this controversy. Manufacturers would undoubtedly prefer greater insulation from liability. Parents of injured children would certainly prefer larger compensation and fewer restrictions on court activity. The Reagan administration would, I am sure, prefer legislation that spends no money.<sup>106</sup>

While the Vaccine Act sets out generous compensation for injury expenses, rehabilitation, and other associated costs for those who win their petitions,<sup>107</sup> there are noteworthy limits. The Vaccine Act provides that claimants can receive a maximum of \$250,000 “[f]or actual and projected pain and

---

<sup>103</sup> *Vaccine Injury Table*, HEALTH RESOURCES & SERVS. ADMIN. (Mar. 21, 2017), <https://www.hrsa.gov/sites/default/files/vaccinecompensation/injurytable.pdf>.

<sup>104</sup> Before the Vaccine Act, states generally required vaccines against polio, diphtheria, tetanus, pertussis, measles, mumps and rubella. See Paul A. Offit, *Vaccine History: Developments by Year*, CHILD. HOSP. PHILA. (Nov. 19, 2014), <http://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year>. The additional vaccines that have been added to the CDC’s ACIP-recommended schedule since are to protect against hepatitis B, rotavirus, *haemophilus influenzae* type b, pneumococcal, influenza, varicella, hepatitis A, meningococcal and human papillomavirus. See *Child and Adolescent Schedule*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html> (last visited Feb. 6, 2017).

<sup>105</sup> Engstrom, *supra* note 59, at 1702–03.

<sup>106</sup> *Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, & H.R. 5184 Before the Subcomm. on Health and the Env’t of the H. Comm. of Energy & Commerce*, 99th Cong. 2 (1986) (statement of Rep. Henry A. Waxman, Chairman, Subcomm. on Health & the Env’t of the H. Comm. of Energy & Commerce).

<sup>107</sup> See 42 U.S.C. § 300aa-15(a)(1)(A)(iii)(I), (a)(1)(b)(iii) (2012).



suffering . . . from the vaccine-related injury.”<sup>108</sup> Special masters have the discretion to completely deny compensation for expert witnesses if they deem the medical expert testimony to be unreasonable.<sup>109</sup> And compensation for wrongful death claims is capped at \$250,000 for all petitioners.<sup>110</sup> These caps, which have remained unchanged since 1986, are worth less than half that amount today.<sup>111</sup>

An excise tax levied on all vaccines in the United States funds the no-fault compensation fund, out of which awards are paid.<sup>112</sup> Since the NVICP began taking claims in 1989, it has handled over 16,500 cases and determined that over 5,500 of those cases were “compensable.”<sup>113</sup> It has paid affected families approximately \$3.7 billion.<sup>114</sup>

### G. Opt-Out Procedure

Part of the Vaccine Act’s compromise is that families must file a claim in the NVICP within three years of the first manifestation of injury.<sup>115</sup> It allows the families, though, to exit the NVICP and bring a civil action in federal district or state court after the 240-day waiting period<sup>116</sup> or if the claimant rejects the special master’s decision.<sup>117</sup> So while the Vaccine Act circumscribes plaintiffs’ access to state and federal civil courts, in theory it upholds the right to go to civil court after first filing in the NVICP.<sup>118</sup>

Engstrom points out, though, that many dimensions of the Vaccine Act made it very difficult to take claims out of the NVICP, even before the *Bruesewitz* decision.<sup>119</sup> The Vaccine Act creates a presumption that all

---

<sup>108</sup> *Id.* § 300aa-15(a)(4).

<sup>109</sup> *See* *Perreira v. Sec’y of the Dep’t of Health & Human Servs.*, 27 Fed. Cl. 29, 31 (1992), *aff’d*, 33 F.3d 1375 (Fed. Cir. 1994) (finding that the petitioner had no definitive medical evidence and, therefore, the medical expert’s testimony was unreasonable and non-compensable); *see also* Katherine Davenport, *Vaccines and the National Vaccine Injury Compensation Program 49* (Apr. 10, 2000) (unpublished third-year paper, Harvard Law School), <https://dash.harvard.edu/handle/1/9453695>.

<sup>110</sup> *See* § 300aa-15(a)(2).

<sup>111</sup> *See id.* Because of inflation, \$250,000 in 1986 is equal to only \$111,890.83 in 2017. *CPI Inflation Calculator*, U.S. BUREAU LAB. STAT., [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm) (last visited Dec. 18, 2017).

<sup>112</sup> *See* Davenport, *supra* note 109, at 43. An “excise tax of 75 cents per dose is imposed on each vaccine covered under the NVICP.” *Id.*

<sup>113</sup> *See* U.S. DEP’T OF HEALTH RES. & HUMAN SERVS. ADMIN., *supra* note 20.

<sup>114</sup> *See id.*

<sup>115</sup> *See* § 300aa-16(a)(2).

<sup>116</sup> *See id.* § 300aa-21(b)(1).

<sup>117</sup> *See id.* § 300aa-21(a); *see also* Shah, *supra* note 56, at 203.

<sup>118</sup> *See* Shah, *supra* note 56, at 203, 220.

<sup>119</sup> Engstrom, *supra* note 59, at 1664.

warnings that the Food and Drug Administration (FDA) approves are adequate, thus preventing state courts from independently assessing warnings.<sup>120</sup> The Vaccine Act also codifies the “learned intermediary doctrine,” thus eliminating any potential claims that the parents or individual did not receive product warnings directly.<sup>121</sup> And in the event that a claimant does go to civil court, punitive damages are unavailable except in cases of fraud, intentional wrongdoing, or other illegal activity.<sup>122</sup>

#### *H. Liability Protection for “Unavoidably Unsafe” Products*

Although a claimant may bring a civil action if she meets the Vaccine Act’s exhaustion requirement, the Vaccine Act limits vaccine manufacturers’ civil liability.<sup>123</sup> The Vaccine Act achieved this through its incorporation of language from the Second Restatement of Torts (Restatement) treatise on products liability, which most state courts adopted in the mid-1960s.<sup>124</sup> The Restatement describes all vaccines as “unavoidably unsafe” products and implicitly recommended that manufacturers not be liable for injuries if doctors administered them properly.<sup>125</sup> The Restatement comment k provides, in relevant part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.<sup>126</sup>

The authors of the Restatement in commentary reasoned that people infected with rabies would accept an unavoidably unsafe vaccine over imminent death.<sup>127</sup> Unfortunately, the Restatement did not address the typical case of a healthy child, not facing imminent death, receiving an unavoidably unsafe product. Despite the fact that this logic is inapt for childhood

---

<sup>120</sup> See § 300aa-22(b)(2).

<sup>121</sup> The Vaccine Act codifies this understanding at § 300aa-22(c).

<sup>122</sup> See § 300aa-23(d)(2).

<sup>123</sup> See generally *id.* § 300aa-22.

<sup>124</sup> Brief of Amici Curiae Kenneth W. Starr and Erwin Chemerinsky in Support of Petitioners Urging Reversal at 18–19, *Bruesewitz v. Wyeth, Inc.*, 562 U.S. 223 (2011) (No. 09-152).

<sup>125</sup> RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST.1965).

<sup>126</sup> *Id.* (emphasis omitted).

<sup>127</sup> *Id.*

immunizations given to healthy children not facing imminent death, this concept is still a fundamental element of the Vaccine Act.

After the NVICP began accepting claims in 1988, no vaccine manufacturer could be liable for a vaccine-related injury or death so long as “the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”<sup>128</sup>

For decades, courts split on whether the Vaccine Act preserved the right to sue for vaccine design defects. Some design defect lawsuits before and after the Vaccine Act were successful, such as the case of *Toner v. Lederle Laboratories*, in which the Ninth Circuit found that Lederle Laboratories was negligent for having failed to improve the design of its vaccine.<sup>129</sup> In *American Home Products Corp. v. Ferrari*, the Supreme Court of Georgia in 2008 unanimously upheld the right of a plaintiff to sue a vaccine manufacturer for including thimerosal, a mercury-containing preservative, in its vaccines as a design defect.<sup>130</sup> The decision confirmed that civil courts must decide whether a vaccine defect was unavoidable on a case-by-case basis.<sup>131</sup> The Pennsylvania Superior Court, the state’s civil appellate court, reached the same conclusion in its interpretation of the Vaccine Act.<sup>132</sup> But from 1986 through 2011, circuit courts came to differing interpretations on the right to sue for vaccine design defects.<sup>133</sup> In 2011, the U.S. Supreme Court held in *Bruesewitz v. Wyeth LLC* that the Vaccine Act preempts all design defect civil claims.<sup>134</sup>

### I. *The Problems of the Vaccine Act*

Engstrom, studying the NVICP as a prototype for proposed specialized health courts, found that it paints a “gloomy portrait.”<sup>135</sup> She argues that the thirty-year NVICP experiment should “shake public confidence in this new alternative mechanism—and inform future analysis.”<sup>136</sup> This must be true both

---

<sup>128</sup> § 300aa-22(b)(1).

<sup>129</sup> *Toner v. Lederle Labs.*, 828 F.2d 510 (9th Cir. 1987),

<sup>130</sup> *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

<sup>131</sup> *See id.*

<sup>132</sup> *See Wright v. Aventis Pasteur Inc.*, 14 A.3d 850, 884 (Pa. Super. Ct. 2011).

<sup>133</sup> *See, e.g., Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988); *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1 (1st Cir. 1994).

<sup>134</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231–32 (2011).

<sup>135</sup> Engstrom, *supra* note 59, at 1715.

<sup>136</sup> *Id.* at 1717.

for future courts in the United States and for potential exportation of this model to the developing world.

The NVICP has not lived up to the expectations Congress set out for it—to be fair, consistent, non-adversarial, and speedy. To show this, Engstrom cites a document from the department of HHS that reviews medical claims before they proceed to the NVICP.<sup>137</sup> This HHS document acknowledges that NVICP judgments are inconsistent.<sup>138</sup> Further, Petitioners’ counsel told Engstrom that the single biggest factor relating to whether they win or lose a case is its special master assignment.<sup>139</sup>

Engstrom’s research shows that the NVICP on average takes two and a half times longer to process claims than the traditional tort system—sixty-six months in the NVICP compared to 25.6 months for tort cases.<sup>140</sup> She also found that NVICP cases on average take longer than consumer class actions, which take roughly thirty-two months.<sup>141</sup> These indicators, coupled with the reality that only 2% of cases rest on presumptive Table injuries,<sup>142</sup> make it clear that the system is not working.

#### *J. HHS Administrative Changes in the 1990s*

In the early 1990s, just a few years after the Vaccine Act took effect, the HHS Secretary Shalala used her discretionary authority to change the Table, eliminating some of the most important presumptions for recovery then in use for injuries from the DPT vaccine.<sup>143</sup> For example, Secretary Shalala removed “residual seizure disorder” from the Table, nullifying the presumptive compensation category for children who suffered seizures immediately after the DPT vaccine. As a result, almost all DPT vaccine seizure disorder cases became off-Table, thus requiring litigation. Those cases met inconsistent results.<sup>144</sup>

---

<sup>137</sup> See HEALTH RES. & SERVS. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP) 8 (2016) (“HHS reviews the medical information in the claim and this review is sent to the DOJ lawyer who represents the Secretary of Health and Human Services . . .”).

<sup>138</sup> See Engstrom, *supra* note 59, at 1677 (citing DIV. OF VACCINE INJURY COMPENSATION, NATIONAL VACCINE INJURY COMPENSATION PROGRAM STRATEGIC PLAN app. H at 25 (2006)).

<sup>139</sup> See *id.*

<sup>140</sup> *Id.* at 1686.

<sup>141</sup> *Id.* at 1686–87.

<sup>142</sup> *Id.* at 1702–03.

<sup>143</sup> 42 C.F.R. § 100.3 (1996).

<sup>144</sup> See *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009) (allowing compensation for seizures caused by DPT vaccine). *But see* *Bruesewitz v. Sec’y of the Dep’t of Health &*

Shalala also changed the Table definition of “encephalopathy,” a recognized compensable injury,<sup>145</sup> leading to a process that has radically reduced the number of on-Table petitions from 74% before 1995 to about 2% by 2015.<sup>146</sup> As Engstrom discusses, a Government Accountability Office report “scolded HHS for ‘bas[ing] its decisions to add or remove table injuries on various factors’ without ‘a clear and transparent methodology to demonstrate that these factors were consistently applied.’”<sup>147</sup> In 1995, the chair of the Advisory Commission on Childhood Vaccines, a body Congress created to oversee the NVICP, referred to the amendments as “a repudiation of the principles on which the compensation program” was created.<sup>148</sup> Even Congress, in a 2000 report, stated that “HHS’s actions had ‘undermin[ed] the remedial nature of the program as intended by the Congress.’”<sup>149</sup>

Plaintiffs challenged the HHS administrative changes and appealed them to the First Circuit. The First Circuit upheld HHS’s administrative discretion to make changes to the Table.<sup>150</sup> These changes altered the character of the NVICP fundamentally. According to Fisher, a vaccine safety advocate, these HHS actions “turned the administrative compensation process into a highly adversarial, lengthy, expensive, traumatic, and unfair imitation of a court trial for vaccine victims and their attorneys.”<sup>151</sup>

Engstrom explains that the statutory malleability of the Table also makes it subject to manipulation.<sup>152</sup> The administrative ability to “dramatically alter a program’s size, scope, and character” can undermine the perception of a

---

Human Servs., No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002) (denying compensation for seizure disorder allegedly caused by DPT vaccine).

<sup>145</sup> Press Release, Patricia Campbell, Health Resources & Servs. Admin, Regulation—Vaccine Compensation (Aug. 21, 1992), <https://wayback.archive-it.org/3926/20130930182617/http://archive.hhs.gov/news/press/1992pres/920821.txt>.

<sup>146</sup> Engstrom, *supra* note 59, at 1702–03.

<sup>147</sup> *Id.* at 1704 (alteration in original) (quoting U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-00-8, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 3 (1999)).

<sup>148</sup> *Id.* (quoting Advisory Comm’n on Childhood Vaccines, U.S. Dep’t of Health & Human Servs., Transcript of Meeting of March 1, 1995, at 2).

<sup>149</sup> *Id.* at 1704 n.338 (alteration in original) (quoting H.R. REP. NO. 106-977, at 2 (2000)).

<sup>150</sup> See *O’Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996) (holding that the Secretary of HHS had the power to promulgate a rule removing residual seizure disorder from the vaccine injury table and changing the definition of encephalopathy). The petitioners also brought an appellate suit in the Court of Federal Claims after they were denied compensation under the NVICP. *O’Connell v. Sec’y of Health & Human Servs.*, 217 F.3d 857 (Fed. Cir. 1999).

<sup>151</sup> Advisory Comm’n on Childhood Vaccines, Dep’t of Health & Human Servs., *supra* note 72, at 14.

<sup>152</sup> See Engstrom, *supra* note 59, at 1703.

tribunal's legitimacy, diminishing the public's faith in government.<sup>153</sup> She asserts that specialized courts are "peculiarly susceptible to being thought partisan."<sup>154</sup>

### K. *Compensating Victims*

NVICP proceedings are exceptionally hostile and frequently take many years. Engstrom cites an example of when it took twelve years, from 1998 until 2010, for the NVICP simply to deny compensation.<sup>155</sup> Furthermore, the rigid three-year statute of limitations likely excludes many legitimate cases of vaccine injury. The Table was drafted when it was believed that almost all vaccine injuries occurred within hours or days of vaccination.<sup>156</sup> That injury occurs so quickly is no longer the view of many physicians and scientists. Some disabilities that may be related to vaccination occur years after the event, and HHS has acknowledged this in some cases.<sup>157</sup> While many lawmakers have proposed a longer statute of limitations, the current three-year window continues in force.

The U.S. Court of Federal Claims decision in *Cloer v. Secretary of Health & Human Services* made the three-year period even more onerous by holding that the three years from first manifestation of injury could not be tolled when subsequent science showed that the injury was vaccine-related after the three-year window.<sup>158</sup> So, if an individual learns more than three years after the first manifestation of multiple sclerosis symptoms that the manifestations might be vaccine-related, as was the case for Dr. Cloer, she may not obtain compensation.

The former Chief Special Master Gary Golkiewicz acknowledged the NVICP's bias against petitioners in an interview with a reporter.<sup>159</sup> He said that

---

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 1705 (quoting David P. Currie & Frank I. Goodman, *Judicial Review of Federal Administrative Action: Quest for the Optimum Forum*, 75 COLUM. L. REV. 1, 72 (1975)).

<sup>155</sup> *Id.* at 1687 (citing *Kolakowski v. Sec'y of Health & Human Servs.*, No. 99-0625V, 2010 WL 5672753 (Fed. Cl. Nov. 23, 2010)).

<sup>156</sup> See *Vaccine Injury Table*, *supra* note 103, where the longest period for first symptom or manifestation of onset or of significant aggravation after vaccine administration is less than or equal to twelve months.

<sup>157</sup> See, e.g., *Poling v. Sec'y of Health & Human Servs.*, No. 02-1466V, 2011 WL 678559, at \*1 (Fed. Cl. Jan. 28, 2011) ("Hannah's encephalopathy eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequel.").

<sup>158</sup> *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1344–45 (Fed. Cir. 2011).

<sup>159</sup> ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER* 293 (2007).

HHS and the DOJ “altered the game so that it’s clearly in their favor . . . . This group has a vested interest in vaccines being good. It doesn’t take a mental giant to see the fundamental unfairness in this.”<sup>160</sup> The Vaccine Act, and the NVICP in particular, simply have not fulfilled its mission to compensate vaccine injury victims like Hannah Bruesewitz, whose vaccine injury case landed in the Supreme Court in 2011.<sup>161</sup>

#### L. *Bruesewitz v. Wyeth*

Hannah Bruesewitz suffered severe brain damage and a permanent seizure disorder within hours after receiving her third DPT vaccine in 1992.<sup>162</sup> She litigated for more than fifteen years and ultimately received no compensation from the NVICP.<sup>163</sup>

Hannah’s pediatrician administered the vaccine to the then-healthy six-month-old, according to the federally recommended childhood immunization schedule.<sup>164</sup> Within hours of vaccination, Hannah experienced her first seizure and experienced a total of 125 seizures over the next sixteen days.<sup>165</sup> Hannah had no previous medical history of seizures.<sup>166</sup> Her symptoms became more severe in the following months; Hannah’s medical records described her as lethargic, developmentally delayed, and presenting “autistic-like features.”<sup>167</sup>

At the age of twenty months, Hannah was non-verbal and understood only simple commands.<sup>168</sup> Seven of eight electroencephalograms (EEGs) taken between April 1992 and July 1995 showed abnormalities, and a computed tomography (CT) scan taken in July 1995 indicated diffuse neuronal loss.<sup>169</sup> Her doctors eventually diagnosed her with residual seizure disorder and developmental delay.<sup>170</sup> Hannah is still diagnosed with both conditions.

---

<sup>160</sup> *Id.*

<sup>161</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

<sup>162</sup> *Bruesewitz v. Sec’y of the Dep’t of Health & Human Servs.*, No. 95-0266V, 2002 WL 31965744, at \*1 (Fed. Cl. Dec. 20, 2002).

<sup>163</sup> The Bruesewitzes filed a petition on April 3, 1995. *See id.* The Supreme Court reached its decision on February 22, 2011. *See Bruesewitz*, 562 U.S. at 223.

<sup>164</sup> *Bruesewitz*, 2002 WL 3196744, at \*2.

<sup>165</sup> *See id.* at \*2–4.

<sup>166</sup> *See* Russ Bruesewitz, *Justice Disserved: The Hannah Bruesewitz Odyssey*, in *VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN* 104–13, 105 (Louise Kuo Habakus & Mary Holland eds., 2d ed. 2012).

<sup>167</sup> *See Bruesewitz*, 2002 WL 31965744, at \*4–5.

<sup>168</sup> *See id.* at \*6.

<sup>169</sup> *See id.* at \*4–7.

<sup>170</sup> *Bruesewitz*, 562 U.S. at 230.

Hannah, now in her twenties, continues to suffer from residual seizure disorder and remains severely developmentally impaired.<sup>171</sup>

Lederle Laboratories, which Wyeth Pharmaceuticals purchased in 1994, manufactured Tri-Immunol, the DPT vaccine that Hannah received.<sup>172</sup> Despite an awareness of DPT's dangers and the availability of an alternative version believed to cause fewer adverse events<sup>173</sup>—the diphtheria-tetanus-acellular pertussis (DTaP) vaccine—Wyeth did not take Tri-Immunol off the market until 1998.<sup>174</sup>

In addition to raising design defect concerns, Hannah's case raised questions about improper manufacturing. Hannah's vaccine dose came from a lot that caused a disproportionately large number of adverse events. The Vaccine Adverse Events Reporting System (VAERS) had already received reports of one death and thirty adverse events by the time Hannah was vaccinated.<sup>175</sup> VAERS reports eventually linked the lot to sixty-five adverse reactions, "including thirty-nine emergency room visits, six hospitalizations, and two deaths."<sup>176</sup>

Within the three-year statute of limitations, in April 1995, Hannah's parents filed a petition for on-Table vaccine injury in the NVICP for vaccine-induced residual seizure disorder and encephalopathy.<sup>177</sup> Although the Vaccine Act established a fixed deadline for the NVICP to issue decisions "not later than 240 days . . . after the date the petition was filed,"<sup>178</sup> a special master denied the Bruesewitzes's claim in December 2002, more than seven years after they filed their petition in the NVICP.<sup>179</sup> The decision cited several grounds for denial, including the fact that residual seizure disorder was no longer included on the Table at the time the Bruesewitzes filed their petition.<sup>180</sup>

In fact, one month prior to the filing of Hannah's petition, HHS Secretary Shalala removed DPT-associated residual seizure disorder from the Table.<sup>181</sup>

---

<sup>171</sup> *See id.*

<sup>172</sup> *See id.*

<sup>173</sup> *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 236 (3d Cir. 2009), *aff'd sub nom. Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

<sup>174</sup> *See id.*

<sup>175</sup> *See* Brief for Petitioner at 20, *Bruesewitz*, 562 U.S. 223 (No. 09-152).

<sup>176</sup> *Bruesewitz*, 561 F.3d at 237.

<sup>177</sup> *Bruesewitz v. Sec'y of the Dep't of Health & Human Servs.*, No-95-0266V, 2002 WL 31965744, at \*1 (Dec. 20, 2002).

<sup>178</sup> 42 U.S.C. § 300aa-12(d)(3)(A)(ii) (2012).

<sup>179</sup> *See Bruesewitz*, 2002 WL 31965744, at \*17.

<sup>180</sup> 42 C.F.R. § 100.3 (1996); *see also Bruesewitz*, 2002 WL 31965744, at \*17.

<sup>181</sup> *See Bruesewitz*, 2002 WL 31965744, at \*1 n.1.



As a result, Hannah was precluded from taking advantage of the presumption of causation she would have received had she filed the claim one month earlier.<sup>182</sup> Absent the presumption, the Bruesewitzes were required to establish causation by a preponderance of the evidence, a burden that the special master concluded they did not meet.<sup>183</sup>

The Bruesewitzes rejected the special master's judgment and commenced an action in Pennsylvania state court in October 2005, more than ten years after they had filed their initial petition in the NVICP. Their complaint alleged theories of strict products liability and negligent vaccine design, claims they could not advance in the NVICP.<sup>184</sup>

Wyeth removed the suit to the Eastern District of Pennsylvania, which granted Wyeth summary judgment on both causes of action, holding that § 300aa-22(b)(1) of the Vaccine Act preempted state common law causes of action for defective design.<sup>185</sup> The Third Circuit affirmed the district court's decision, concluding that the Vaccine Act's language barred design defect claims.<sup>186</sup>

#### *M. The Supreme Court's Decision*

The Bruesewitzes petitioned for certiorari to the U.S. Supreme Court in August 2009, as did American Home Products Corporation, then-owned by Wyeth, the respondent in *Ferrari*, another case raising the issue of vaccine design defect under the Vaccine Act.<sup>187</sup> The Supreme Court granted certiorari in *Bruesewitz*, and issued its decision in February 2011.<sup>188</sup>

Justice Scalia authored the Court's decision in which Chief Justice Roberts and Justices Kennedy, Thomas, Breyer, and Alito joined. Justice Sotomayor wrote a dissenting opinion, which Justice Ginsburg joined. Justice Kagan recused herself as she had been Solicitor General when the DOJ had prepared

---

<sup>182</sup> See National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7691 (Feb. 8, 1995); see also *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374, 1382 (Fed. Cir. 2009) (finding sufficient medical evidence to establish causation in fact for claim of seizure disorder caused by DPT vaccine).

<sup>183</sup> See *Bruesewitz*, 2002 WL 31965744, at \*13–17.

<sup>184</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231 (2011).

<sup>185</sup> *Id.* at 231.

<sup>186</sup> *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 255–56 (3d Cir. 2009), *aff'd sub nom. Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

<sup>187</sup> *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), *vacated*, 562 U.S. 1254 (2011).

<sup>188</sup> See *Bruesewitz*, 562 U.S. at 223.

its briefs in the case.<sup>189</sup> The Court held that the Vaccine Act's text and structure bar all state law claims of design defect against vaccine manufacturers.<sup>190</sup>

Justice Scalia began by setting forth the relevant statutory text, which the Supreme Court of Georgia<sup>191</sup> and the Third Circuit<sup>192</sup> had interpreted differently:

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, *if* the injury or death resulted from side effects that were unavoidable *even though* the vaccine was properly prepared and was accompanied by proper directions and warnings.<sup>193</sup>

Although he did not describe this as an express preemption clause, one can infer that Justice Scalia believed that § 22(b)(1) provided sufficient evidence of a clear and manifest preemptive purpose to qualify it as express preemption.<sup>194</sup>

Several of the Justices pointed out that this statutory provision is extremely ambiguous and poorly drafted.<sup>195</sup> The Court's decision hinged on the "even though" clause's ability to clarify the meaning of the word "unavoidable" on its own.<sup>196</sup> According to the Court, properly preparing a vaccine and accompanying it with proper warnings render all resulting side effects unavoidable for purposes of the Vaccine Act, exempting manufacturers from design defect liability.<sup>197</sup> Justice Scalia found this interpretation necessary so that the word "unavoidable" has meaning, as "[a] side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not

---

<sup>189</sup> See *id.* at 243; *Solicitor General: Elena Kagan*, U.S. DEP'T JUST. (Oct. 31, 2014), <https://www.justice.gov/osg/bio/elena-kagan>.

<sup>190</sup> See *Bruesewitz*, 562 U.S. at 240, 243.

<sup>191</sup> See *Am. Home Prods. Corp.*, 668 S.E.2d at 237–38.

<sup>192</sup> *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *aff'd sub nom. Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

<sup>193</sup> 42 U.S.C. § 300aa-22(b)(1) (2012) (emphasis added).

<sup>194</sup> *Bruesewitz*, 562 U.S. at 238 (“[W]e do not suggest that the absence of guidance alone suggests preemption. But the lack of guidance for design defects combined with the extensive guidance for the two grounds of liability specifically mentioned in the [Vaccine] Act strongly suggests that design defects were not mentioned because they are not a basis for liability.”)

<sup>195</sup> Transcript of Oral Argument at 16, *Bruesewitz*, 562 U.S. 223 (No. 09-152) (Justice Breyer: “I think [the language is] ambiguous”).

<sup>196</sup> See *Bruesewitz*, 562 U.S. at 231–32.

<sup>197</sup> See *id.*

containing the harmful element.”<sup>198</sup> According to Justice Scalia, a vaccine’s design is “a given” and “not subject to question in the tort action.”<sup>199</sup>

Justice Scalia concluded that a textual interpretation did not depend on the “if” clause.<sup>200</sup> Justice Scalia subsequently focused only on the plain dictionary definition of the word “unavoidable.”<sup>201</sup> This is problematic because “unavoidable” is a term of art in strict products liability and directly relates to the interpretation of § 22(b)(1).

Comment k to the Restatement § 402A exempts from strict products liability:

*Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many . . . drugs, vaccines, and the like . . . .<sup>202</sup>

In contrast to Justice Scalia’s view, most state approaches to comment k do “not entail a categorical pronouncement that a particular product is unavoidably unsafe in all circumstances.”<sup>203</sup> Rather, the majority view is that a court must make case-by-case determinations as to whether a particular side effect was unavoidable.<sup>204</sup>

According to the dissent, comment k transformed the phrase “unavoidably unsafe” into a term of art.<sup>205</sup> Despite extensive legislative history to the contrary,<sup>206</sup> Justice Scalia found “no reason to believe” that Congress invoked

<sup>198</sup> *Id.* at 232.

<sup>199</sup> *Id.*

<sup>200</sup> *Id.* at 233.

<sup>201</sup> *Id.* at 234–35.

<sup>202</sup> RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST.1965) (emphasis omitted).

<sup>203</sup> Brief of Amici Curiae Kenneth W. Starr and Erwin Chemerinsky in Support of Petitioners Urging Reversal, *supra* note 124, at 19.

<sup>204</sup> *Id.* (“Under the majority approach to comment k, a court must make a case-by-case determination of whether a certain side effect is unavoidable. Comment k does not entail a categorical pronouncement that a particular product is unavoidably unsafe in all circumstances.”).

<sup>205</sup> *Bruesewitz*, 562 U.S. at 257, (Sotomayor, J., dissenting).

<sup>206</sup> See H.R. REP. NO. 99–908, at 25 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6366 (“This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) . . . .”); see also *id.* at 26, 1986 U.S.C.C.A.N. at 6367 (“The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding ‘unavoidably unsafe’ products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.”).

comment k in drafting § 22(b)(1) because it used the word “unavoidable” instead of the phrase “unavoidably unsafe.”<sup>207</sup> Refusing to give the word any special significance, the Court concluded that § 22(b)(1) categorically preempts design defect claims against vaccine manufacturers.<sup>208</sup>

Perhaps in recognition of the problematic nature of its textual argument, the Court grounded its reading of § 22(b)(1) in the structure of the Vaccine Act as a whole. Justice Scalia argued that because neither the Vaccine Act nor FDA regulations ever expressly mentioned design defects, “Congress must have intended to remove issues concerning the design of FDA-licensed vaccines from the tort system.”<sup>209</sup> This fails to acknowledge, however, that the FDA was silent on vaccine design defects before the Vaccine Act’s passage, during which time vaccine manufacturers were liable for defective design in state courts.<sup>210</sup> As Justice Sotomayor wrote in dissent:

That the Vaccine Act did not itself set forth a comprehensive regulatory scheme with respect to design defects is thus best understood to mean not that Congress suddenly decided to change course *sub silentio* and pre-empt a longstanding, traditional category of state tort law, but rather, that Congress intended to leave the status quo alone (except, of course, with respect to those aspects of state tort law that the [Vaccine] Act expressly altered.<sup>211</sup>

And while Justice Scalia is correct that “whenever the FDA concludes that a vaccine is unsafe, it may revoke the license,”<sup>212</sup> the author is unaware that it has ever done so.<sup>213</sup>

Justice Scalia argued that tort claims for design defects cannot serve any additional purpose because the Vaccine Act, through the NVICP, provides means both to encourage improved designs and to compensate injuries.<sup>214</sup> But as Justice Sotomayor pointed out, the NVICP’s no-fault scheme cannot possibly spur vaccine manufacturers to innovate because it imposes no legal duty on them to ensure that they provide the safest products possible in light of

---

<sup>207</sup> *Bruesewitz*, 562 U.S. at 234 (majority opinion).

<sup>208</sup> *See id.* at 234.

<sup>209</sup> *Id.* at 268 (Sotomayor, J., dissenting).

<sup>210</sup> *Id.*

<sup>211</sup> *Id.* at 269.

<sup>212</sup> *Id.* at 239 (majority opinion).

<sup>213</sup> *See Vaccine Recalls*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 28, 2015), <https://www.cdc.gov/vaccinesafety/concerns/recalls.html> (“Vaccine recalls or withdrawals are almost always initiated voluntarily by the vaccine manufacturer.”).

<sup>214</sup> *See Bruesewitz*, 562 U.S. at 238.

scientific and technological advances.<sup>215</sup> States have traditionally imposed such a duty by allowing civil damages for design defects.<sup>216</sup>

Justice Scalia's statement that the Court would be skeptical "unless the congressional substitute operated like the tort system,"<sup>217</sup> seems to disregard how the NVICP actually functions. Because of the compensation program's no-fault nature, vaccine manufacturers themselves have no financial responsibility for injuries from defectively designed vaccines. And because HHS is the respondent in all NVICP cases, vaccine manufacturers do not even face the burden of defending themselves.

Moreover, it is not possible to bring traditional product liability causes of action in the NVICP, only claims for personal injury. Most troubling, however, is the Court's view that the NVICP is an adequate substitute for the tort system.<sup>218</sup> Justice Scalia's idealized view of the NVICP implies that almost all cases are on-Table, as Congress intended. But the reality is that 98% of cases are fiercely litigated in a forum designed as an administrative tribunal.

Finally, the Court asserted that vaccine manufacturers contribute a portion of their profits toward the compensation program's trust fund, a *quid pro quo* for receiving immunity from liability for defective designs.<sup>219</sup> This is inaccurate, however. In fact, consumers entirely fund the trust fund, paying a \$0.75 excise tax on each vaccine to the federal government.<sup>220</sup> Justice Scalia's suggestion that vaccine market demand is elastic<sup>221</sup> is also misleading. Given state childhood vaccination mandates as well as patents and other high barriers to entry that keep market competition to a minimum, it is unlikely that vaccine excise taxes influence manufacturers' profits. The world's leading vaccine manufacturers received over \$16.8 billion from childhood vaccine sales alone

---

<sup>215</sup> See *id.* at 269–70 (Sotomayor, J., dissenting).

<sup>216</sup> See *id.* at 270.

<sup>217</sup> *Id.* at 240.

<sup>218</sup> *Id.*

<sup>219</sup> *Id.* at 239–40.

<sup>220</sup> "The majority's suggestion that 'vaccine manufacturers fund from their sales' the compensation program is misleading. Although the manufacturers nominally pay the tax, the amount of the tax is specifically included in the vaccine price charged to purchasers. Accordingly, the only way the vaccine manufacturers can be said to actually 'fund' the compensation program is if the cost of the excise tax has an impact on the number of vaccines sold by the vaccine manufacturer. The majority points to no evidence that the excise tax—which ordinarily amounts to 75 cents per dose—has any impact whatsoever on the demand for vaccines." *Id.* at 272 n.22 (citations omitted).

<sup>221</sup> *Id.* at 239 n.64 (majority opinion) ("The dissent's unsupported speculation that demand in the vaccine market is inelastic sheds no light on whether Congress regarded the tax as a *quid pro quo*, most Members of Congress being neither professional economists nor law-and-economics scholars." (citations omitted)).

in 2015.<sup>222</sup> Thus, vaccine manufacturers have gained immensely from almost-blanket tort liability protection with no quid pro quo.

#### *N. The Dissent*

In a long and scathing dissent, Justice Sotomayor dissected the majority decision and argued in effect that it was decided according to policy preference rather than law. In holding that the Vaccine Act preempts all design defect claims for vaccine injuries, she wrote:

[T]he Court imposes its own bare policy preference over the considered judgment of Congress. In doing so, the Court excises 13 words from the statutory text, misconstrues the [Vaccine] Act’s legislative history, and disturbs the careful balance Congress struck between compensating vaccine-injured children and stabilizing the childhood vaccine market. Its decision leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products.<sup>223</sup>

Justice Sotomayor noted that the majority’s decision, based largely on Wyeth’s own arguments, seemed intent on averting an imagined “crushing wave” of over 5,000 former NVICP petitions reaching civil courts to allege a causal link between vaccines and autism spectrum disorders.<sup>224</sup> Wyeth had argued that such tort litigation about vaccine design defect in civil courts “would bankrupt vaccine manufacturers and deplete vaccine supply.”<sup>225</sup> Justice Sotomayor wrote that “[t]his concern underlies many of the policy arguments in respondent’s brief and appears to underlie the majority and concurring opinions in this case.”<sup>226</sup> She noted, however, that this parade of horrors seemed “wholly speculative.”<sup>227</sup>

Justice Sotomayor wrote that the NVICP had rejected vaccine-autism claims and that the NVICP “rulings do highlight the substantial hurdles to recovery” that plaintiffs face.<sup>228</sup> She also pointed out that trial courts have

---

<sup>222</sup> See Bruce Carlson, *Five Things to Know About the Vaccine Industry in 2016*, KALORAMA INFO. (Dec. 16, 2016), <https://www.kaloramainformation.com/Content/Blog/2016/12/16/Five-Things-to-Know-About-the-Vaccine-Industry-in-2016> (stating that 57.6% of the global revenue in 2014 of \$29.3 billion was due to pediatric vaccines).

<sup>223</sup> *Bruesewitz*, 562 U.S. at 250 (Sotomayor, J., dissenting).

<sup>224</sup> *Id.* at 274 n.25.

<sup>225</sup> *Id.* (citing Brief for Respondent at 28, *Bruesewitz*, 562 U.S. 223 (No. 09-152)).

<sup>226</sup> *Id.*

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

“considerable experience in efficiently handling and disposing of meritless products liability claims, and decades of tort litigation (including for design defect) in the prescription-drug context have not led to shortages in prescription drugs.”<sup>229</sup> She discounted such “doomsday predictions” as “remote at best.”<sup>230</sup> But she argued that regardless of the merits of the policy arguments, the Court’s job is to ensure Congress’s intent.

She concluded in a critically important footnote that the text, structure, and legislative history of the Vaccine Act “compel the conclusion that Congress intended to leave the courthouse doors open for children who have suffered severe injuries from defectively designed vaccines. The majority’s policy-driven decision to the contrary usurps Congress’ role and deprives such vaccine-injured children of a key remedy that Congress intended them to have.”<sup>231</sup>

### *O. The Impact of the Vaccine Act and the Bruesewitz Decision*

The *Bruesewitz* decision removed incentives for pharmaceutical corporations to conduct the extensive research and development necessary to ensure that FDA-approved vaccines remain as safe and effective as possible after licensure. FDA approval alone has not been a sufficient guarantee of drug safety, owing in part to the FDA’s limited authority to compel further safety research after final approval.<sup>232</sup> Rather, vigorous litigation over drug defects has spurred manufacturers voluntarily to remove numerous drugs from the market based on unreleased data on adverse effects, unethical practices, and flaws in the FDA’s regulatory procedures.<sup>233</sup>

With no private party able to hold vaccine manufacturers responsible for post-marketing safety defects, vaccine manufacturers in the United States enjoy the benefits of a captive market for mandated products with few economic incentives to make them as safe and effective as possible. While vaccine-injured victims have the misfortune to serve as “drug safety researchers of last resort,”<sup>234</sup> they are barred in the United States from bringing lawsuits against manufacturers that might both compensate victims and stimulate manufacturers to improve vaccine safety.

---

<sup>229</sup> *Id.*

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

<sup>231</sup> *Id.*

<sup>232</sup> See, e.g., Aaron S. Kesselheim & Jerry Avorn, Commentary, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 308 (2007).

<sup>233</sup> See *id.*

<sup>234</sup> *Id.* at 311.

*P. Empirical Research on Vaccine Injury Before and After the Vaccine Act*

An important empirical study recently published confirms that the inability to sue vaccine manufacturers in U.S. civil courts since 1986 is associated with a decrease in vaccine safety in FDA-approved vaccines after 1986.<sup>235</sup> In this peer-reviewed analysis, Professor DeLong looked at what happened to vaccine safety after “delitigation” or removal of litigation risk through the Vaccine Act. Using national and state-level data, she found that vaccines the FDA licensed after the Vaccine Act are associated with more adverse events than those it licensed earlier when consumers could sue.<sup>236</sup>

The study examines the question whether a regulator, the FDA in this case, can enforce an optimal level of care, or whether litigation forces firms to correct unforeseen problems once products are on the market.<sup>237</sup> If a regulator cannot enforce an optimal level of safety without added litigation risk, then “delitigation [is] associated with deteriorating product safety.”<sup>238</sup>

DeLong observes that after the Vaccine Act passed in 1986, the amount of investment in biologic products, including vaccines, tripled from \$85.6 million in 1986 to \$273.7 million in 1989.<sup>239</sup> Also the number of investigational new drug applications more than doubled from the 1980s to the 1990s, suggesting that manufacturers had incentives to produce new and potentially riskier products.<sup>240</sup>

DeLong used the VAERS, which only existed after the Vaccine Act took effect, as her source of data for adverse event reports. While there is no better data source available, she acknowledges its limitations: VAERS is a passive reporting system. Medical personnel are not required to report adverse vaccine events; and while individuals can report events, they too are not required to do so.<sup>241</sup> Furthermore, reported events are not verified, so some events may not actually be due to vaccines.<sup>242</sup> Also, vaccine adverse events are likely drastically underreported.<sup>243</sup>

---

<sup>235</sup> Gayle DeLong, *Is “Delitigation” Associated with a Change in Product Safety? The Case of Vaccines*, REV. IND. ORG. (June 14, 2017), <https://link.springer.com/article/10.1007/s11151-017-9579-7>.

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

<sup>237</sup> *Id.* at pt. 1.

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

<sup>239</sup> *Id.* at pt. 4.

<sup>240</sup> *Id.*

<sup>241</sup> *Id.* at pt. 5.3.

<sup>242</sup> *Id.*

<sup>243</sup> *Id.*



DeLong cites to a study from 2007 that tracked vaccine recipients and found that 20.5 adverse events occur per 1,000 vaccine doses.<sup>244</sup> Using that data suggests likely one in every 170 adverse events is reported.<sup>245</sup> DeLong assumes that the adverse event rate for vaccines approved before 1986 is the same before and after the introduction of VAERs because the FDA does not permit manufacturers to alter FDA-approved drugs.<sup>246</sup>

DeLong found that vaccines licensed after 1986 are associated with approximately 5.2 more reported adverse events per 100,000 vaccine doses than the vaccines that were licensed before the passage of Vaccine Act.<sup>247</sup> The weighted averages suggest that pre-legislation vaccines are associated with 14.0 adverse events per 100,000 while post-legislation vaccines are associated with 19.2 adverse events per 100,000.<sup>248</sup> This difference is statistically significant at the 1% level.<sup>249</sup>

DeLong showed that the proportion of people that reported a serious complication from a vaccine after 1986 is more than double the proportion of people who experienced a serious complication from a disease before a vaccine for it was available.<sup>250</sup> The difference is statistically significant and is likely greater because of underreporting.<sup>251</sup>

DeLong's analysis suggests that the Vaccine Act "gave firms greater incentives to capture the regulator: If consumers cannot sue firms for product liability, the only barrier to sales is regulatory approval."<sup>252</sup>

She suggests that the Vaccine Act may be creating "moral hazard" because vaccine manufacturers do not have to answer to people damaged by their products.<sup>253</sup> The manufacturers do not even contribute to the compensation fund; excise taxes from consumers fund it. DeLong has shown empirically that "[d]elimitation appears to have removed an important safety monitor in the

---

<sup>244</sup> *Id.* ("Hinrichsen et al. (2007) tracked vaccine recipients and found 20.5 adverse events per 1,000 doses administered. . . . [While] the VAERS database reflected 0.12 AEs per 1,000 vaccine doses, which suggests that approximately one in every 170 (=20.5/0.12) AEs is reported.").

<sup>245</sup> *Id.*

<sup>246</sup> *Id.* at pt. 5 ("Since the FDA does not permit manufacturers to alter an FDA-approved drug, the AE ratio of a licensed vaccine should not change over time.").

<sup>247</sup> *Id.* at pt. 5.1 tbl.2.

<sup>248</sup> *Id.*

<sup>249</sup> *Id.*

<sup>250</sup> *Id.* at pt. 6.1.

<sup>251</sup> *Id.*

<sup>252</sup> *Id.* at pt. 8.

<sup>253</sup> *Id.*

vaccine industry” and suggests the need for further study.<sup>254</sup> She suggests that Dr. Salk, who opposed the creation of the NVICP in congressional hearings before Congress passed the Vaccine Act, “appears to be prescient in his concerns that indemnification would reduce incentives to improve an existing vaccine and to change vaccine policy.”<sup>255</sup>

*Q. Liability Protection in Emergencies: The PREP Act*

The NVICP does not apply to all vaccines. It applies only to those vaccines that are listed on the Vaccine Injury Table.<sup>256</sup> It does not apply to many vaccines, such as the shingles vaccine for adults. Individuals harmed by those vaccines may sue in civil court. The NVICP also does not apply to vaccines put to use in declared public health emergencies.<sup>257</sup>

In 2005, Congress passed a tort shield law, the PREP Act, to protect manufacturers of drugs and other “covered countermeasure[s],” including vaccines, from the risk of damages in the event of a declared public health emergency.<sup>258</sup> This statute goes considerably further than the Vaccine Act to create an exclusive limited administrative remedy. The PREP Act disallows those injured to apply to the NVICP; they must apply to an administrative program that HHS administers itself.<sup>259</sup> The PREP Act covers vaccines, antidotes, medications, medical devices, and other products used to respond to pandemics and biological and chemical threats.<sup>260</sup>

If the HHS Secretary declares a public health emergency, then liability protection covers not only manufacturers, but all medical administrators of the covered countermeasures to prevent, treat or mitigate an epidemic.<sup>261</sup> The Secretary’s declaration is not reviewable by any court.<sup>262</sup>

The PREP Act sets up an administrative Countermeasures Injury Compensation Program (CICP) in HHS for people seriously injured from the

---

<sup>254</sup> *Id.* at pt. 9.

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

<sup>256</sup> 42 U.S.C. § 300aa-11(b)(1)(A) (2012).

<sup>257</sup> Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d (2012).

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

<sup>259</sup> *See Countermeasures Injury Compensation Program*, HEALTH RESOURCES & SERVS. ADMIN. (Oct. 2017), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicpfactsheet.pdf>.

<sup>260</sup> *See id.*

<sup>261</sup> § 247d-6d(a)(2)(B).

<sup>262</sup> *Id.* § 247d-6d(b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”).

use of products under a PREP Act declaration.<sup>263</sup> The CICIP has a one-year statute of limitations.<sup>264</sup> While a claimant may hire a lawyer, unlike in the NVICP, the CICIP does not pay any attorney fees.<sup>265</sup> The CICIP offers no hearings or appeals from the CICIP decisions; however, a claimant may request reconsideration of her claim within sixty days if CICIP rejected it on the first review.<sup>266</sup> There are no published records of CICIP's compensation decisions, so it is impossible to analyze them. CICIP's website lists medical expenses, lost employment income, and survivor death benefits as possible compensation, but it is unclear whether or to what extent CICIP has paid them, as there are no published decisions.

As of September 2015, HHS adopted a final rule regarding compensation through the CICIP.<sup>267</sup> The rule includes a Covered Countermeasures Injury Table (Countermeasures Table), which contains presumptive injuries from pandemic flu vaccines and, specifically, the pandemic flu vaccine for the 2009 H1N1 virus, as well as antiviral drugs to treat pandemic flu.<sup>268</sup> The Countermeasures Table creates presumptions of causation in the event of anaphylaxis within zero to four hours after administration of a pandemic flu vaccine or the onset of Guillain-Barré Syndrome from three to forty-two days after vaccine administration.<sup>269</sup>

HHS has created these presumptions based on “compelling, reliable, valid, medical and scientific evidence.”<sup>270</sup> The Countermeasures Table creates a rebuttable presumption of injury causation for people who meet its criteria, but HHS still has the right to contest eligibility in individual cases.<sup>271</sup> In addition, if an individual alleges injuries that do not fall within the Countermeasures Table, she may still pursue her claim, but she must demonstrate that “the

---

<sup>263</sup> Countermeasures Injury Compensation Program, 42 C.F.R. §110.1 (2016).

<sup>264</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., EPIDEMIOLOGY AND PREVENTION OF VACCINE PREVENTABLE DISEASES app. D-9 (Jennifer Hamborsky et al. eds., 13th ed. 2015); *see also Frequently Asked Questions*, HEALTH RESOURCES & SERVS. ADMIN. (Oct. 2017), <https://www.hrsa.gov/cicp/faq/index.html> (“[Y]ou have ONE (1) YEAR from the date that the covered countermeasure was received to file for CICIP benefits . . .”).

<sup>265</sup> *Frequently Asked Questions*, HEALTH RESOURCES & SERVS. ADMIN., <https://www.hrsa.gov/cicp/faq/requesters.html> (last reviewed Oct. 2017).

<sup>266</sup> *Id.*

<sup>267</sup> 42 C.F.R. § 110.30–33.

<sup>268</sup> 42 C.F.R. § 110.100.

<sup>269</sup> *Id.*

<sup>270</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 264, at app. D-9.

<sup>271</sup> Countermeasures Injury Compensation Program: Pandemic Influenza Countermeasures Injury Table, 80 Fed. Reg. 47,411, 47,412 (Aug. 7, 2015) (codified at 42 C.F.R. § 110.30) (“[T]his Table creates a rebuttable presumption of causation for eligible individuals . . .”).

covered countermeasure directly caused the injury” by “compelling, reliable, valid, medical and scientific evidence.”<sup>272</sup>

The only exception to the PREP Act’s blanket liability protection for industry is when a victim can show evidence of a manufacturer’s “willful misconduct,” which is a defined term in the statute.<sup>273</sup> To be liable, the defendant must have committed an act or omission that it undertook: “(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.”<sup>274</sup>

An injured person may only sue a defendant for willful misconduct in the federal district court in Washington, D.C.,<sup>275</sup> and she bears the burden to prove willful misconduct “by clear and convincing evidence,” not the usual preponderance of the evidence standard used in the NVICP or civil court.<sup>276</sup>

In addition to these almost insurmountable hurdles to justiciability, the PREP Act further requires that a three-judge panel hear any case of willful misconduct<sup>277</sup> and that civil discovery be limited only “to matters directly related to [the] material issue[]” in dispute.<sup>278</sup> Defendants also cannot be liable for willful misconduct if the person in question “acted consistent with applicable directions, guidelines, or recommendations” of the HHS Secretary.<sup>279</sup> Furthermore, unless the HHS Secretary or the Attorney General has initiated an enforcement action regarding the alleged willful misconduct, the act or omission cannot constitute willful misconduct under the PREP Act.<sup>280</sup> In other words, the realistic opportunity to sue for willful conduct is almost nil.

The PREP Act became law over significant consumer and congressional opposition. Senator Kennedy and twenty colleagues in Congress wrote a letter to the Speaker of the House and majority leader to repeal the PREP Act.<sup>281</sup> In

---

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

<sup>273</sup> Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247(d)-6d(e)(1)(A), (d)(1) (2012).

<sup>274</sup> *Id.* § 247(d)-6d(e)(1)(A).

<sup>275</sup> *Id.* § 247d-6d(e)(1).

<sup>276</sup> *Id.* § 247d-6d(c)(3); *see* discussion of NVICP preponderance of the evidence standard, *supra* note 100.

<sup>277</sup> § 247d-6d(e)(5).

<sup>278</sup> *Id.* § 247d-6d(e)(6)(B).

<sup>279</sup> *Id.* § 247d-6d(e)(4).

<sup>280</sup> *Id.* § 247d-6d(e)(5).

<sup>281</sup> *Sen. Kennedy, Colleagues Call on Majority Leader Frist, Speaker Hastert to Repeal ‘Dead of Night’*

their letter, they characterized the PREP Act as “a travesty of the legislative process,” and stated that it could “be used to allow manufacturers of virtually any drug or vaccine to escape responsibility for gross negligence or even criminal acts.”<sup>282</sup> They accused the law’s sponsors of creating “an empty shell of a compensation program for injured patients with none of the funding needed to make compensation a reality.”<sup>283</sup>

The PREP Act’s constitutionality is questionable, raising issues of preemption, judicial review, and due process.<sup>284</sup> Perhaps more importantly, though, some have suggested that the PREP Act incentivizes manufacturers of emergency medical products to willfully disregard or consciously avoid problematic risk information so that they cannot fall within the Act’s “knowing” requirements. In an article in the *Journal of the American Medical Association* about the role of litigation in defining drug risks, the authors cite a memorandum from a drug company executive, which states: “If the FDA asks for bad news, we have to give, but if we don’t have it, we can’t give it to them.”<sup>285</sup> It appears that the PREP Act may incentivize precisely this kind of thinking.

The HHS Secretary has declared nine public health emergencies under the PREP Act, including declarations for H1N1 pandemic flu vaccines, Ebola virus vaccines, and Zika virus vaccines.<sup>286</sup> Even a superficial comparison of the PREP Act with the Vaccine Act shows that consumers played little if any role in drafting the PREP Act.<sup>287</sup> With effective access only to an administrative tribunal, with a one-year statute of limitations, and with no opportunity for appeal or review in any court, consumers have exceptionally limited recourse under the PREP Act.

---

*Vaccine Liability Provision, Enact Real Protections*, U.S. FED. NEWS, Feb. 15, 2006, 2006 WLNR 2705752 [hereinafter *Kennedy Letter*].

<sup>282</sup> *Id.*

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

<sup>284</sup> See, e.g., Samuel C. Bauer, Note, *Ebola and the Public Readiness and Emergency Preparedness Act: Defining the Outer Boundaries of Unreviewable Administrative Action*, 8 NE. U. L.J. 223 (2016); Brian Kurt Copper, Note, “High and Dry?” *The Public Readiness and Emergency Preparedness Act and Liability Protection for Pharmaceutical Manufacturers*, 40 J. HEALTH L. 65 (2007); Angela Marino, Note, *The Cost of a Countermeasure: The Expansive Liability Protection of the Public Readiness and Emergency Preparedness Act of 2005*, 20 U. FLA. J.L. & PUB. POL’Y 199 (2009).

<sup>285</sup> Kesselheim & Avorn, *supra* note 232, at 309 (quoting Alex Berenson, *Trial Lawyers Are Now Focusing on Lawsuits Against Drug Makers*, N.Y. TIMES, May 18, 2003, at A1).

<sup>286</sup> U.S. Dep’t of Health & Human Servs., *Public Readiness and Emergency Preparedness Act*, PUB. HEALTH EMERGENCY (May 10, 2017), <https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx>.

<sup>287</sup> *Kennedy Letter*, *supra* note 281 (noting that the PREP Act was a “stealth provision,” not “debated in the open . . . [and] sneaked into a larger bill behind closed doors as a favor to special interests”).

Most consumers in the United States pay little attention to the fine print when they get vaccines. Yet whether a person receives a seasonal flu vaccine or an emergency pandemic one, such as the H1N1 flu shot, could make a world of difference in what recourse might be available in the event of injury.

\*\*\*

Neither the Vaccine Act nor the PREP Act provide encouraging models to balance public health with individual rights. Both models seem skewed to favor industry, which appears to have exerted significant influence during the drafting and implementation phases of both statutes.<sup>288</sup> While neither statute provides a good model, the Vaccine Act is the better of the two, as it provides at least for some level of judicial review.<sup>289</sup>

Because both U.S. models have significant shortcomings, however, it is important to look at other potential models.

## II. THE EUROPEAN UNION'S DIFFERENT APPROACH

On June 21, 2017, the ECJ for the European Union ruled on a case regarding vaccine injury and potential vaccine manufacturer liability.<sup>290</sup> Courts and tribunals in the European Union's twenty-eight countries refer questions of interpretation of E.U. law to the ECJ.<sup>291</sup> The ECJ did not decide the underlying case that France's highest court referred to it, *N.W. v. Sanofi Pasteur MSD SNC*,<sup>292</sup> but the ECJ did offer guidance on its interpretation of E.U. Directive 85/374, regarding liability for defective products, which applies throughout the European Union.<sup>293</sup> The ECJ's decision applies in all E.U. cases in which

---

<sup>288</sup> For more on industry influence in the drafting of the Vaccine Act, see *infra* notes 41–44. For more on industry influence on the PREP Act, see Kennedy letter, *supra* note 281 (“Republicans gave drug companies and those who administer a countermeasure effectively complete immunity from suit . . .”).

<sup>289</sup> For a discussion of judicial review of decisions in the NVICP, see note 57. For more on the review of CICIP decisions under the PREP Act, see notes 262, 284.

<sup>290</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC* (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

<sup>291</sup> See *Countries*, EUROPA (Dec. 20, 2017), [https://europa.eu/european-union/about-eu/countries\\_en#28members](https://europa.eu/european-union/about-eu/countries_en#28members); *Court of Justice of the European Union (CJEU)*, EUROPA (Dec. 20, 2017), [https://europa.eu/european-union/about-eu/institutions-bodies/court-justice\\_en](https://europa.eu/european-union/about-eu/institutions-bodies/court-justice_en).

<sup>292</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC* (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

<sup>293</sup> See Council Directive 85/374, 1985 O.J. (L 210) 28, 29 (EC).

similar issues about defective products are involved, and not just cases regarding vaccines.<sup>294</sup>

#### A. *N.W. v. Sanofi Pasteur MSD SNC*

Mr. W., a French man who received three hepatitis B vaccines manufactured by Sanofi Pasteur between December 1998 and July 1999, brought the original case.<sup>295</sup> Starting in August 1999, Mr. W. began to have health problems which led to the diagnosis of multiple sclerosis in November 2000.<sup>296</sup> By January 2001, Mr. W was no longer able to work because of his disease, and his health declined progressively until October 2011, when he died.<sup>297</sup>

In 2006, Mr. W, his wife, and two daughters brought a claim against Sanofi Pasteur for damages under strict liability provisions of the French Civil Code that require a producer to be liable for damage from a product defect.<sup>298</sup> French law requires the plaintiff “to prove the damage, the defect and the causal relationship between defect and damage.”<sup>299</sup> Mr. W. and his family argued that the close timing between the vaccinations and the onset of his disease symptoms, as well as the lack of any personal or family history of the disease gave rise to “serious, specific and consistent presumptions” about the existence of a defect in the vaccine, and a causal link between the vaccine and the development of disease.<sup>300</sup>

In French, the word *présomption* is a method of legal reasoning where one fact that is not proven can be inferred from another fact that has been

---

<sup>294</sup> See *Presentation*, CURIA, [https://curia.europa.eu/jcms/jcms/Jo2\\_7024/en/](https://curia.europa.eu/jcms/jcms/Jo2_7024/en/) (last visited Dec. 20, 2017) (“The Court of Justice’s reply is not merely an opinion, but takes the form of a judgment or reasoned order. The national court to which it is addressed is, in deciding the dispute before it, bound by the interpretation given. The Court’s judgment likewise binds other national courts before which the same problem is raised.”).

<sup>295</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC*, para. 9 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=192054&pageIndex=0&doclang=EN&mode=req&dir=first&part=1&cid=848112>.

<sup>296</sup> *Id.*

<sup>297</sup> *Id.* at para. 10.

<sup>298</sup> *Id.* at para. 11; Case C-621/15, *W. v. Sanofi Pasteur MSD SNC*, para. 9 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=188628&pageIndex=0&doclang=EN&mode=req&dir=first&part=1>.

<sup>299</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC*, paras. 7, 8 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=192054&pageIndex=0&doclang=EN&mode=req&dir=first&part=1&cid=848112> (citing art. 1386-9 of the French Civil Code).

<sup>300</sup> *Id.* at para. 11.

proven.<sup>301</sup> The presumption can be factual or legal and can be rebuttable, irrebuttable, or absolute.<sup>302</sup> So based on the timing of Mr. W.'s vaccines, the disease onset, and the lack of family history, Mr. W. asked the court to infer from these facts that the vaccine was the presumptive cause.<sup>303</sup>

From 2006 through 2015, French courts ruled first in favor of Mr. W., and then against him on whether he had established a causal link between the vaccine and his disease. The Nanterre Regional Court, the court of first instance, decided in favor of Mr. W., upholding his claim.<sup>304</sup>

The Versailles Court of Appeal reversed the decision, holding that a presumption of injury from the vaccine was insufficient to prove that the vaccine was defective.<sup>305</sup> The Court of Cassation overturned the Versailles court's decision, however, holding that the Versailles Court of Appeal had not provided an adequate legal rationale for its decision.<sup>306</sup>

The case then went to the Paris Court of Appeal (to avoid bias),<sup>307</sup> which again overturned the Nanterre court's decision in favor of Mr. W., holding that there was no scientific consensus to support a causal relationship between the hepatitis B vaccine and multiple sclerosis.<sup>308</sup> The Paris Court of Appeal wrote that national and international health authorities rejected an association between demyelinating diseases, like multiple sclerosis, with the hepatitis B vaccine.<sup>309</sup> It also noted that the cause of multiple sclerosis is unknown and

---

<sup>301</sup> Case C-621/15, W. v. Sanofi Pasteur MSD SNC, para. 29 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=188628&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1>.

<sup>302</sup> *Id.*

<sup>303</sup> Case C-621/15, N.W. v. Sanofi Pasteur MSD SNC, para. 11 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=192054&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=848112>.

<sup>304</sup> *Id.* at para. 14.

<sup>305</sup> Case C-621/15, W. v. Sanofi Pasteur MSD SNC, para. 10 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=188628&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1>.

<sup>306</sup> *Id.*

<sup>307</sup> See Dorit Rubinstein Reiss, *European Court Vaccine Decision – A Legal Analysis*, SKEPTICAL RAPTOR (June 25, 2017), <https://www.skepticalraptor.com/skepticalraptorblog.php/european-court-vaccine-decision-analysis/> (“The case was sent back down to a different court of appeal (as is usual, to avoid bias in the original court of appeal), the Court of Appeal of Paris.”).

<sup>308</sup> Case C-621/15, W. v. Sanofi Pasteur MSD SNC, para. 11 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=188628&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1>.

<sup>309</sup> *Id.* at para. 12.



that epidemiological studies show that 92% to 95% of people with the disease have no family history of it.<sup>310</sup>

Mr. W. then again appealed the case to the Court of Cassation, which stayed the proceeding, pending a preliminary ruling of the ECJ on how to interpret Article 4 of EU Directive 85/374 (the Directive) concerning liability for defective products.<sup>311</sup> In addition to the parties, the Czech, German, and French governments and the European Commission submitted written briefs and, except for the German government, participated in oral argument at the hearing at the ECJ in 2016.<sup>312</sup>

The ECJ's ruling interpreted the apparently simple text of Article 4 as "[t]he injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage."<sup>313</sup> The French Court of Cassation's first question to the ECJ was: Does Article 4 permit a national court to consider "serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease," even though medical research neither accepts nor rejects a causal association?<sup>314</sup> The ECJ answered that a national court may consider "serious, specific and consistent evidence" regarding a vaccine defect, even if medical research has not yet established or ruled out a connection.<sup>315</sup> In Solomonic language, though, the ECJ cautions that national courts must ensure that the plaintiff continues to bear the burden of proof of a causal link when the science is equivocal.<sup>316</sup>

The Court of Cassation's second question was contingent on the first: Assuming a court may hear "serious, specific and consistent presumptions" regarding vaccine defect when the science is not clear, is the court precluded

---

<sup>310</sup> *Id.*

<sup>311</sup> *Id.* at para. 13.

<sup>312</sup> *Id.* at para. 14.

<sup>313</sup> Case C-621/15, N.W. v. Sanofi Pasteur MSD SNC, para. 5 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112> (quoting Council Directive 85/374, 1985 O.J. (L 210) 28, 31 (EC)).

<sup>314</sup> *Id.* at para. 17–18; Case C-621/15, W. v. Sanofi Pasteur MSD SNC, para. 13 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=188628&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1>.

<sup>315</sup> Case C-621/15, N.W. v. Sanofi Pasteur MSD SNC, paras. 37–38, 43 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

<sup>316</sup> *Id.* at para. 38.

from creating a presumption for similar facts in future cases?<sup>317</sup> To this, the ECJ answered that there can be no presumptions when the medical literature is equivocal on a potential link.<sup>318</sup>

The Court of Cassation's third question, which the ECJ did not reach, was whether a scientific consensus must exist about a causal relationship between a vaccine and a specific injury for a plaintiff to be able to win.<sup>319</sup> The ECJ effectively answered this question, though, finding that a medical consensus is not necessary to rule in favor of the plaintiff when other compelling evidence is present.<sup>320</sup>

The ECJ discussed the requirements of the Directive's Article 6(1), which considers a product

defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account, including:

- (a) the presentation of the product;
- (b) the use to which it could reasonably be expected that the product would be put;
- (c) the time when the product was put into circulation.<sup>321</sup>

Furthermore, a court's assessment must take account of the "reasonable expectations of the public at large."<sup>322</sup>

The ECJ noted that if the only method of proof a plaintiff can rely on is medical research, it would be "excessively difficult" or "impossible to establish producer liability," and would undermine the Directive's core principle of corporate liability.<sup>323</sup> The ECJ also noted that if it were to set a

---

<sup>317</sup> *Id.* at para. 17; Case C-621/15, *W. v. Sanofi Pasteur MSD SNC*, para. 13 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=188628&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1>.

<sup>318</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC*, para. 55 (June 21, 2017), <http://curia.europa.eu/ocument/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

<sup>319</sup> *Id.* at paras. 17, 56; Case C-621/15, *W. v. Sanofi Pasteur MSD SNC*, para. 13 (Mar. 7, 2017), <http://curia.europa.eu/juris/document/document.jsf?text=&docid=188628&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1>.

<sup>320</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC*, para. 43 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

<sup>321</sup> *Id.* at para. 6 (quoting Council Directive 85/374, 1985 O.J. (L 210) 28, 31 (EC)).

<sup>322</sup> *Id.* at para. 23.

<sup>323</sup> *Id.* at para. 31.

threshold, requiring a scientific consensus or definitive medical proof, the “fair apportionment of the risks inherent in modern technological production between the injured person and the producer” sought by the Directive would not be attainable.<sup>324</sup>

Thus the ECJ instructs national courts that to find in favor of a plaintiff, they must find the plaintiff’s evidence “sufficiently serious, specific and consistent to warrant the conclusion that . . . a defect in the product appears to be the most plausible explanation for the occurrence of the damage, with the result that the defect and the causal link may reasonably be considered to be established.”<sup>325</sup> While the ECJ does not decide the underlying disputes of the cases referred to it—the national courts have to resolve them—it did opine in this case that the timing between the hepatitis B vaccines and the onset of multiple sclerosis, the lack of family history, and the significant number of reported cases of disease-onset following such vaccinations, “appears on the face of it to constitute evidence which . . . may lead a national court to consider that a victim has discharged his burden of proof under Article 4 of Directive 85/374.”<sup>326</sup>

The ECJ goes on to say that this could be a case where “the vaccine is the most plausible explanation” for the disease onset and where, under Article 6, the product “causes abnormal and particularly serious damage to the patient who, in the light of the nature and function of the product, is entitled to expect a particularly high level of safety.”<sup>327</sup> But the ECJ cautions that national courts must reach such decisions “in a fully enlightened manner in each specific case,” making it clear that such cases are extremely fact-specific and require careful case-by-case consideration.<sup>328</sup>

The ECJ opposed any irrebuttable or absolute presumptions, however.<sup>329</sup> It argued that the use of such presumptions would undermine Article 4 and would “risk compromising the very effectiveness of the system of liability” that the Directive introduced.<sup>330</sup> National courts may not use evidentiary rules based on presumptions when there is no scientific consensus of causal link.

---

<sup>324</sup> *Id.* at para. 32.

<sup>325</sup> *Id.* at para. 37.

<sup>326</sup> *Id.* at para. 41.

<sup>327</sup> *Id.*

<sup>328</sup> *Id.* at para. 42.

<sup>329</sup> *Id.* at para. 53.

<sup>330</sup> *Id.*

### B. *Commentary on the ECJ Decision*

The Associated Press (AP), CNN, and other media outlets immediately attacked the ECJ's decision, with headlines like the AP's "EU Court: Vaccines Can Be Blamed for Illnesses Without Proof."<sup>331</sup> The AP story quoted Dr. Paul Offit, a leading U.S. vaccine proponent, who said, "Using those criteria, you could reasonably make the case that someone should be compensated for developing leukemia after eating a peanut butter sandwich."<sup>332</sup> He suggested further that courts cannot be trusted to make such decisions: "To prove whether one thing causes another has to happen in a scientific venue, and the courts are not a scientific venue."<sup>333</sup> He went on to say that the court's judgment created a "ridiculously low bar for causality."<sup>334</sup>

Laurie Garrett, a prominent journalist covering vaccines and their role in global epidemics,<sup>335</sup> wrote an article entitled, "Science Won't Save Vaccines from Lawsuits Anymore: Europe's Highest Court Has Just Cleared the Way for Vaccine-Truthers to Sue Manufacturers, Even Without Any Evidence."<sup>336</sup> She wrote that the decision comes at a "fragile time for the international vaccine regime," when it is "under assault . . . by a growing culture of anti-scientific paranoia."<sup>337</sup> Inaccurately, she suggested, "If there was a burden to prove, or disprove, such a link [between a vaccine defect and disease onset], it

---

<sup>331</sup> Associated Press, *EU Court: Vaccines Can Be Blamed for Illnesses Without Proof*, CBS NEWS (June 21, 2017, 10:27 AM), <http://www.cbsnews.com/news/eu-court-vaccines-can-be-blamed-for-illnesses-without-proof/>.

<sup>332</sup> *Id.* For more on Dr. Offit's role as a vaccine proponent, see, for example, Paul A. Offit, M.D., CHILD. HOSP. PHIL., <http://www.chop.edu/doctors/offit-paul-a> (last visited Dec. 21, 2017) ("Dr. Offit is an internationally recognized expert in the fields of virology and immunology, and was a member of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention."). For information about Dr. Offit's potential financial conflicts of interest regarding vaccines, see *Millions of Children Infected with "Vaccine Safety Experts" Rotateq Vaccine: Dr. Paul Offit*, GREENMEDINFO (Sept. 25, 2014, 5:15 PM), <http://www.greenmedinfo.com/blog/breaking-news-millions-children-infected-vaccine-safety-experts-rotateq-vaccine> (alleging a conflict of interest between Dr. Offit's role promoting vaccines and the fact that he co-invented a rotavirus vaccine, from which he derived substantial income). The AP article cited here does not mention any financial conflicts of interest.

<sup>333</sup> Associated Press, *supra* note 331.

<sup>334</sup> *Id.*

<sup>335</sup> See *About*, LAURIE GARRETT, <http://lauriegarrett.com/about/> (last visited Dec. 21, 2017); *Vaccine-Preventable Outbreaks Map*, LAURIE GARRETT, <http://lauriegarrett.com/vaccine-preventable-outbreaks-interactive-map/> (last visited Dec. 21, 2017).

<sup>336</sup> Laurie Garrett, *Science Won't Save Vaccines from Lawsuits Anymore: Europe's Highest Court Has Just Cleared the Way for Vaccine-Truthers to Sue Manufacturers, Even Without Any Evidence*, FOREIGN POL'Y (June 26, 2017, 12:56 PM), <http://foreignpolicy.com/2017/06/26/science-wont-save-vaccines-from-lawsuits-anymore/>.

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

would be placed on the defendants. Voila! Science be damned.”<sup>338</sup> She continued that “crackpot theories” of vaccine injury now “can be presented in a European court of law, absent the merest modicum of evidence.”<sup>339</sup>

Other scientific and legal commentators have been more balanced. The scientific journal *Nature* ran the headline “Vaccine Ruling from Europe’s Highest Court Isn’t as Crazy as Scientists Think: Media and Scientific Uproar over Admissible Evidence ‘Exaggerated’, Say Legal Scholars.”<sup>340</sup> The authors quote Alex Stein, an expert in civil liability law and medical evidence, as saying “credible medical evidence showing that the vaccine is safe will win the case . . . . Those who say that the ECJ decision has opened a floodgate for multiple vaccine liability suits are therefore mistaken.”<sup>341</sup>

Stein stated that defendants will ensure that courts hear the most compelling medical evidence in their favor.<sup>342</sup> He argues that the ECJ has not lowered the bar for claims; it merely has allowed courts “to admit whatever relevant evidence they wish and judge it on its own merits along with the rest.”<sup>343</sup> The authors also quote Joasia Luzak, an expert in consumer law, saying that “[t]he judgment is measured.”<sup>344</sup> In her view, the ruling makes clear that courts must “reject spurious and weak evidence.”<sup>345</sup>

Prominent vaccine proponent and legal scholar Dorit Reiss<sup>346</sup> also wrote a nuanced assessment of the ECJ’s decision, arguing that the decision does not say “courts can ignore science.”<sup>347</sup> On the contrary, she argued, the ECJ held that when there is no clear medical evidence for or against causation, the plaintiff does not automatically lose because she does not have definite scientific evidence.<sup>348</sup>

---

<sup>338</sup> *Id.*

<sup>339</sup> *Id.*

<sup>340</sup> Laura Castells & Declan Butler, *Vaccine Ruling from Europe’s Highest Court Isn’t as Crazy as Scientists Think: Media and Scientific Uproar over Admissible Evidence ‘Exaggerated,’ Says Legal Scholars*, *NATURE* (June 28, 2017), <https://www.nature.com/news/vaccine-ruling-from-europe-s-highest-court-isn-t-as-crazy-as-scientists-think-1.22222>.

<sup>341</sup> *Id.*

<sup>342</sup> *Id.*

<sup>343</sup> *Id.*

<sup>344</sup> *Id.*

<sup>345</sup> *Id.*

<sup>346</sup> See Dorit Rubinstein Reiss, U.C. HASTINGS C.L. S.F., <http://www.uchastings.edu/faculty/reiss/> (last visited Dec. 21, 2017); *Law and Vaccines: List of Dorit Reiss’ Blog Posts and Articles*, U.C. HASTINGS C.L. S.F., <http://sites.uchastings.edu/lawandvaccines/> (last visited Dec. 21, 2017) (arguing against non-medical exemptions and for tort liability for failure to vaccinate).

<sup>347</sup> Reiss, *supra* note 307.

<sup>348</sup> *Id.*

Reiss points out that this is a more favorable standard for plaintiffs than the U.S. standard in which plaintiffs must present evidence that meets a scientific threshold.<sup>349</sup> In U.S. courts, judges serve as gatekeepers to assess experts and evidence under the *Daubert* standard.<sup>350</sup> A judge may only permit the jury to hear credible scientific evidence, which usually means that the peer review process has confirmed the scientific information and that the information is based on standard scientific methodologies.<sup>351</sup> Reiss affirms that the ECJ's more favorable standard for plaintiffs is reasonable under principles of product liability, which recognize the substantial power imbalance between manufacturers and consumers, tilting steeply in the manufacturer's favor.<sup>352</sup>

The ECJ decision, she opines, "is not a blank check to blame vaccines for any problem."<sup>353</sup> She sees no better alternative, however, than that a court makes the decision on vaccine injury compensation.<sup>354</sup> "The court has to balance individual justice with absolute truth. Rules like the French causation rule are a way to try and do that."<sup>355</sup> She concludes that "it's not unreasonable to place the burden of scientific uncertainty, when there are other factors that can support causation, on large manufacturers over consumers."<sup>356</sup>

The ECJ decision affirms an individual's right to sue vaccine manufacturers for harms that she reasonably could not have expected based on the product warnings and on the "particularly high level of safety" she is entitled to expect for vaccines.<sup>357</sup>

This decision permits lawsuits in Europe for defectively designed vaccines that individuals cannot bring in any court in the United States. There are several vaccines on the global market now, including pentavalent and hexavalent infant vaccines and human papilloma virus vaccines for teenagers, which appear to be associated with significant injuries and deaths, despite the

---

<sup>349</sup> *Id.*

<sup>350</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) (holding that while "general acceptance" is not a precondition to admissibility of scientific evidence under the Federal Rules of Evidence, judges must consider scientific method, peer review, and other indicators of scientific credibility).

<sup>351</sup> *Id.*

<sup>352</sup> *See* Reiss, *supra* note 307.

<sup>353</sup> *Id.*

<sup>354</sup> *Id.*

<sup>355</sup> *Id.*

<sup>356</sup> *Id.*

<sup>357</sup> Case C-621/15, *N.W. v. Sanofi Pasteur MSD SNC*, para. 41 (June 21, 2017), <http://curia.europa.eu/juris/document/document.jsf?text&docid=192054&pageIndex=0&doclang=EN&mode=req&dir&occ=first&part=1&cid=848112>.

lack of clear scientific consensus of a causal link.<sup>358</sup> *N.W. v. Sanofi Pasteur MSD SNC* may permit more vaccine injury litigation in Europe, which in turn could improve vaccine safety globally. Because many of the vaccines on the market in Europe are identical to those marketed elsewhere and produced by the same handful of manufacturers,<sup>359</sup> if litigation induces manufacturers to change their product designs for the European market, they might implement those changes elsewhere in the world.

### III. THE COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS

In January 2017, a number of international public and private actors formed a new global institution, the CEPI, to help create vaccines for emerging epidemic threats, particularly in the developing world.<sup>360</sup> The governments of Germany, Japan, and Norway, together with the Bill & Melinda Gates Foundation and the Wellcome Trust, made initial investments of \$540 million;<sup>361</sup> the European Commission has pledged 250 million euros.<sup>362</sup> India is expected to donate as well.<sup>363</sup> Several vaccine manufacturers, including GlaxoSmithKine, Johnson & Johnson, Merck, Pfizer, Sanofi Pasteur, and Takeda, became CEPI partners rather than donors, as did the inter-governmental WHO and non-profit Doctors Without Borders.<sup>364</sup> CEPI's partners announced this new effort at the World Economic Forum in Davos, Switzerland in early 2016.<sup>365</sup>

---

<sup>358</sup> See, e.g., Jacob Puliyeel & C. Sathyamala, Comment, *Infanrix Hexa and Sudden Death: A Review of the Periodic Safety Update Reports Submitted to the European Medicines Agency*, INDIAN J. MED. ETHICS ONLINE FIRST (Sept. 5, 2017), [http://ijme.in/wp-content/uploads/2017/09/20170909\\_infanrixhexa\\_and\\_sudden.pdf](http://ijme.in/wp-content/uploads/2017/09/20170909_infanrixhexa_and_sudden.pdf); Letter from B.M Hegde, Affiliate Professor, Univ. of N. Colo., et. al. to Narendra Modi, Prime Minister (Nov. 25, 2014), <http://jacob.puliyeel.com/download.php?id=342>. Regarding HPV vaccines, see *Human Papillomavirus (HPV) Disease and Vaccine*, NAT'L VACCINE INFO. CTR., <http://www.nvic.org/Vaccines-and-Diseases/hpv.aspx> (last visited Dec. 21, 2017); SANEVAX, INC., <http://sanevax.org/> (last visited Dec. 21, 2017) (extensive global news on HPV vaccine injuries and deaths).

<sup>359</sup> See, e.g., Amie Batson, *Global Vaccine Market: Global Vaccine and Immunization Research Forum*, WHO (March 2016), [http://www.who.int/immunization/research/forums\\_and\\_initiatives/1\\_ABatson\\_Global\\_Vaccine\\_Market\\_gvirf16.pdf](http://www.who.int/immunization/research/forums_and_initiatives/1_ABatson_Global_Vaccine_Market_gvirf16.pdf) (showing at slide 8 the key global vaccine manufacturers Sanofi Pasteur, Merck, Pfizer, and GlaxoSmithKline, and at slides 18–26, that the same vaccines are in use globally).

<sup>360</sup> Donald G. McNeil Jr., *Donors and Drug Makers Offer \$500 Million to Control Global Epidemics*, N.Y. TIMES (Jan. 18, 2017), <https://www.nytimes.com/2017/01/18/health/partnership-epidemic-preparedness.html>; see also Ed Yong, *A Global Plan to Defend Against the Future's Deadliest Diseases*, ATLANTIC (Jan. 18, 2017), <https://www.theatlantic.com/science/archive/2017/01/cepi-vaccines/513335/>; *CEPI Officially Launched*, CEPI (Jan. 18, 2017), <http://cepi.net/cepi-officially-launched>.

<sup>361</sup> *Coalition for Epidemic Preparedness Innovation*, CEPI (Feb. 16, 2017), [http://cepi.net/sites/default/files/CEPI\\_2pager\\_16\\_Feb\\_17.pdf](http://cepi.net/sites/default/files/CEPI_2pager_16_Feb_17.pdf).

<sup>362</sup> *Id.*

<sup>363</sup> *Id.*

<sup>364</sup> McNeil Jr., *supra* note 360.

<sup>365</sup> *Id.*

The 2014 Ebola epidemic in West Africa that killed 11,000 people spurred the creation of this public-private partnership.<sup>366</sup> The global public health community perceived that its response to the Ebola epidemic was inadequate.<sup>367</sup> Although vaccines against Ebola were developed, they were available only after the epidemic was waning and many thousands had already died.<sup>368</sup> CEPI aims to create a new infrastructure that will ensure greater global preparedness for future pandemics by developing and stockpiling the vaccines most likely to be useful.<sup>369</sup>

The first three vaccines CEPI plans to develop are for MERS, Lassa, and Nipah viruses, which are on the WHO's list of priority pathogens.<sup>370</sup> These infectious diseases primarily affect the developing world, and the marketplace on its own likely would not develop vaccines against these diseases quickly.<sup>371</sup> CEPI takes a comprehensive approach, ensuring support for vaccine candidates through late preclinical studies and will support vaccine technologies that enable rapid development.<sup>372</sup> CEPI's scientific advisory committee chose these three diseases based on potential for public health impact, risk of outbreak, and feasibility of vaccine development.<sup>373</sup> CEPI also plans to sponsor research into a new class of vaccines, known as RNA vaccines, to allow much faster development.<sup>374</sup>

CEPI also notes that it will collaborate with WHO objectives, including “[d]evelopment and implementation of new norms and standards adapted to and appropriate for an epidemic context.”<sup>375</sup> While this statement is vague, it

---

<sup>366</sup> *Id.*

<sup>367</sup> *See id.*

<sup>368</sup> *Approach*, CEPI, <http://cepi.net/approach> (last visited Dec. 21, 2017) (“Recent epidemics and pandemics have exposed serious flaws in the world’s capacity to prepare for and respond to infectious disease outbreaks. The Ebola outbreak in West Africa and Zika in the Americas are the most recent instances.”).

<sup>369</sup> *Id.*

<sup>370</sup> *Resources*, CEPI, <http://cepi.net/resources#Priority-diseases> (last visited Dec. 21, 2017).

<sup>371</sup> *See* CEPI, A GLOBAL INSURANCE POLICY TO DEFEND AGAINST FUTURE EPIDEMICS, [http://cepi.net/sites/default/files/CEPI%20booklet%20final\\_0.pdf](http://cepi.net/sites/default/files/CEPI%20booklet%20final_0.pdf) (“Mission: To stimulate, finance and co-ordinate vaccine development against diseases with epidemic potential in cases where market incentives fail.”).

<sup>372</sup> *Id.*

<sup>373</sup> *Resources*, *supra* note 370.

<sup>374</sup> Yong, *supra* note 360 (“The beauty of these RNA vaccines is that once you develop a way of delivering the RNA into a patient—some kind of scaffold or shell—you can theoretically customize it to deal with all kinds of diseases. Just swap the Ebola RNA for that of some other virus, and you’d have a new vaccine in a matter of weeks. And if you could show that the scaffold is safe, no matter whose RNA it carries, then you could speed that new vaccine through the regulatory process.”).

<sup>375</sup> John-Arne Røttingen, *Coalition for Epidemic Preparedness Innovations (CEPI): Presentation to the WHO*, WHO, slide 20 (July 21, 2017), <http://www.who.int/medicines/ebola-treatment/TheCoalitionEpidemicPreparednessInnovations-an-overview.pdf>.



appears from news reports that the CEPI board is exploring different models for manufacturer liability protection and victim compensation.<sup>376</sup> A PowerPoint on the WHO website notes that CEPI must create “market security,” comprised of “positive externalities,” “minimal disruptions,” and “market predictability.”<sup>377</sup> Furthermore, CEPI declares that it “will rely on WHO as the global normative lead agency on health.”<sup>378</sup>

Dr. Jeremy Farrar, director of Wellcome Trust and a CEPI board member, said to the *New York Times* that CEPI favors the U.S. NVICP model, under which vaccine makers cannot be sued directly, but must contribute money they collect as excise taxes from consumers to a fund that compensates those injured.<sup>379</sup> But Andrew P. Witty, chairman of GlaxoSmithKline, said that industry preferred protection along the lines of the PREP Act, “which exempts vaccine makers from all liability—except for willful misconduct—once the [Secretary of HHS has] declare[d] a public health emergency.”<sup>380</sup>

#### CONCLUSION

Given the well-documented problems with both the Vaccine Act and PREP Act regimes discussed above, it would be unfortunate to see CEPI unquestioningly embrace these models and export them to the developing world. Neither model has performed well. The NVICP has not functioned as Congress intended, and many question the constitutionality of the PREP Act as well as its effectiveness.

The recent ECJ decision strikes a more judicious balance, allowing individuals to bring claims for defective vaccines to court. If CEPI is to inspire vaccine confidence in emergency situations in developing countries, it would be well-advised to ensure some access to courts in cases of injury. If CEPI fails to do this, vaccines may be less safe than they could be, and, as a result, people will inevitably lose confidence both in vaccines and in those recommending them.

---

<sup>376</sup> McNeil Jr., *supra* note 360.

<sup>377</sup> Rottingen, *supra* note 375, at slide 4.

<sup>378</sup> *Id.* at slide 19.

<sup>379</sup> McNeil Jr., *supra* note 360; *Governance*, CEPI, <http://cepi.net/governance> (last visited Dec. 21, 2017).

<sup>380</sup> McNeil Jr., *supra* note 360.